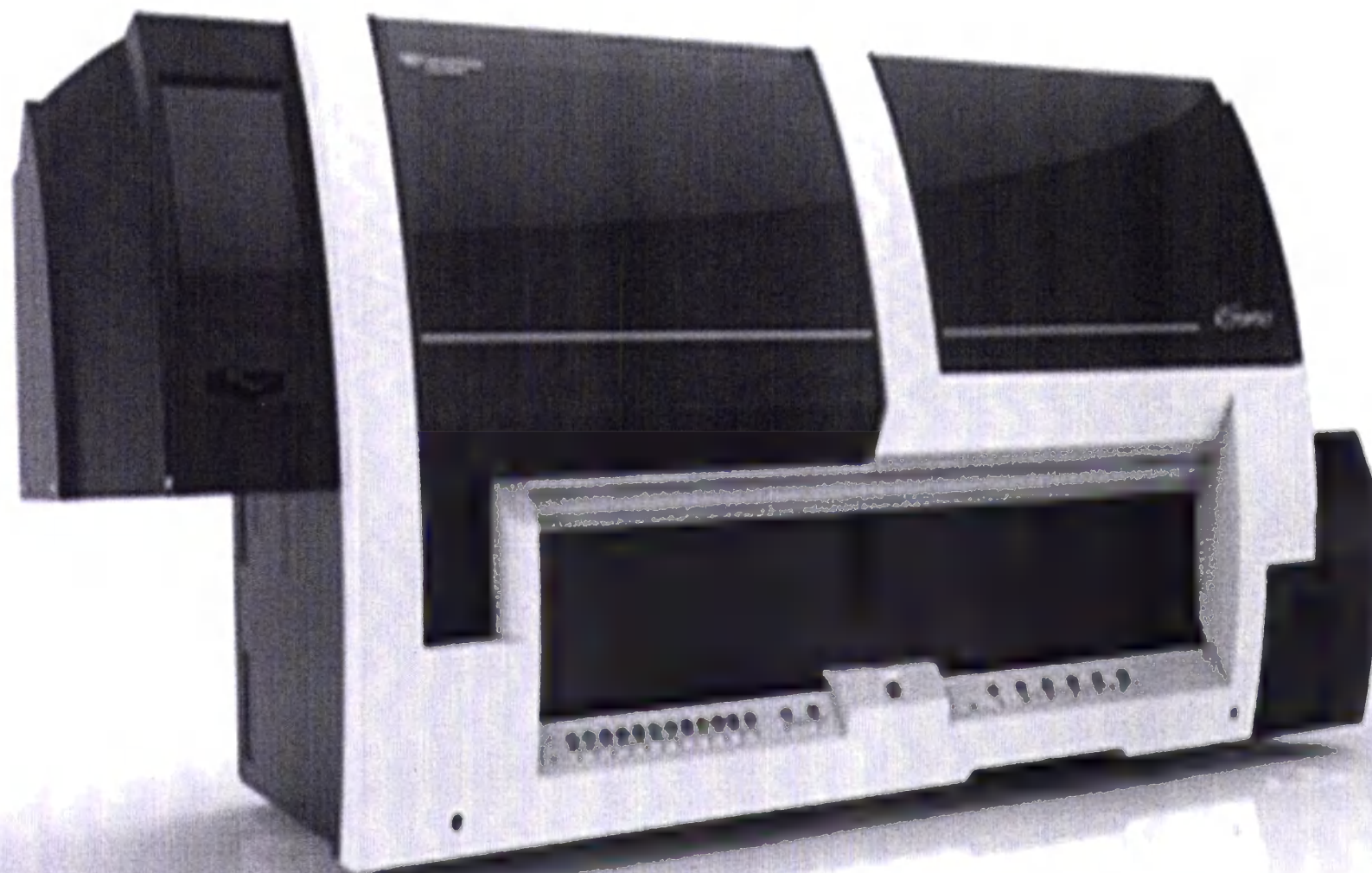
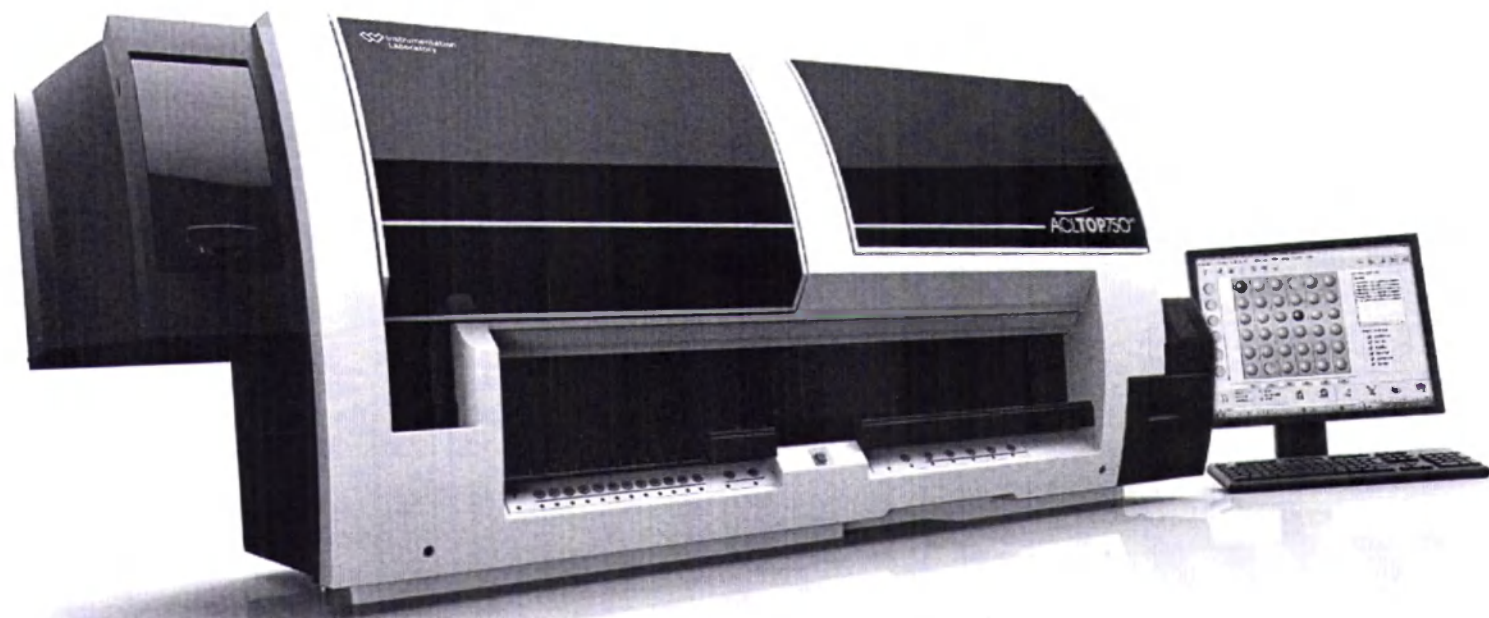


ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ МЕДИЦИНСКОГО ИЗДЕЛИЯ

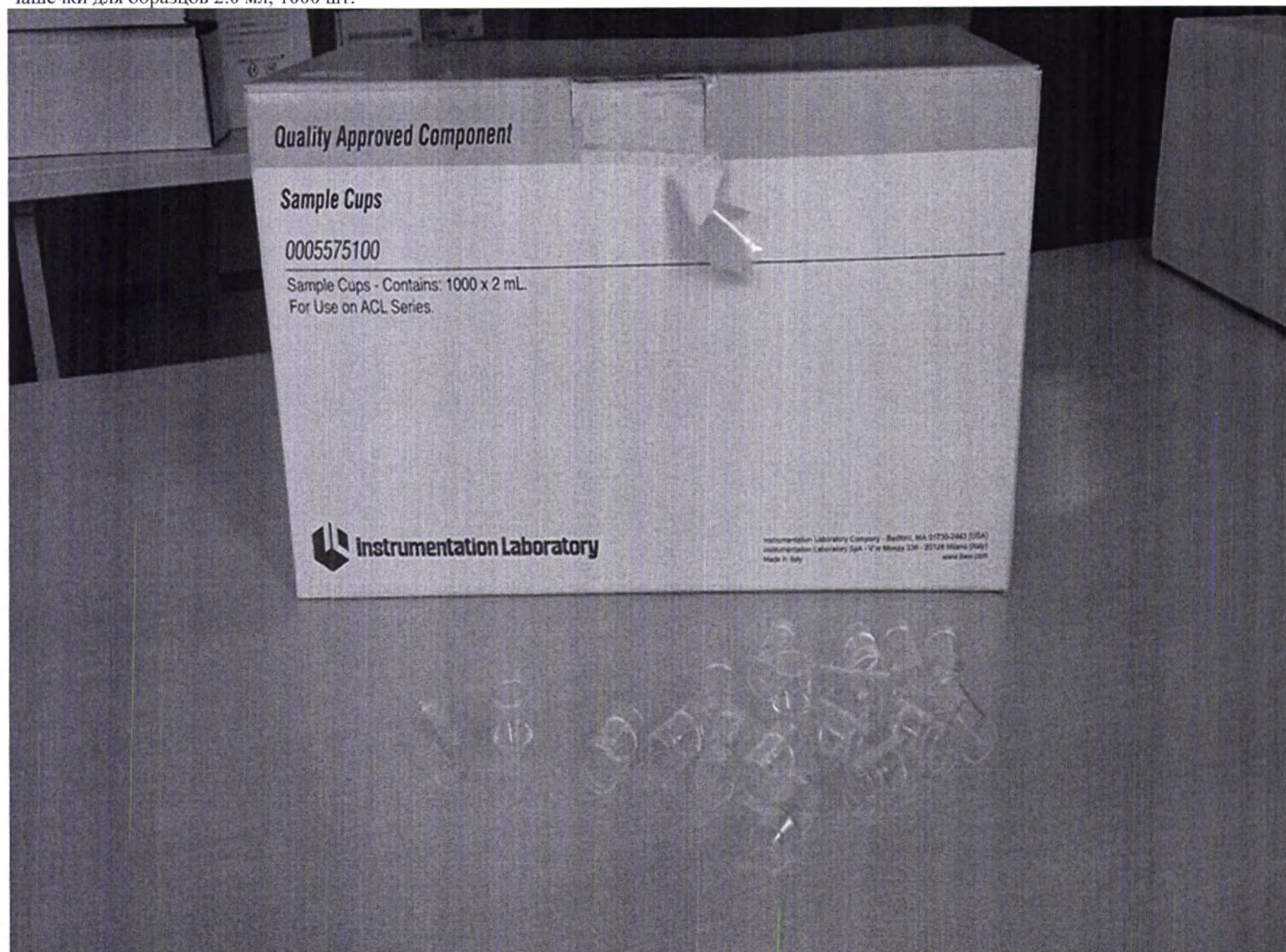
**Анализатор автоматический коагулометрический для диагностики in vitro ACL TOP,
вариант исполнения ACL TOP 750 LAS**

Анализатор

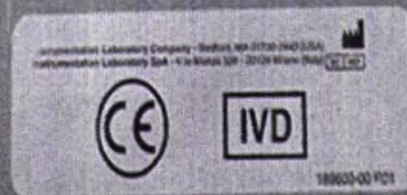


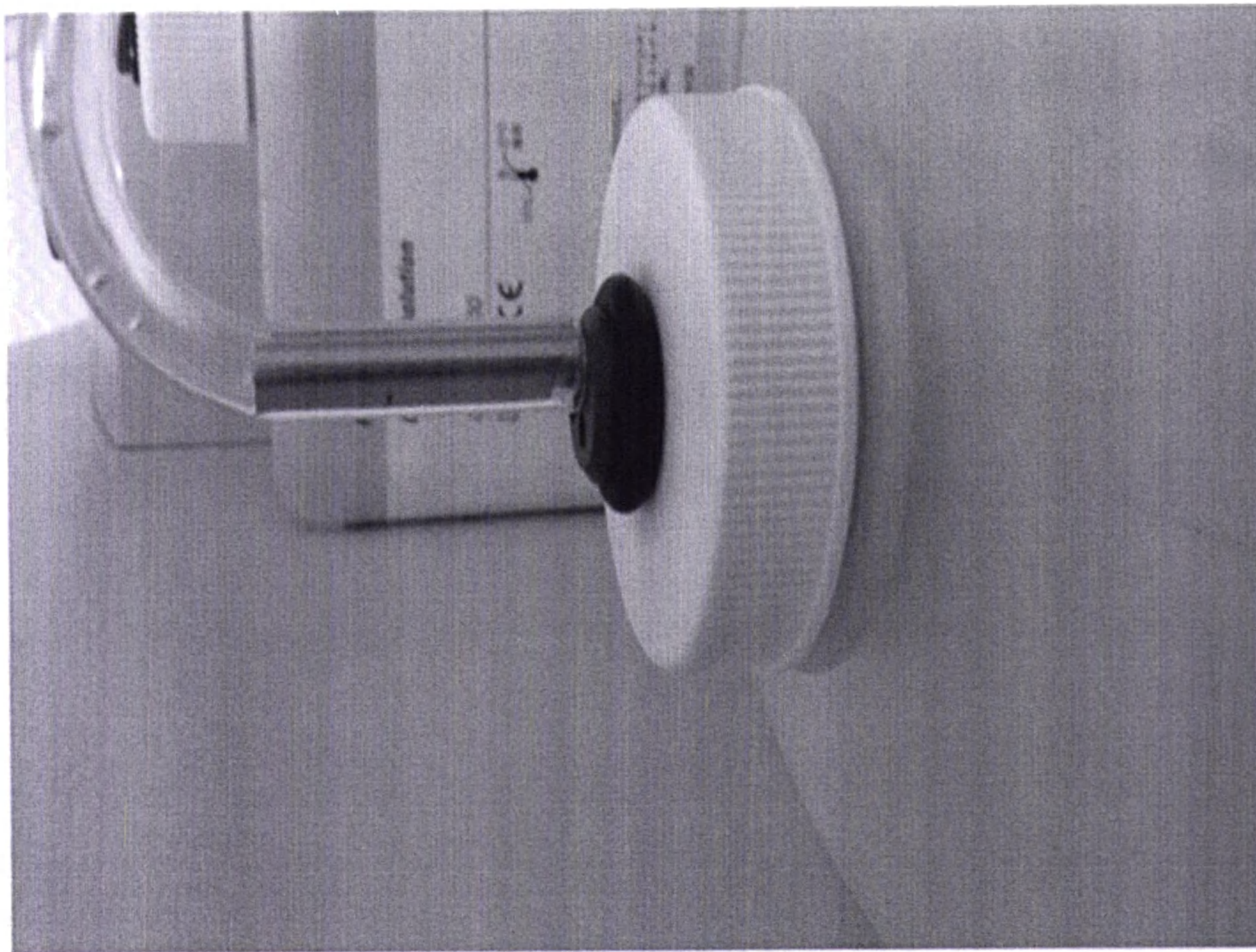


Чашечки для образцов 2.0 мл, 1000 шт.

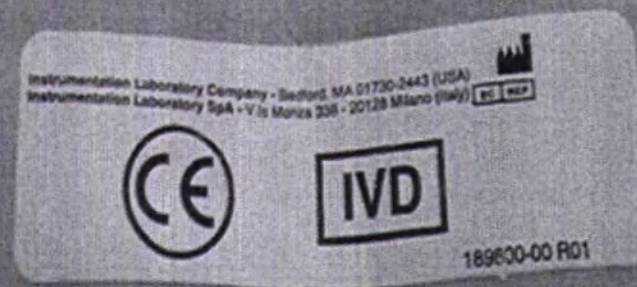
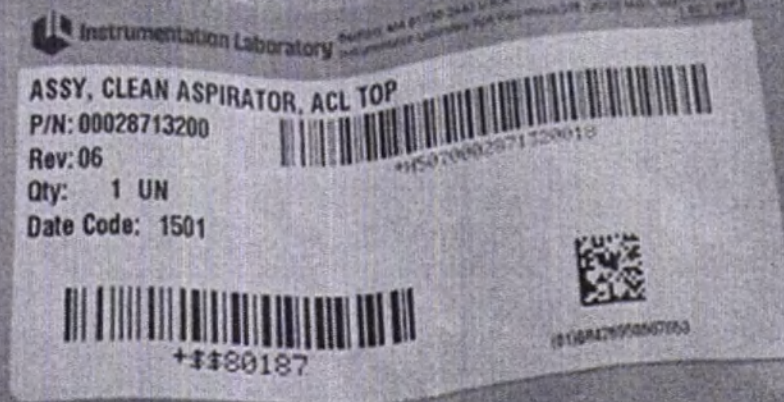


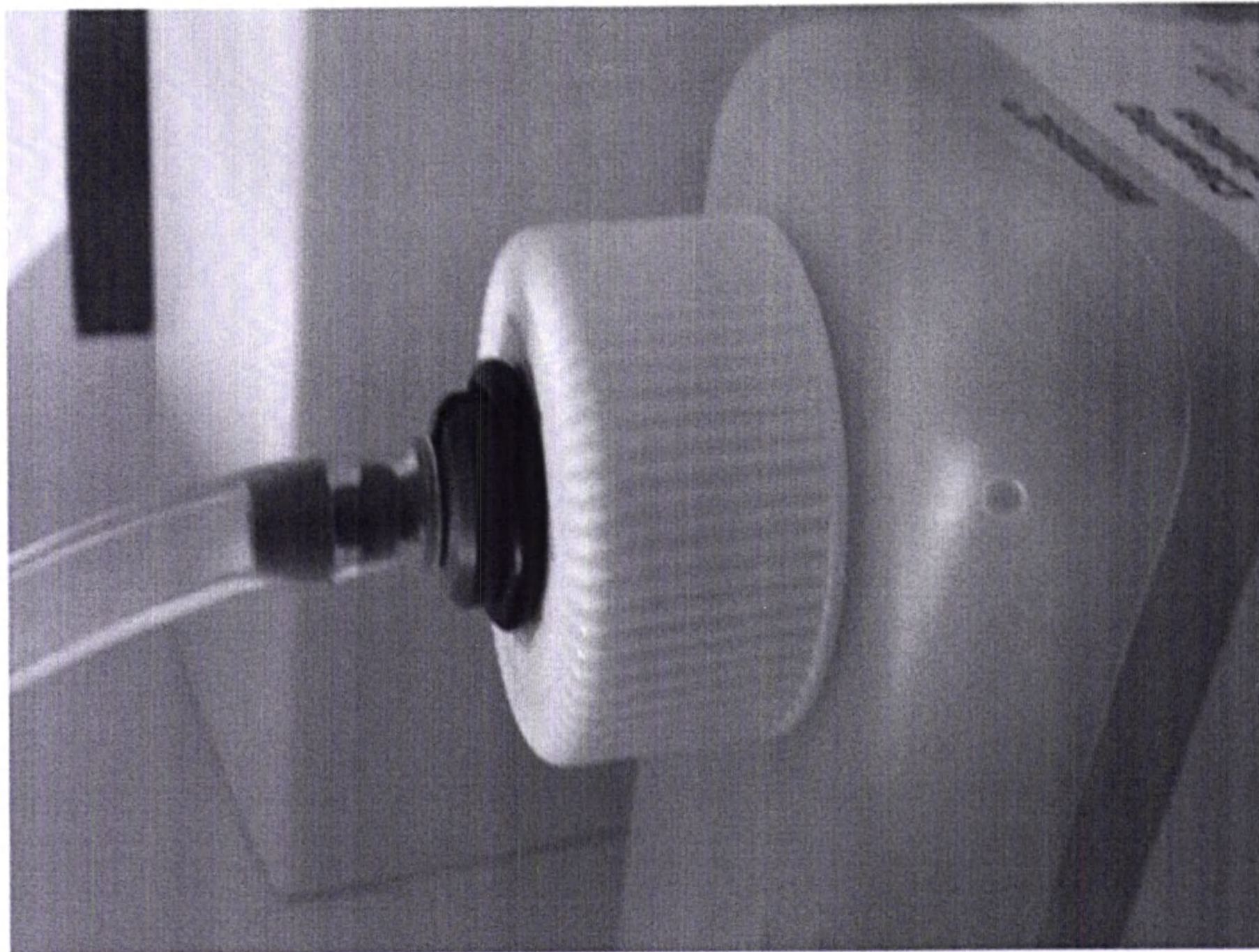
Аспиратор промывочного раствора 4 л для ACL TOP, 1 шт.



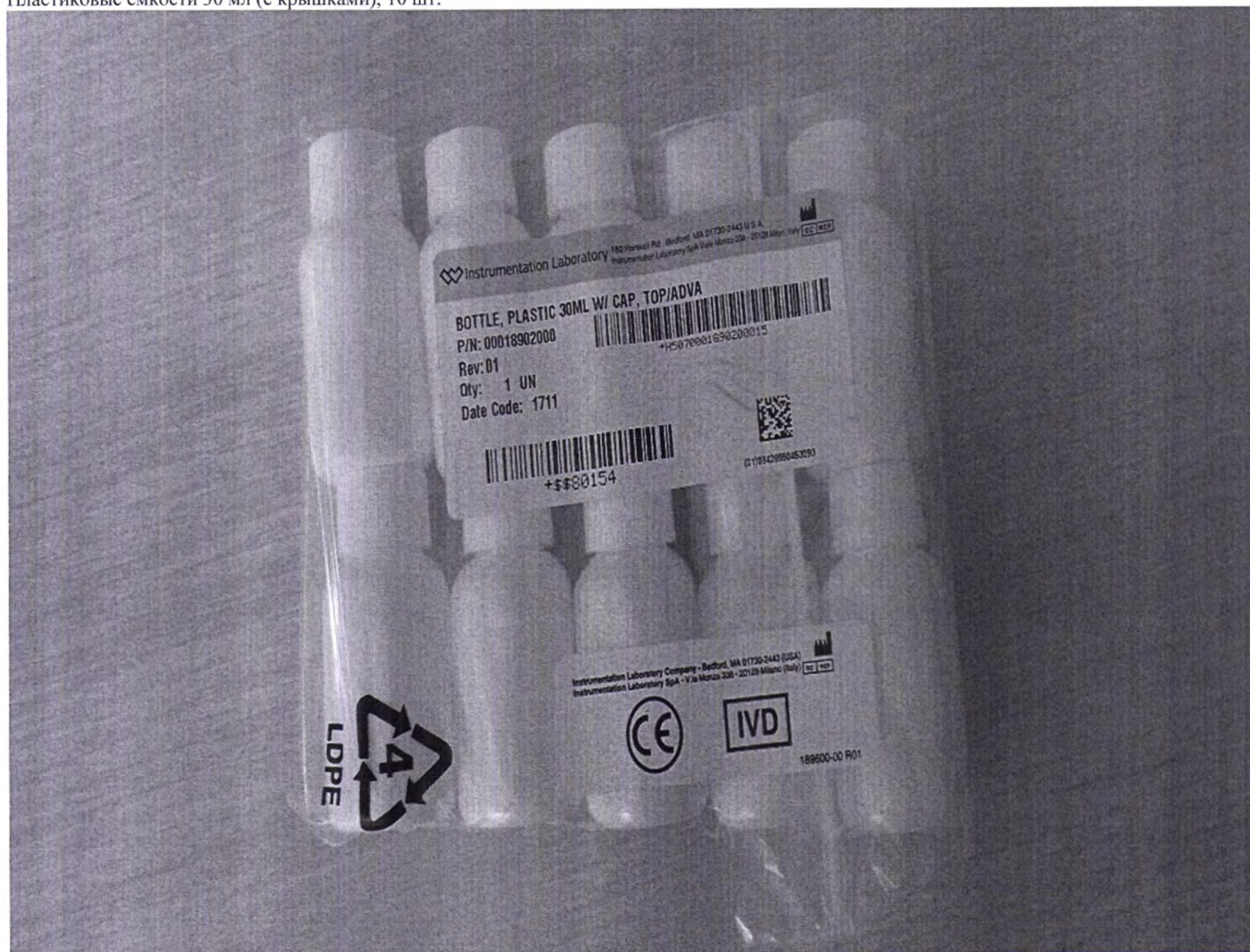


Аспиратор моющего раствора для ACL TOP, 1 шт.

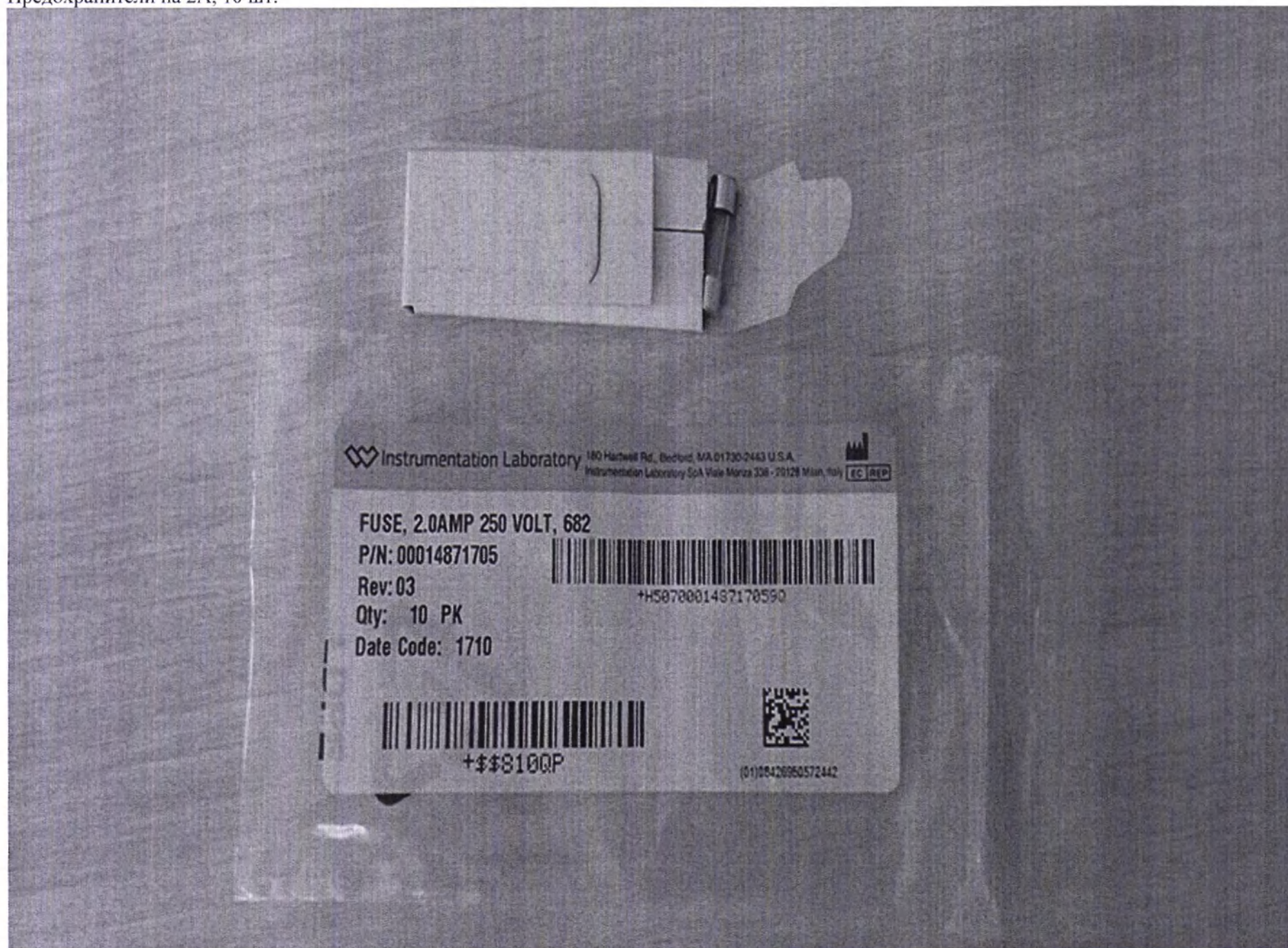




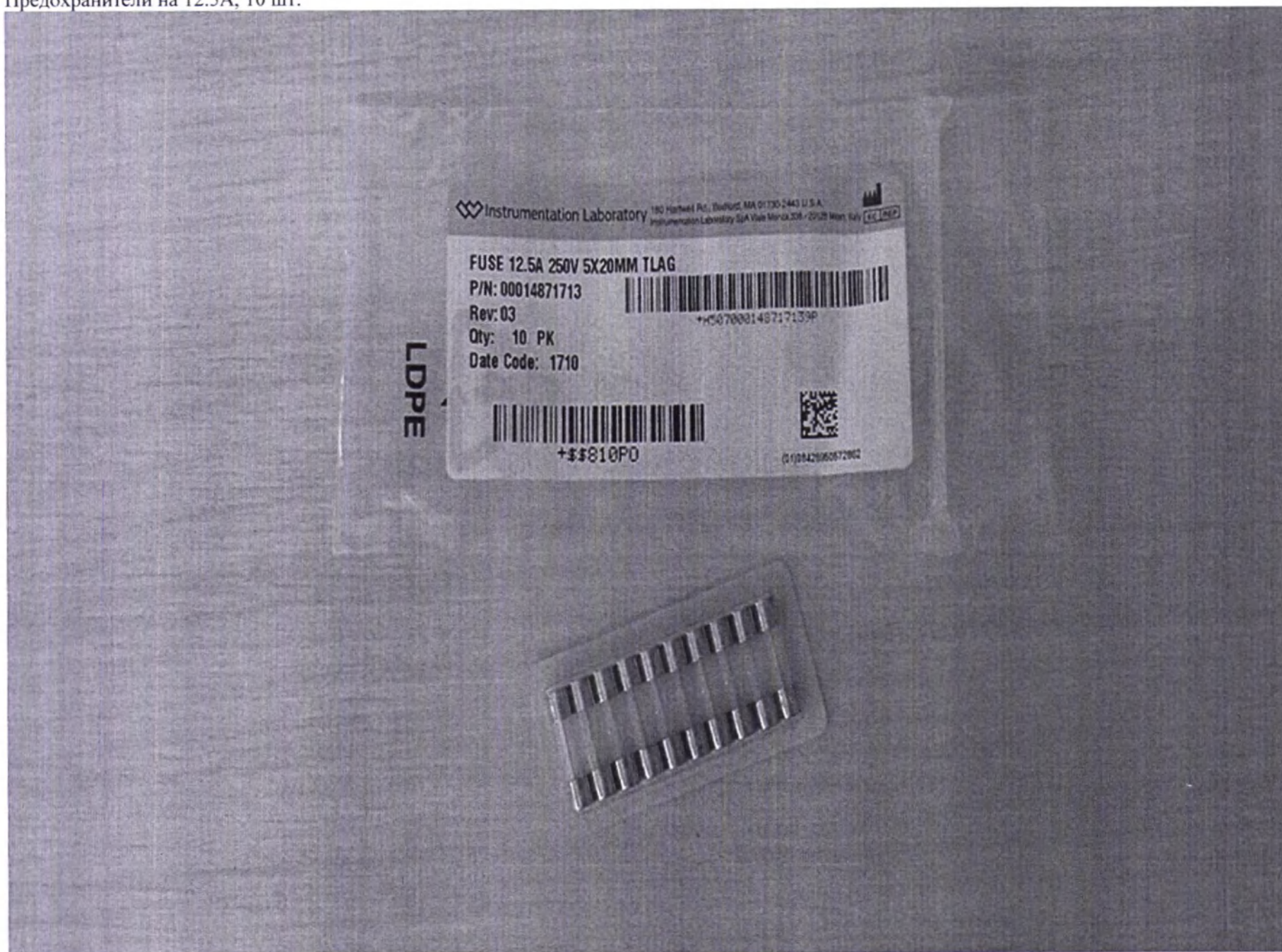
Пластиковые емкости 30 мл (с крышками), 10 шт.



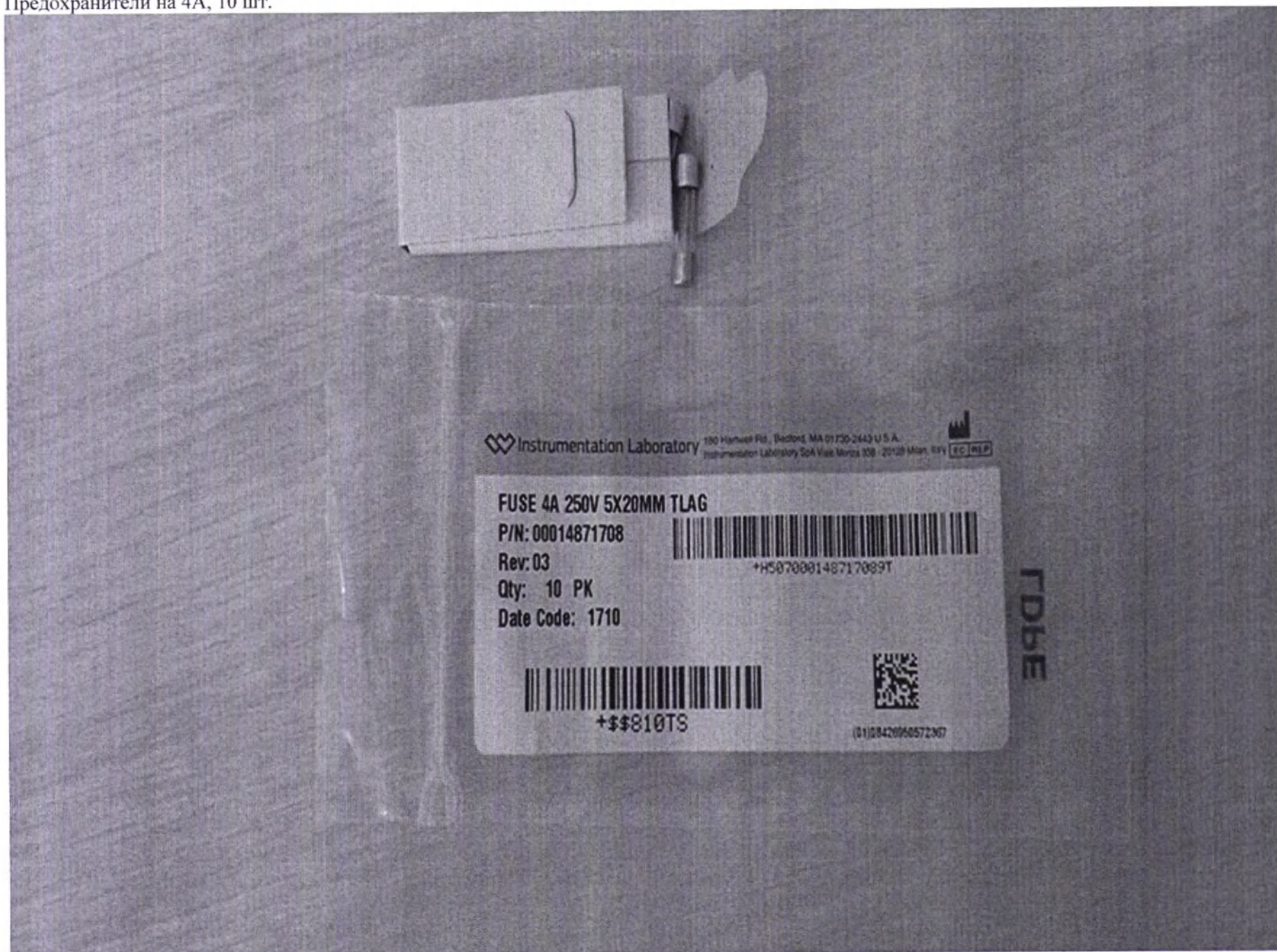
Предохранители на 2А, 10 шт.



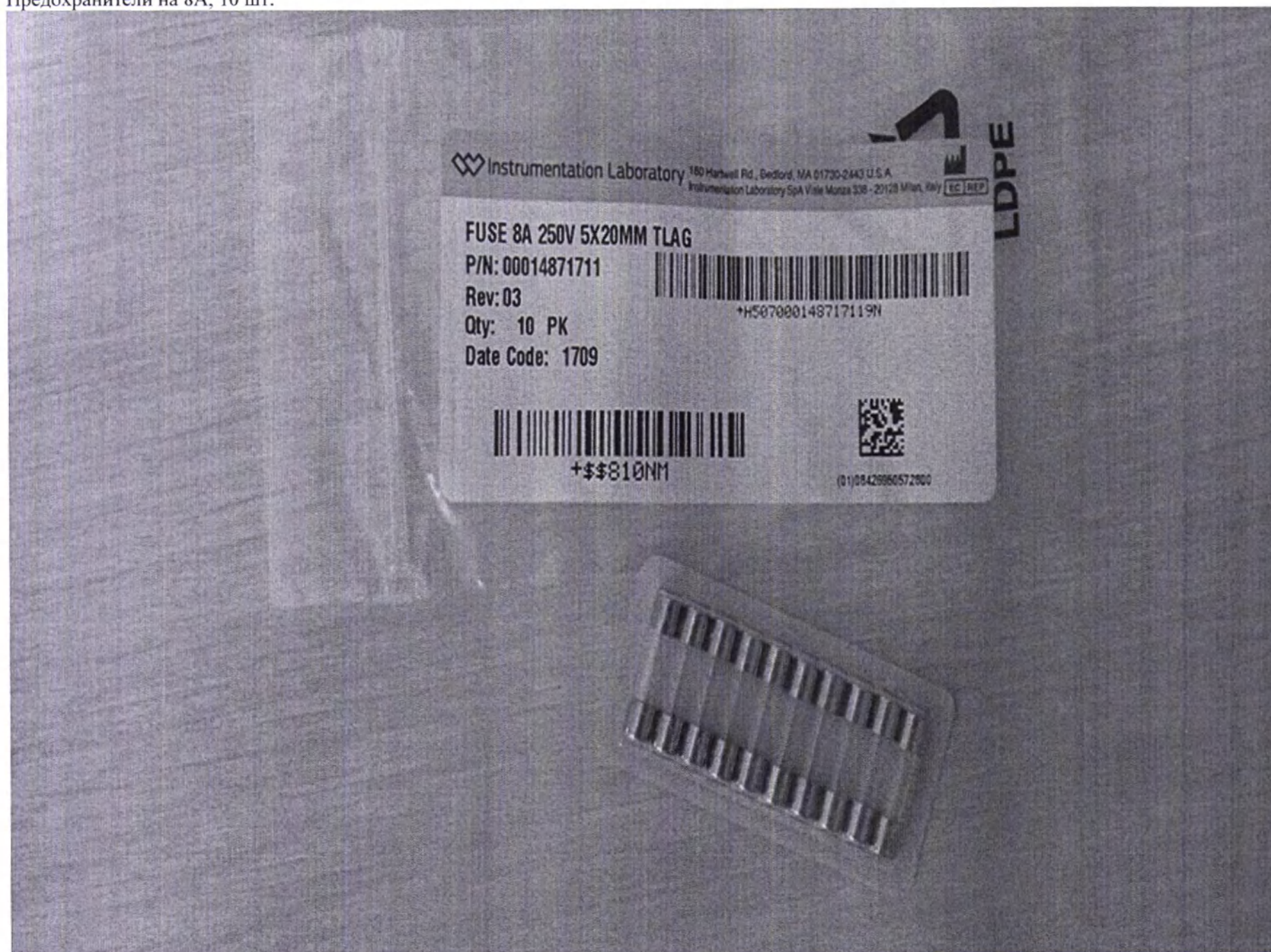
Предохранители на 12.5А, 10 шт.



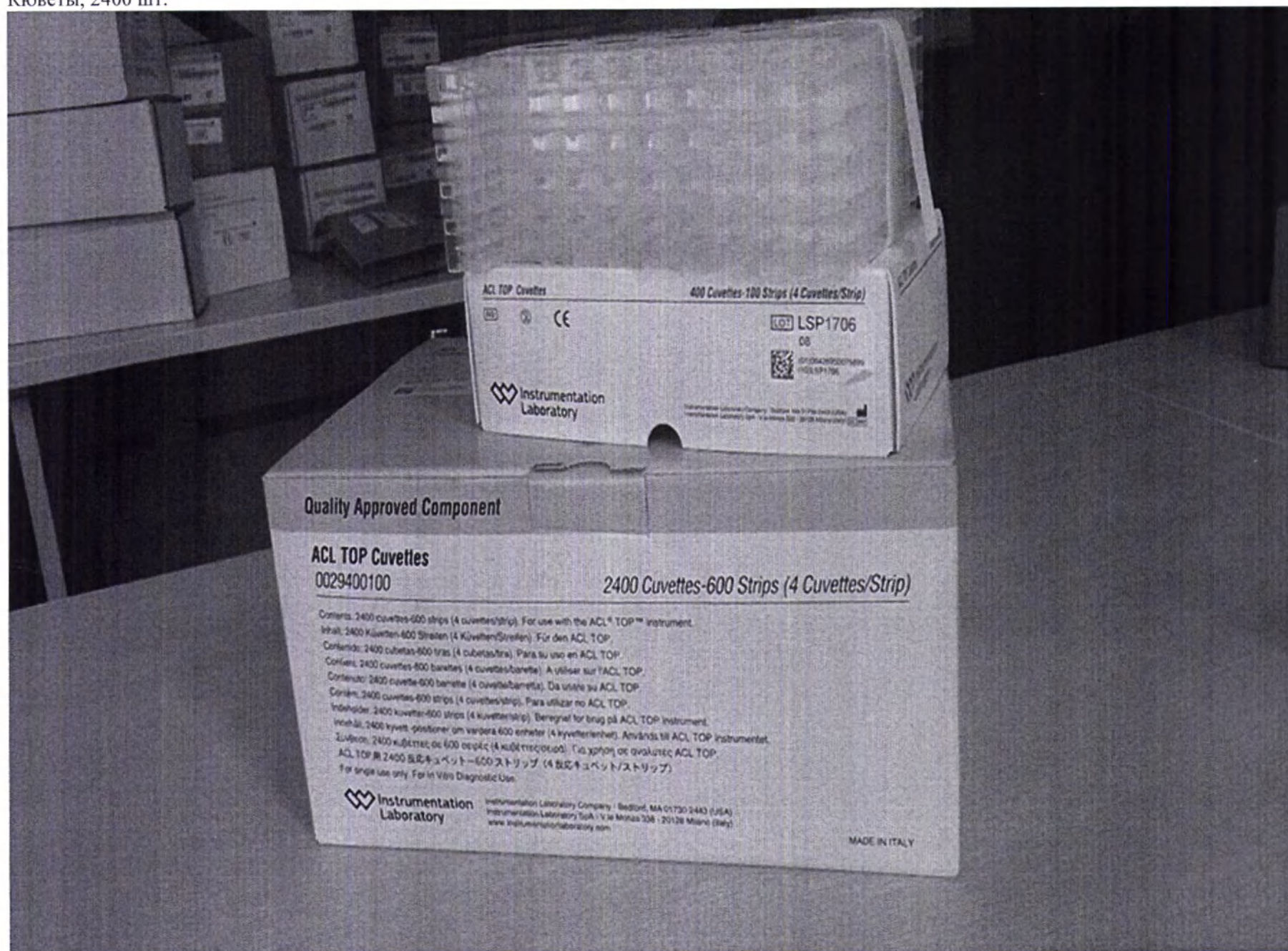
Предохранители на 4А, 10 шт.



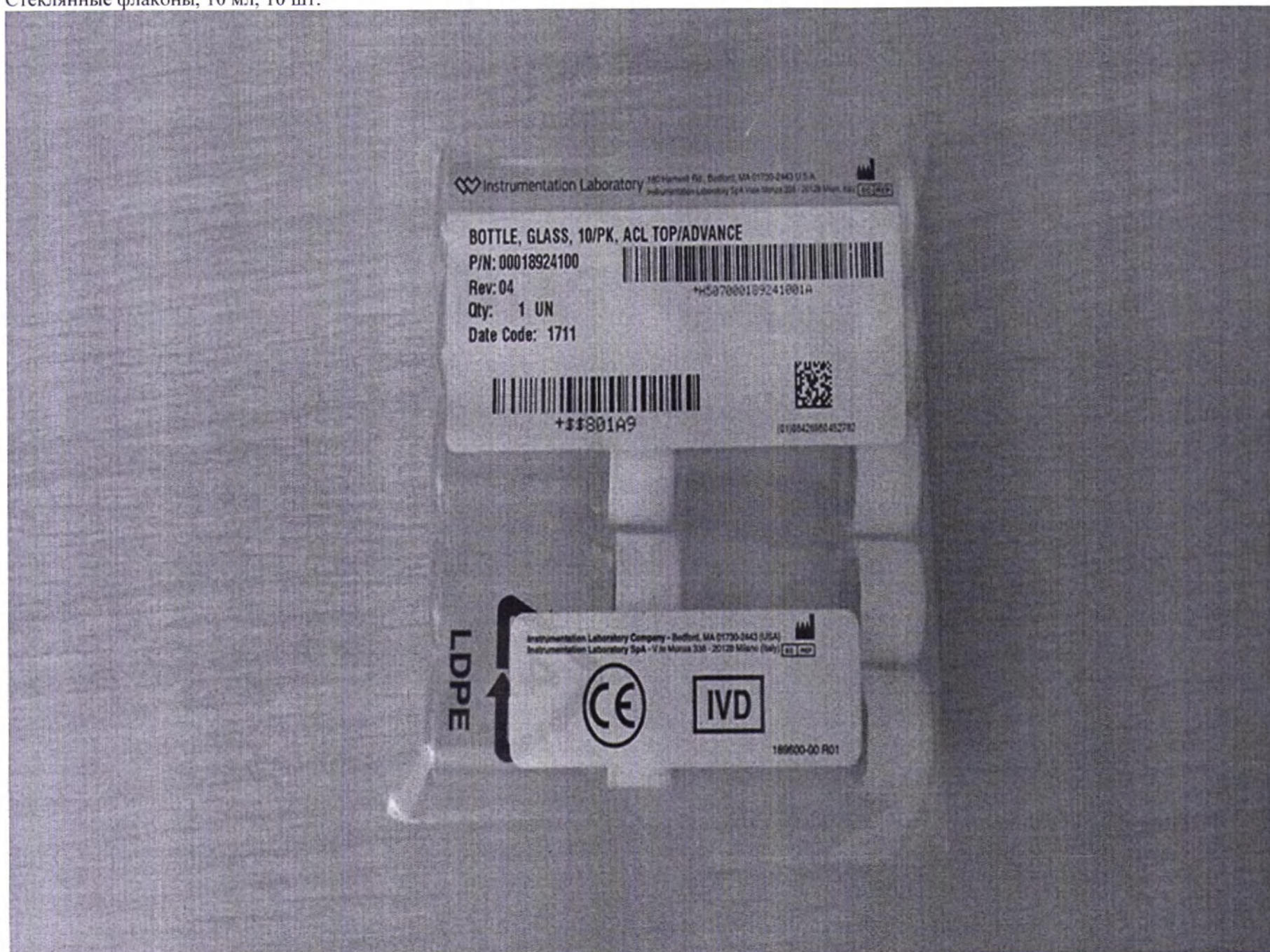
Предохранители на 8А, 10 шт.



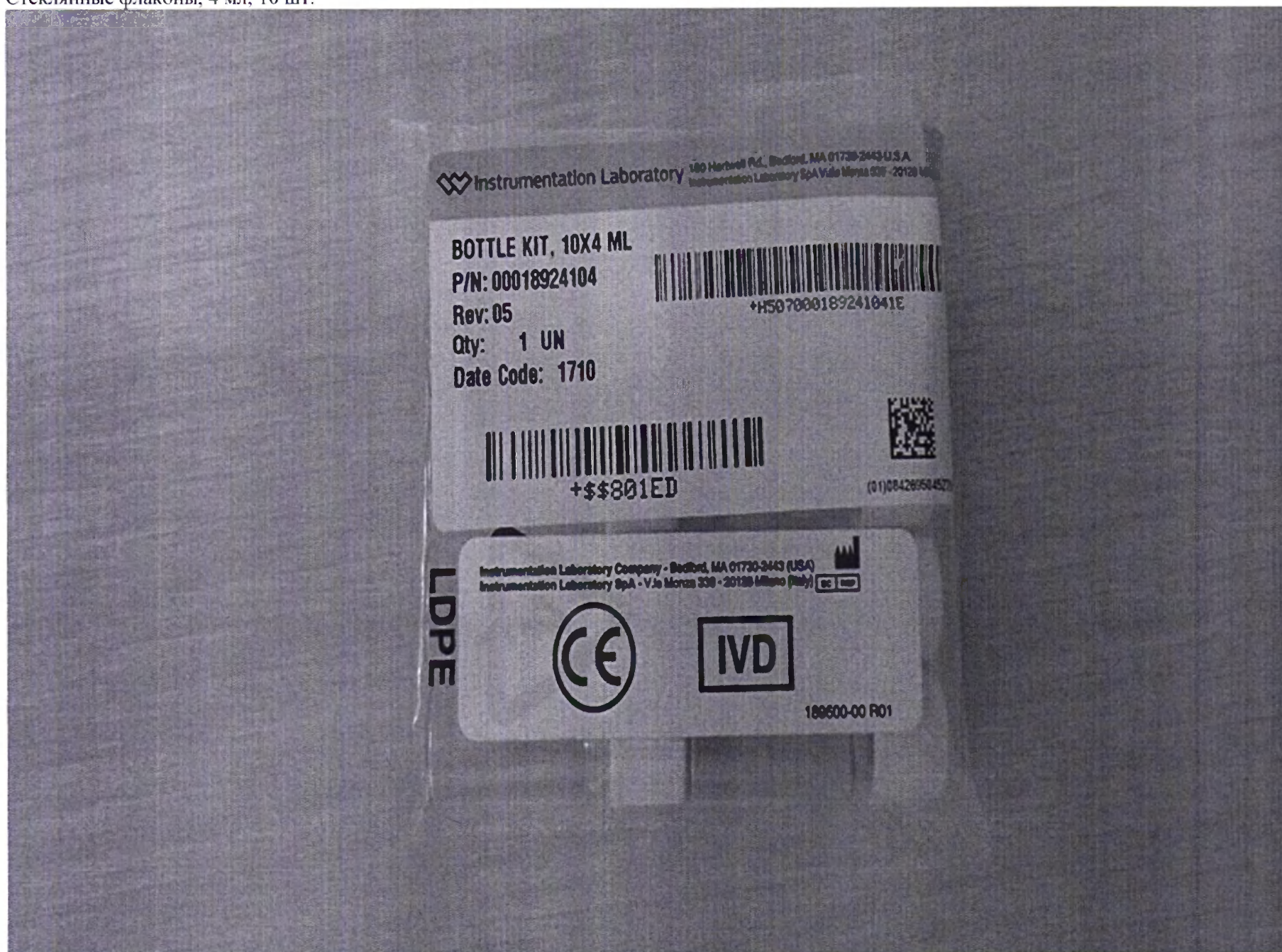
Кюветы, 2400 шт.



Стеклянные флаконы, 10 мл, 10 шт.



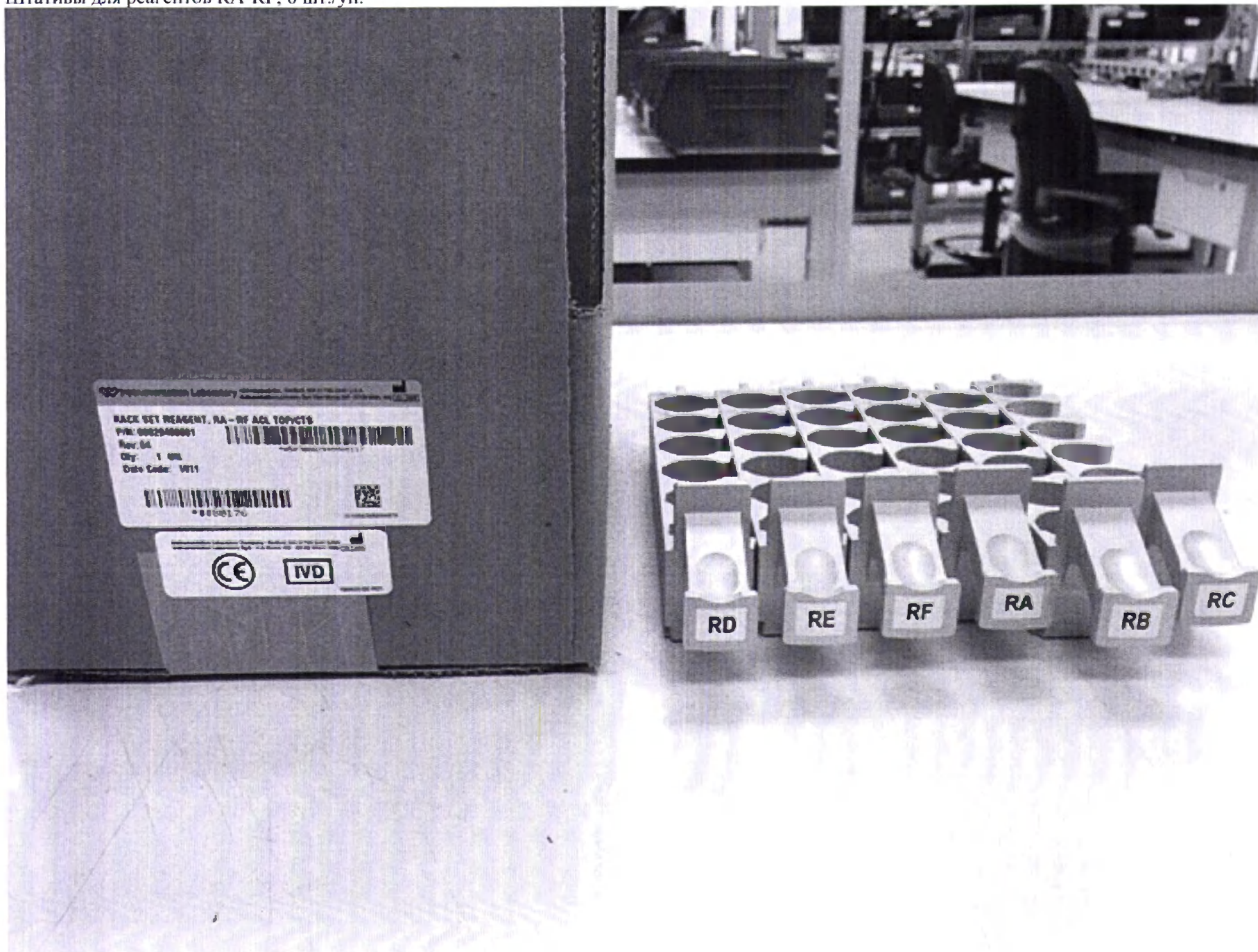
Стеклянные флаконы, 4 мл, 10 шт.



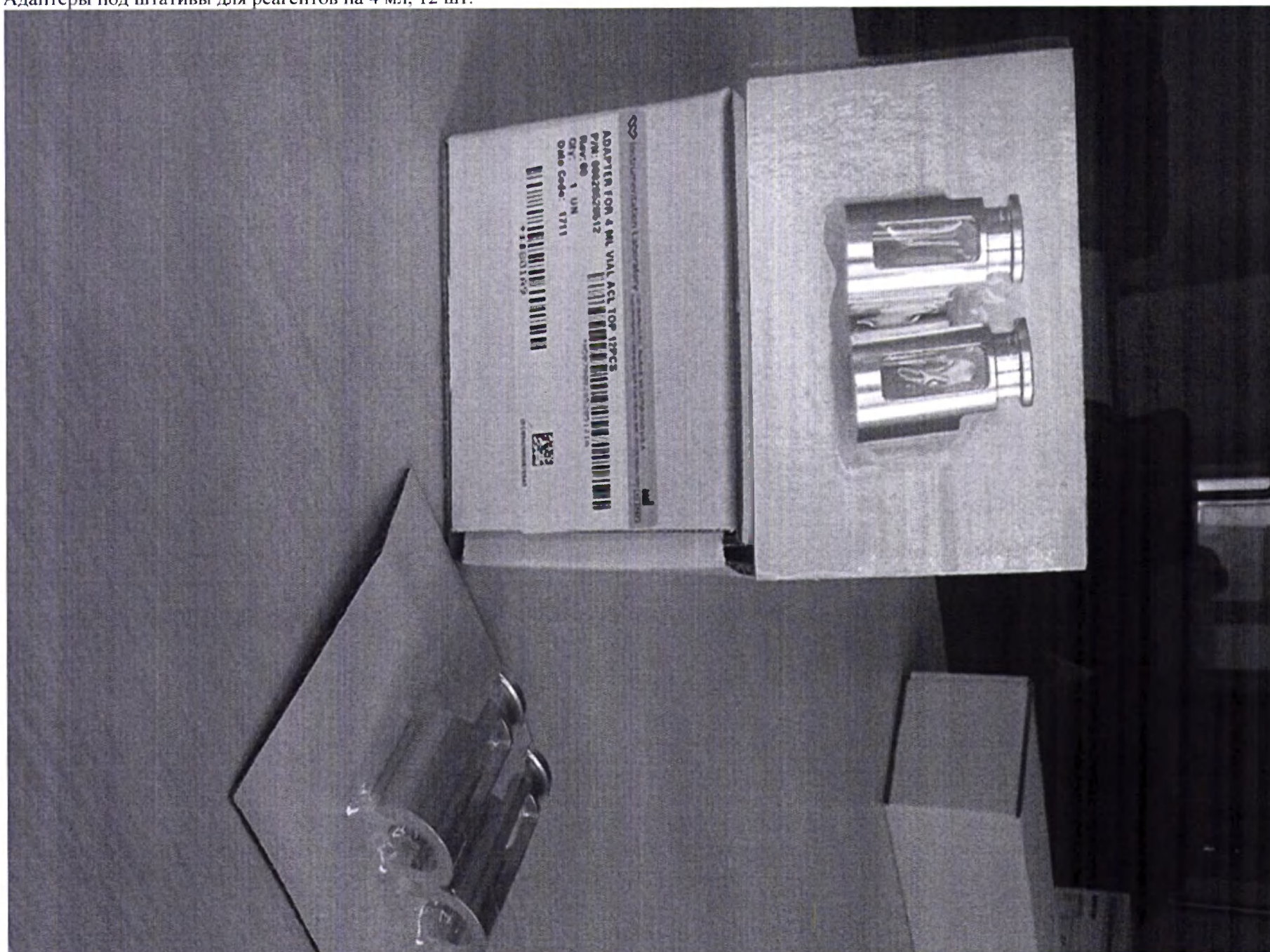
Штативы для разбавителей DA-DC, 3 шт./уп.



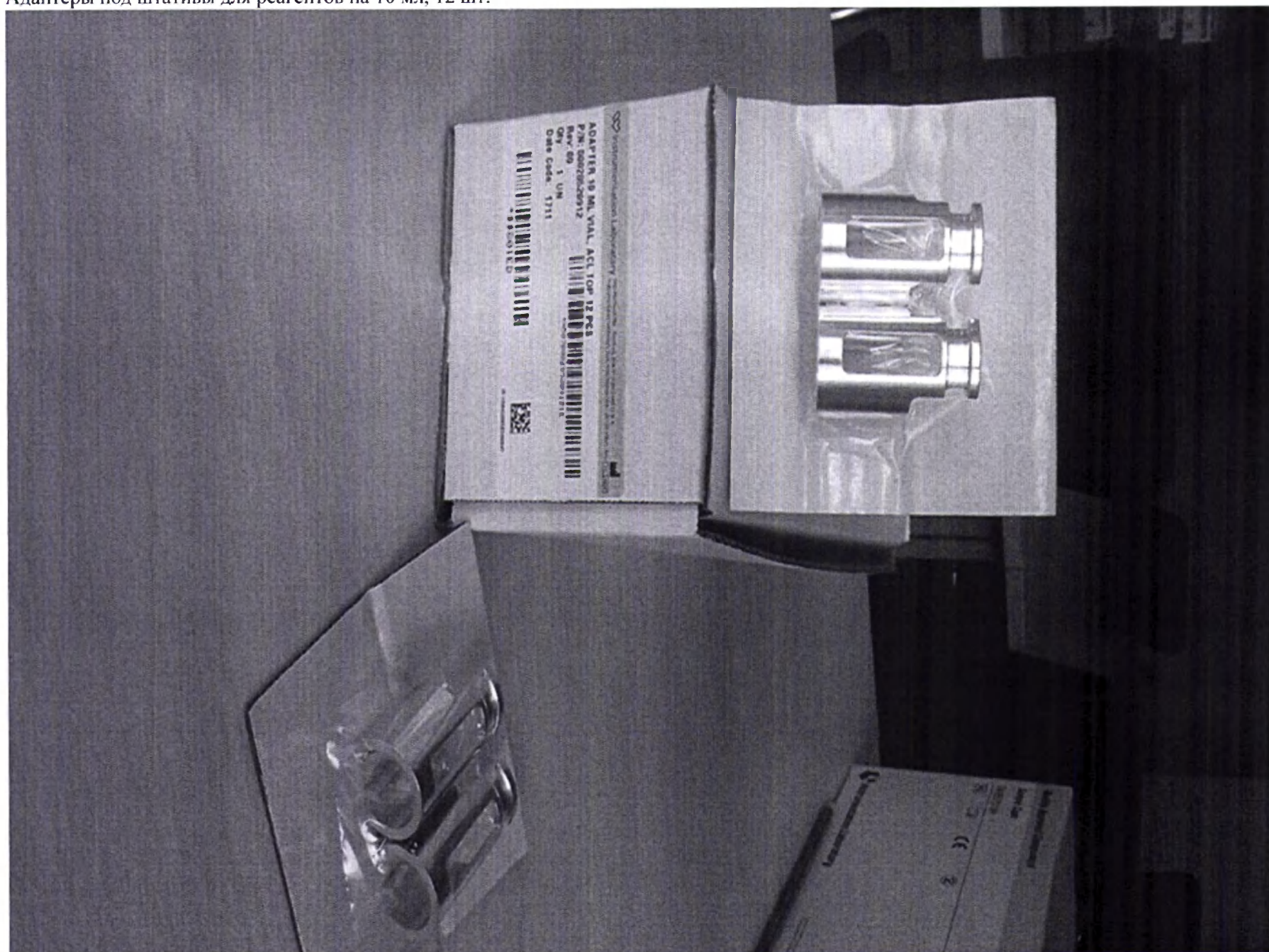
Штативы для реагентов RA-RF, 6 шт./уп.



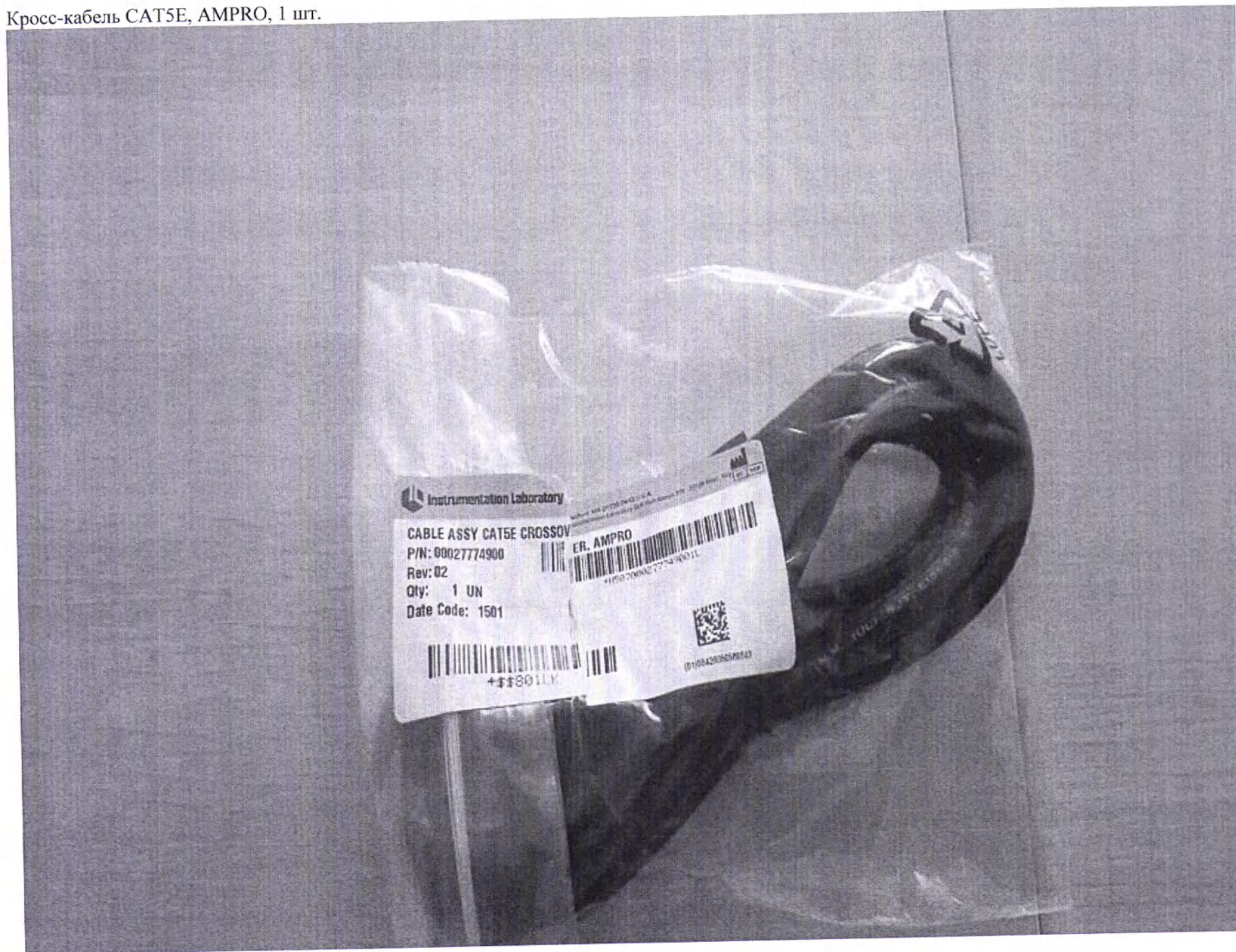
Адаптеры под штативы для реагентов на 4 мл, 12 шт.



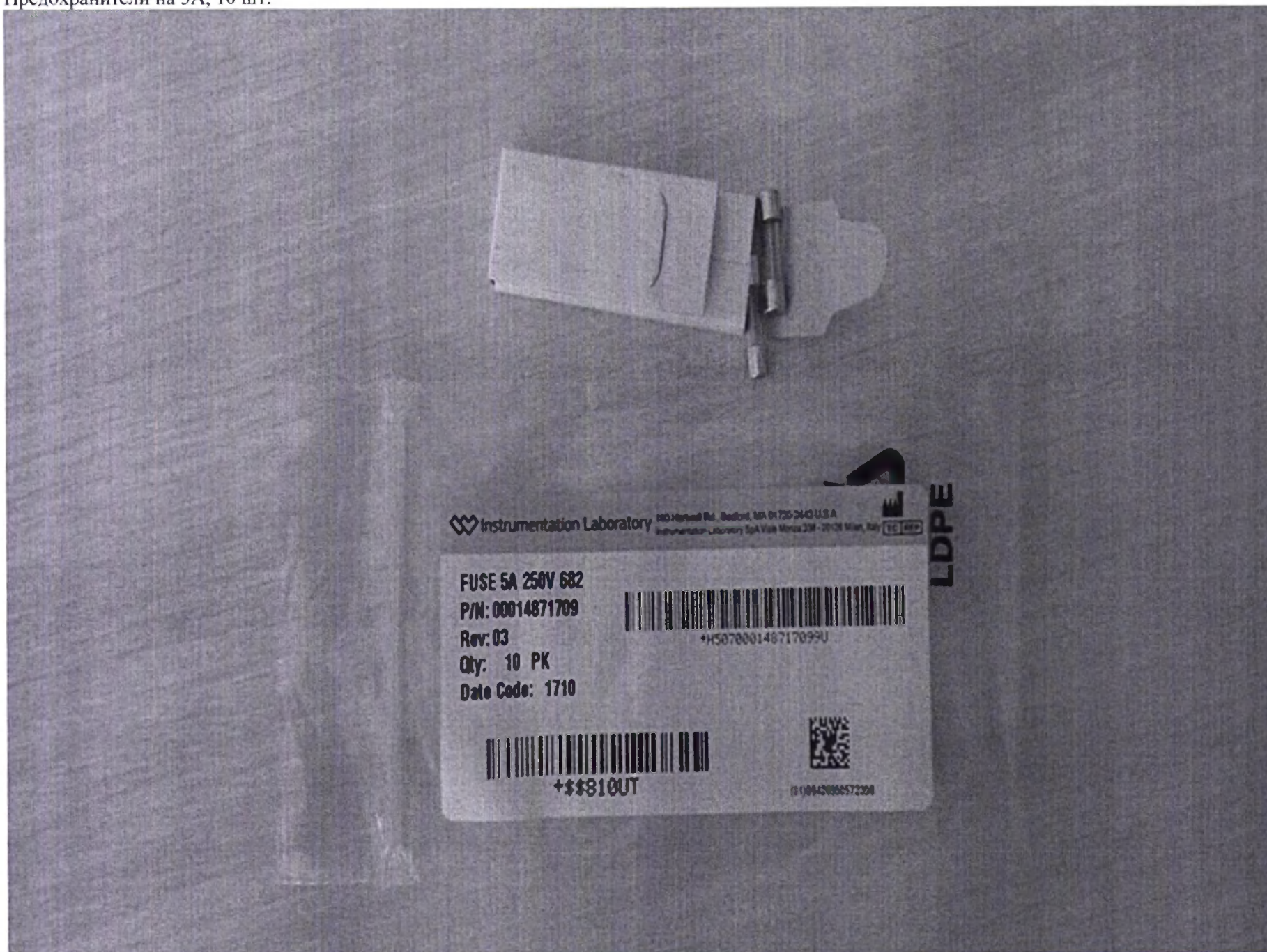
Адаптеры под штативы для реагентов на 10 мл, 12 шт.



Кросс-кабель CAT5E, AMPRO, 1 шт.



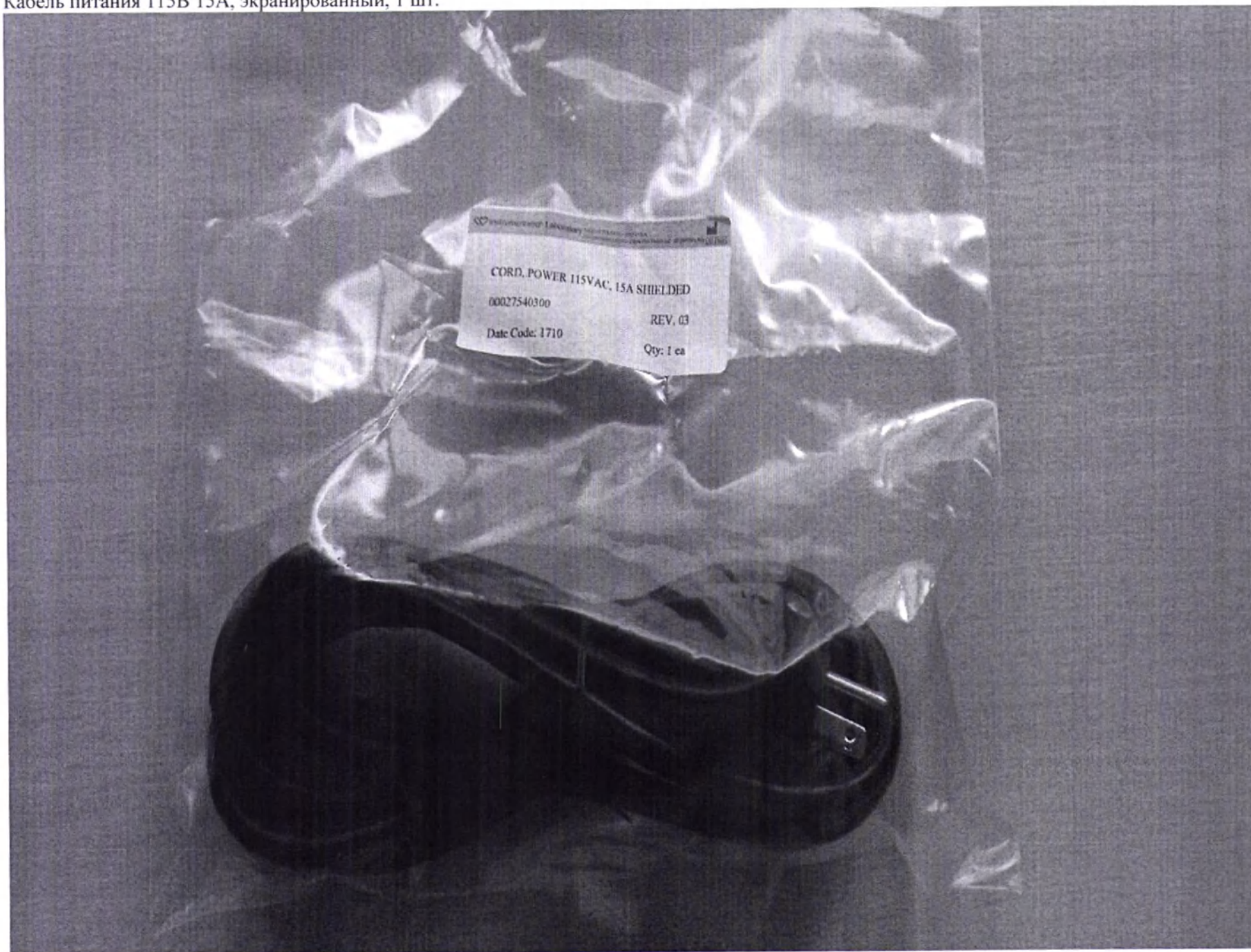
Предохранители на 5А, 10 шт.



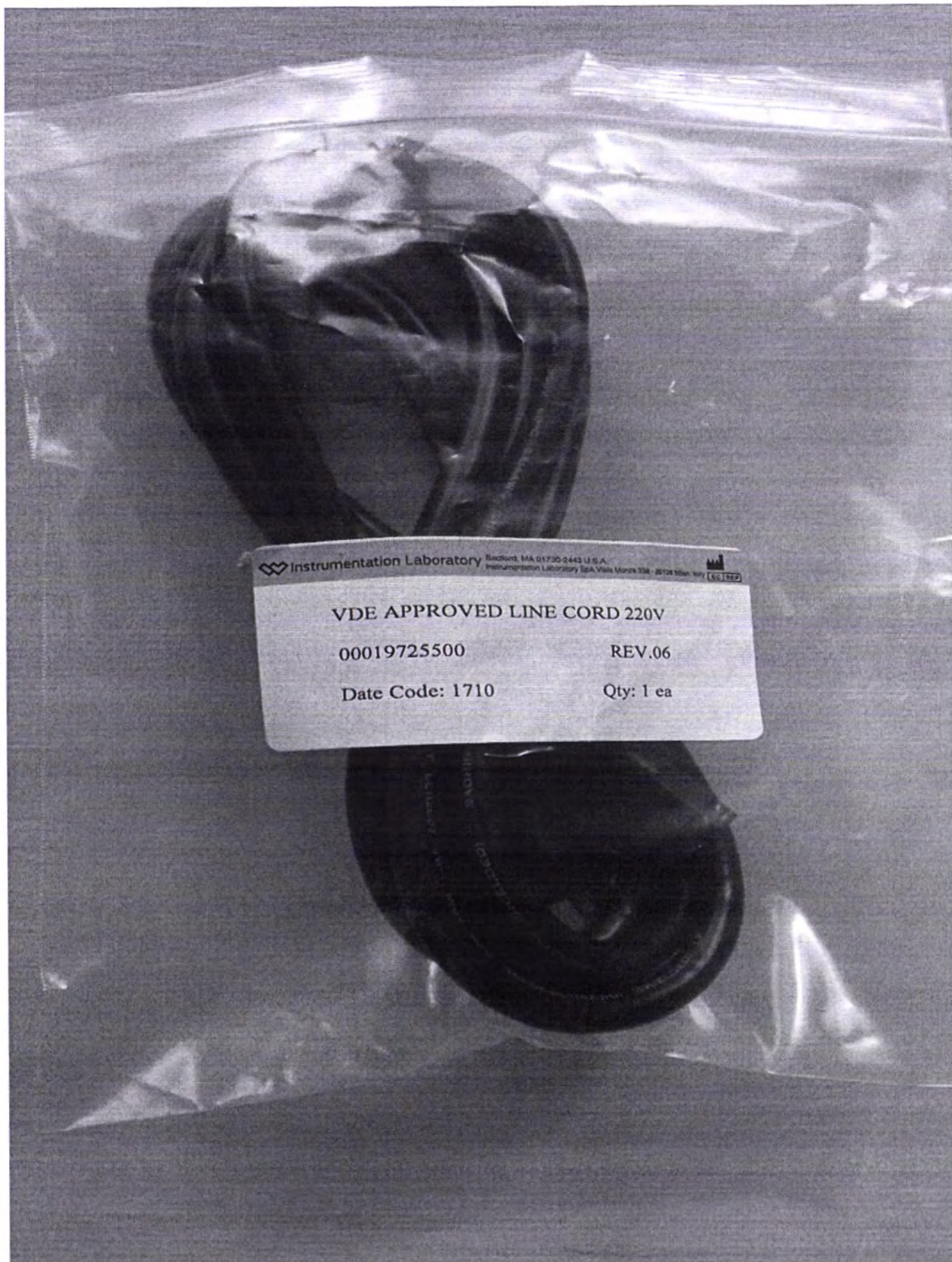
Предохранители на 1.25A, 10 шт.



Кабель питания 115В 15А, экранированный, 1 шт.



Кабель питания 220 В, 1 шт.



Instrumentation Laboratory Bedford, MA 01730-2443 U.S.A.
Instrumentation Laboratory SpA Viale Mattei 33B - 20128 Milan, Italy

VDE APPROVED LINE CORD 220V

00019725500

REV.06

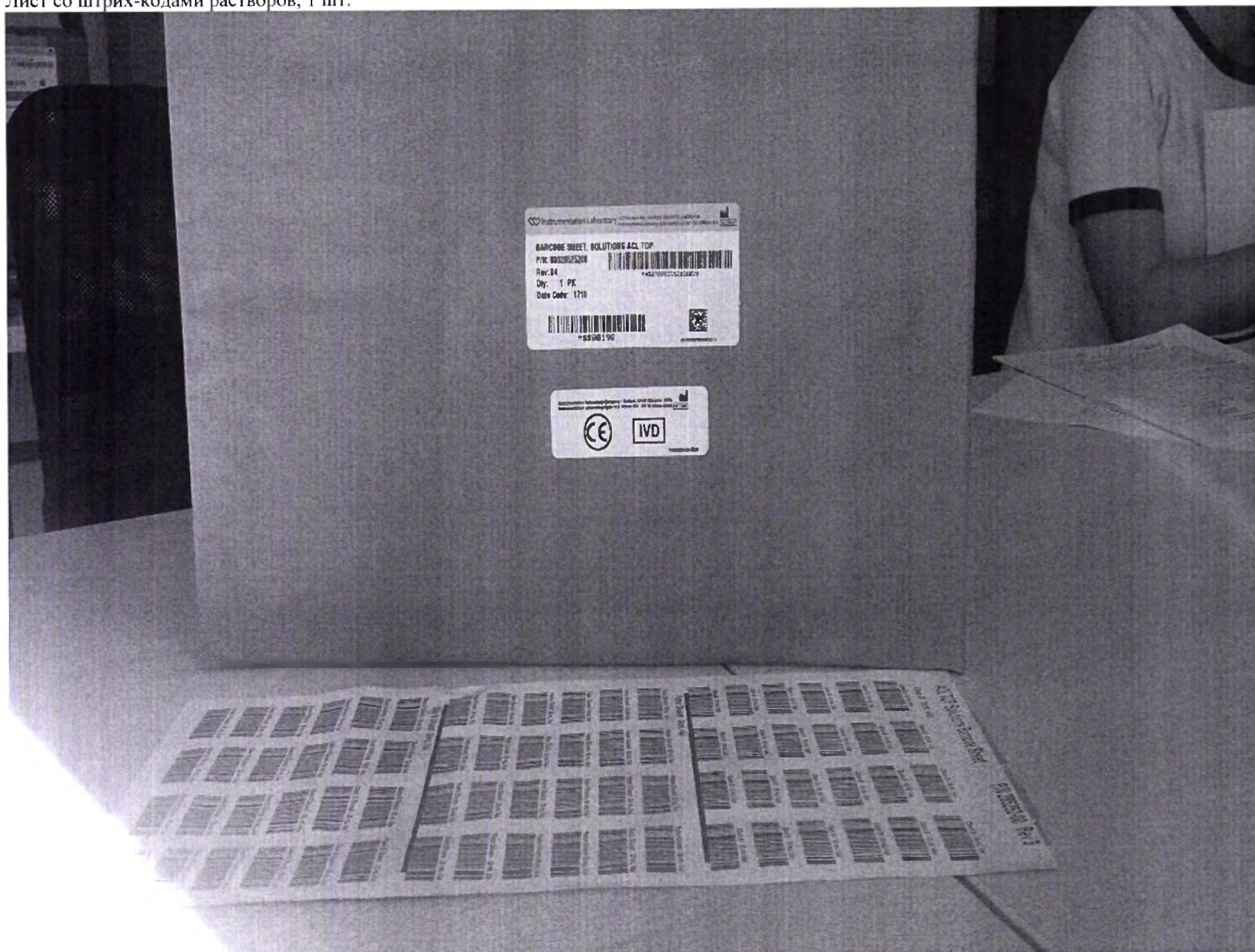
Date Code: 1710

Qty: 1 ea

Контейнер для твердых отходов, 10 шт.



Лист со штрих-кодами растворов, 1 шт.

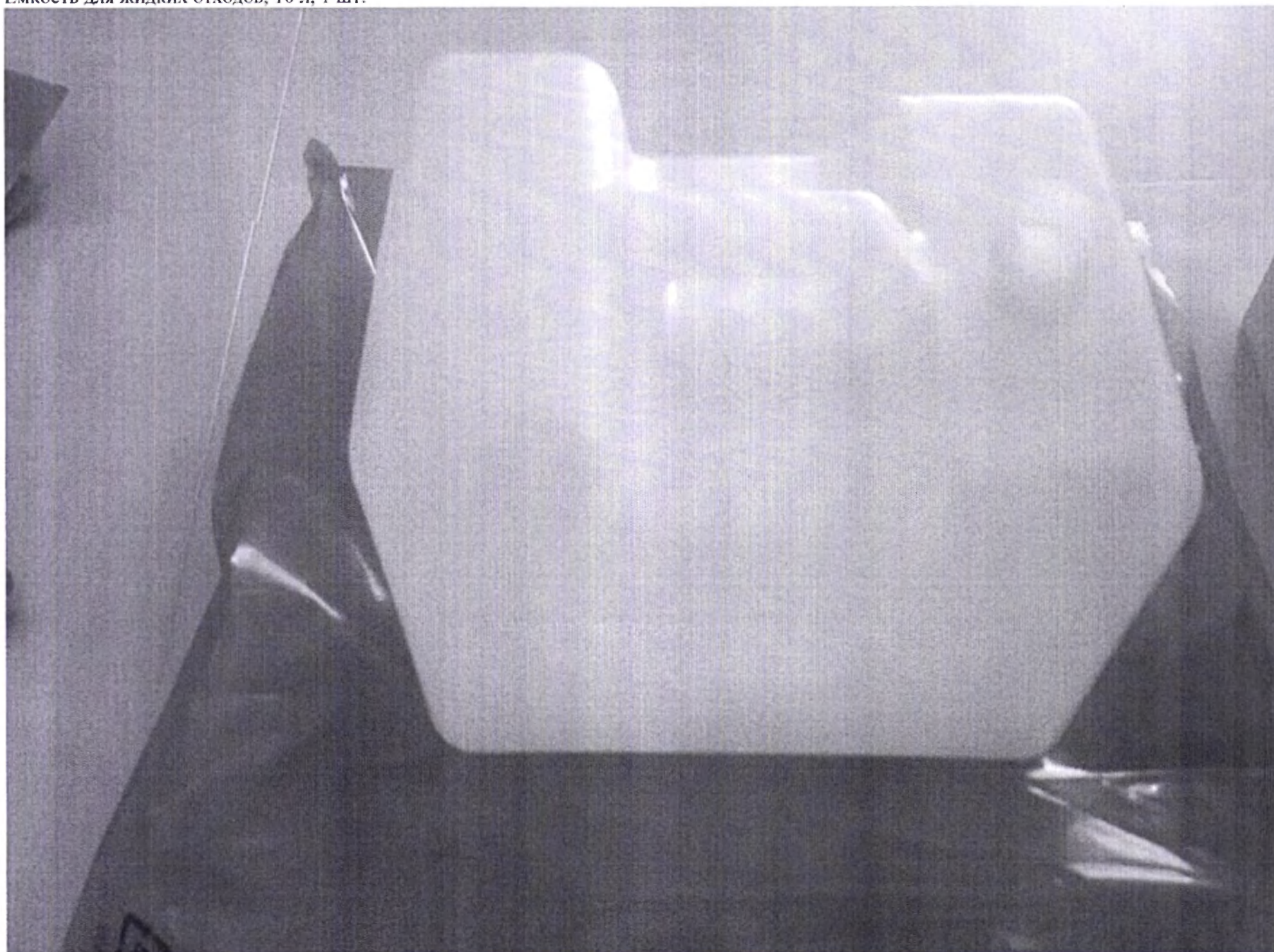


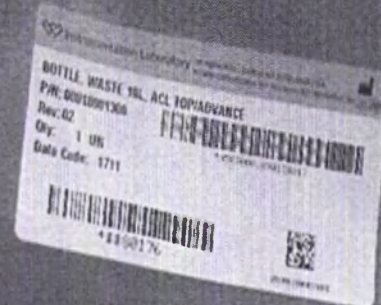
Датчик контейнера для жидких отходов, 1 шт.



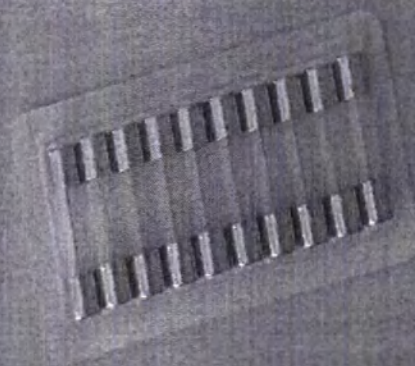
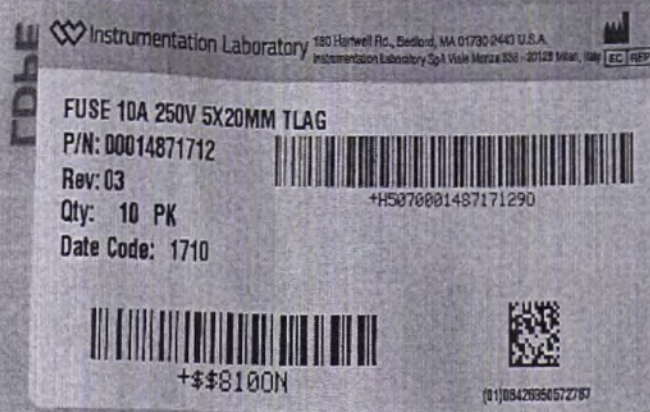


Емкость для жидких отходов, 10 л, 1 шт.

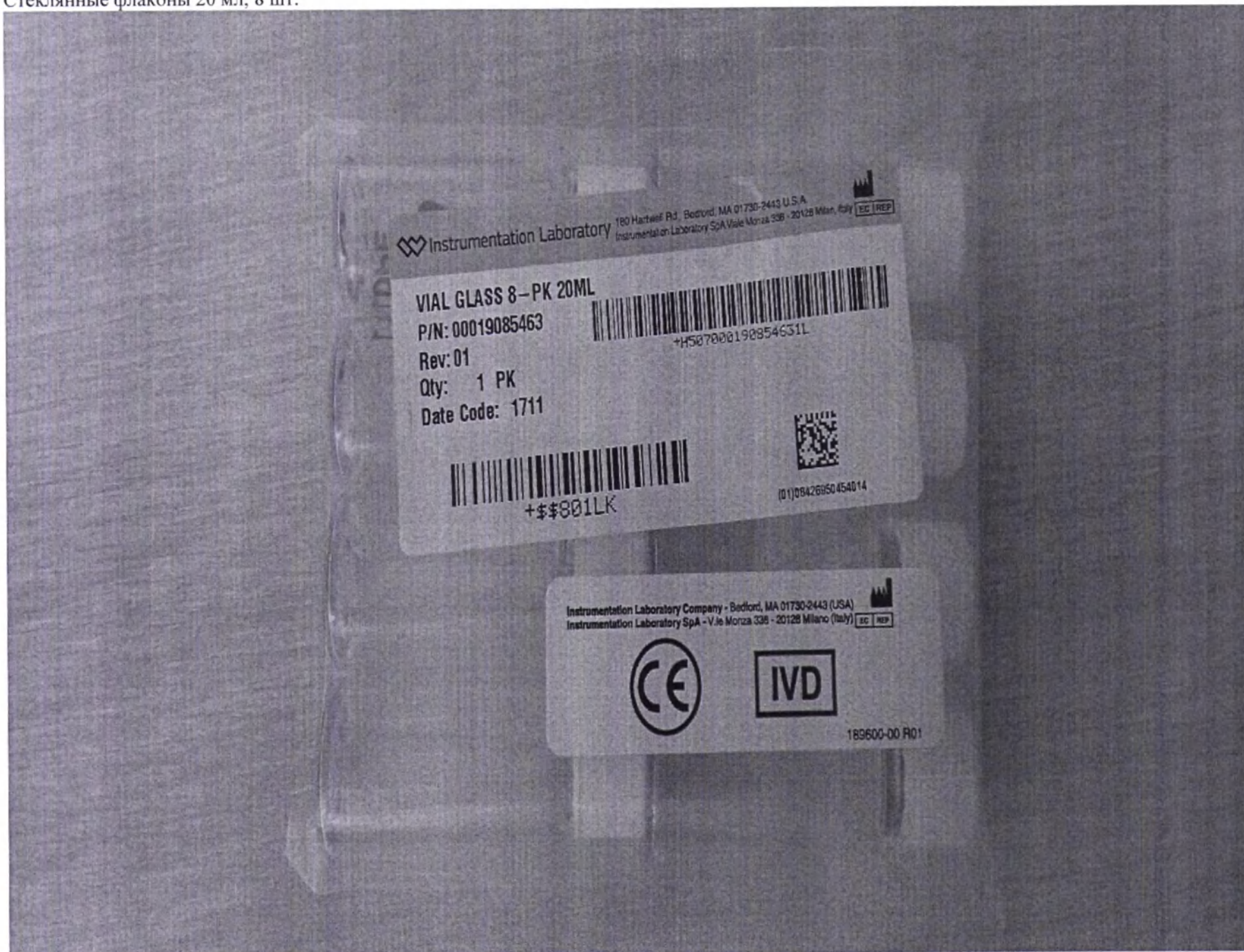




Предохранители на 10А, 10 шт.



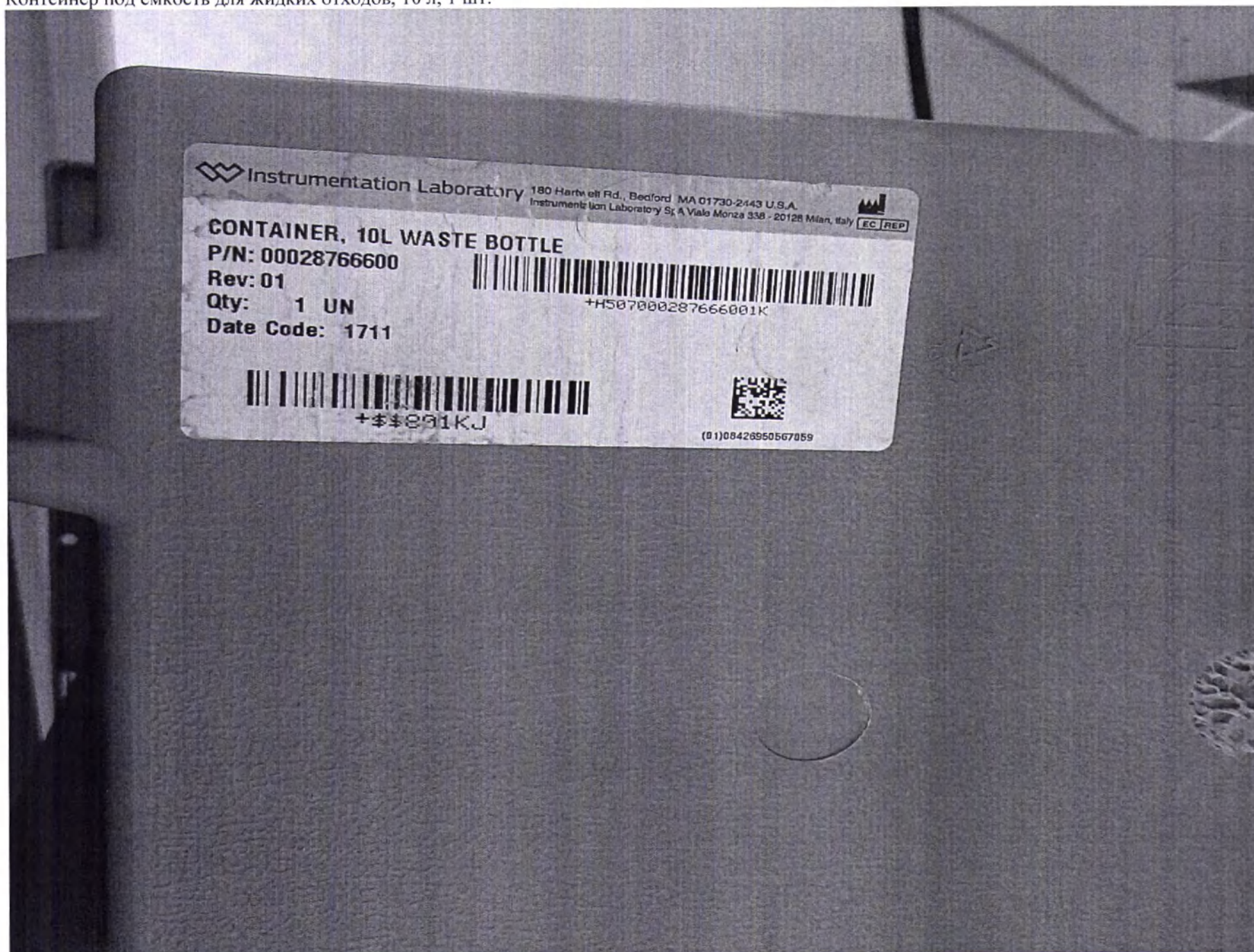
Стеклянные флаконы 20 мл, 8 шт.



Адаптеры под штативы для образцов: адаптеры для аликвотных пробирок, 5 шт.; адаптеры для педиатрических пробирок, 5шт.



Контейнер под емкость для жидких отходов, 10 л, 1 шт.



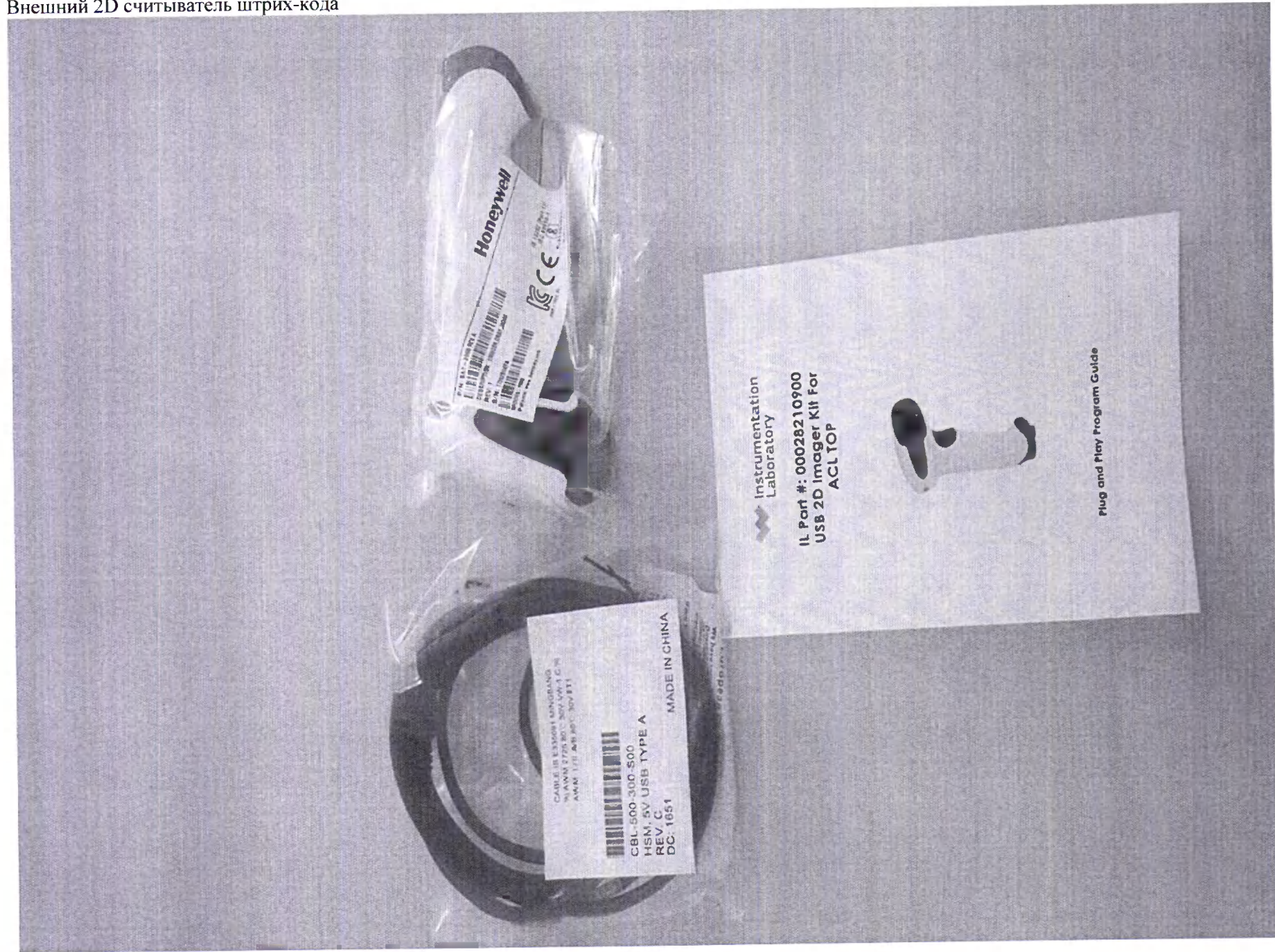


Подставка под 6 штативов для образцов, 1 шт.



Адаптеры под штативы для разбавителей на 4 мл, 6 шт





Кабель RS232, AMPRO, 1 шт.



Магнитные мешалки, 6 шт.

MAGNETIC STIR BARS, 6/PK

Q.ty : 1

Item N° : 0009746606

Instrumentation Laboratory Company - Bedford, MA 01730-2443 (USA)
Instrumentation Laboratory SpA - V.le Monza 338 - 20128 Milano (Italy)



EC REP

(Italy)



189600-00 R01

Штативы для образцов под открытые пробирки 01-12, 12 шт./уп.



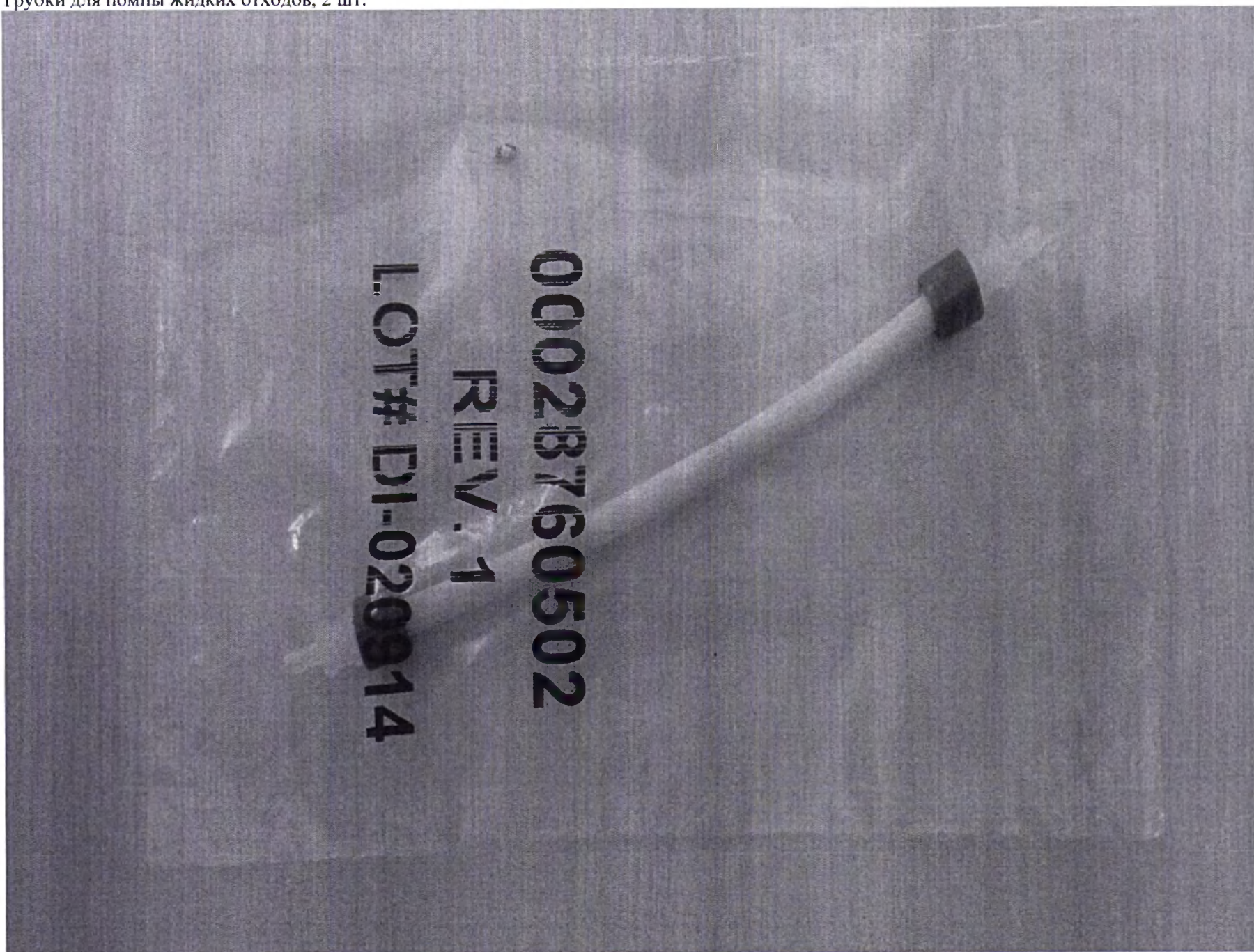
Адаптеры под штативы для разбавителей на 10 мл, 6 шт.



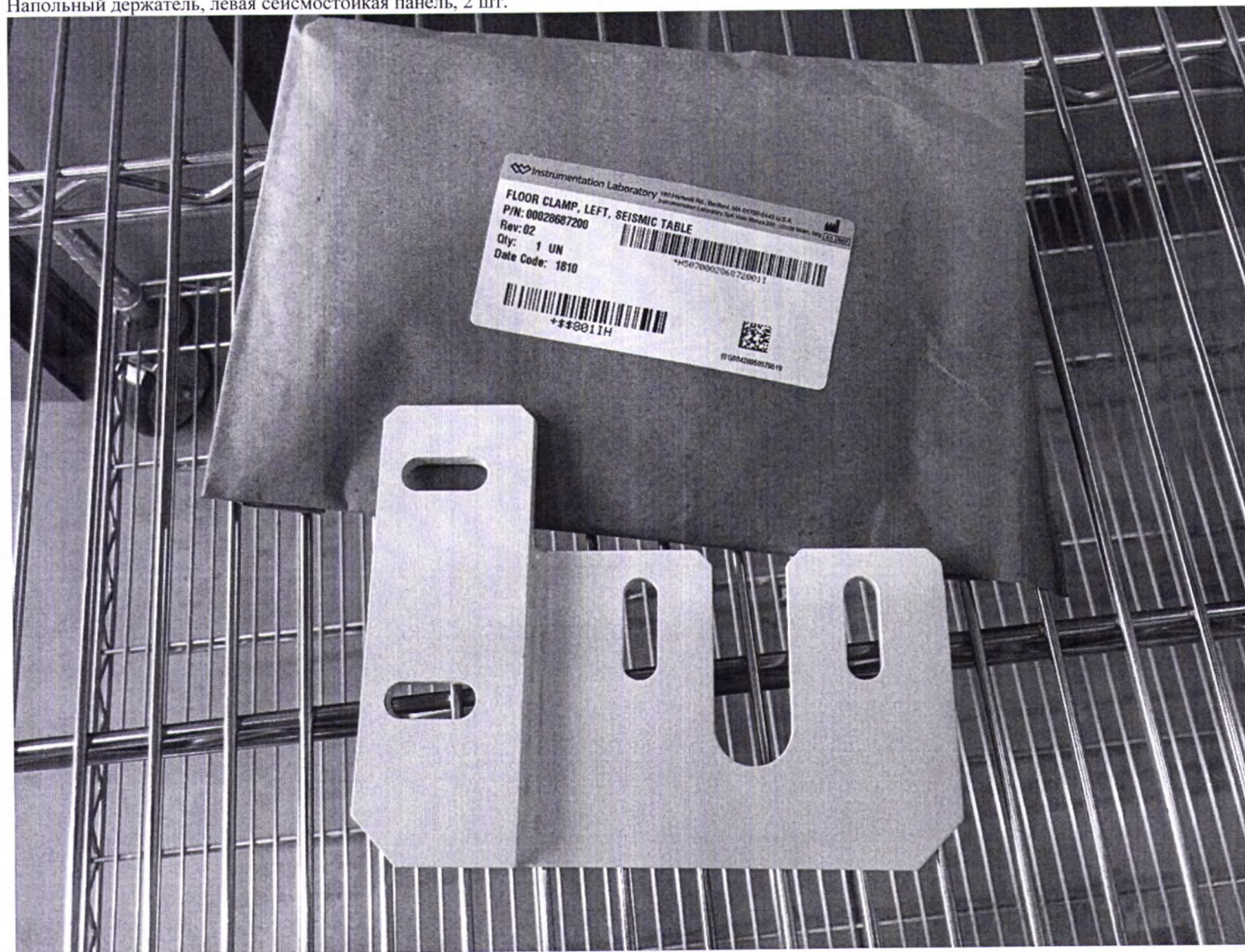
Адаптеры под штативы для разбавителей на 20 мл, 6 шт.



Трубки для помпы жидких отходов, 2 шт.



Напольный держатель, левая сейсмостойкая панель, 2 шт.



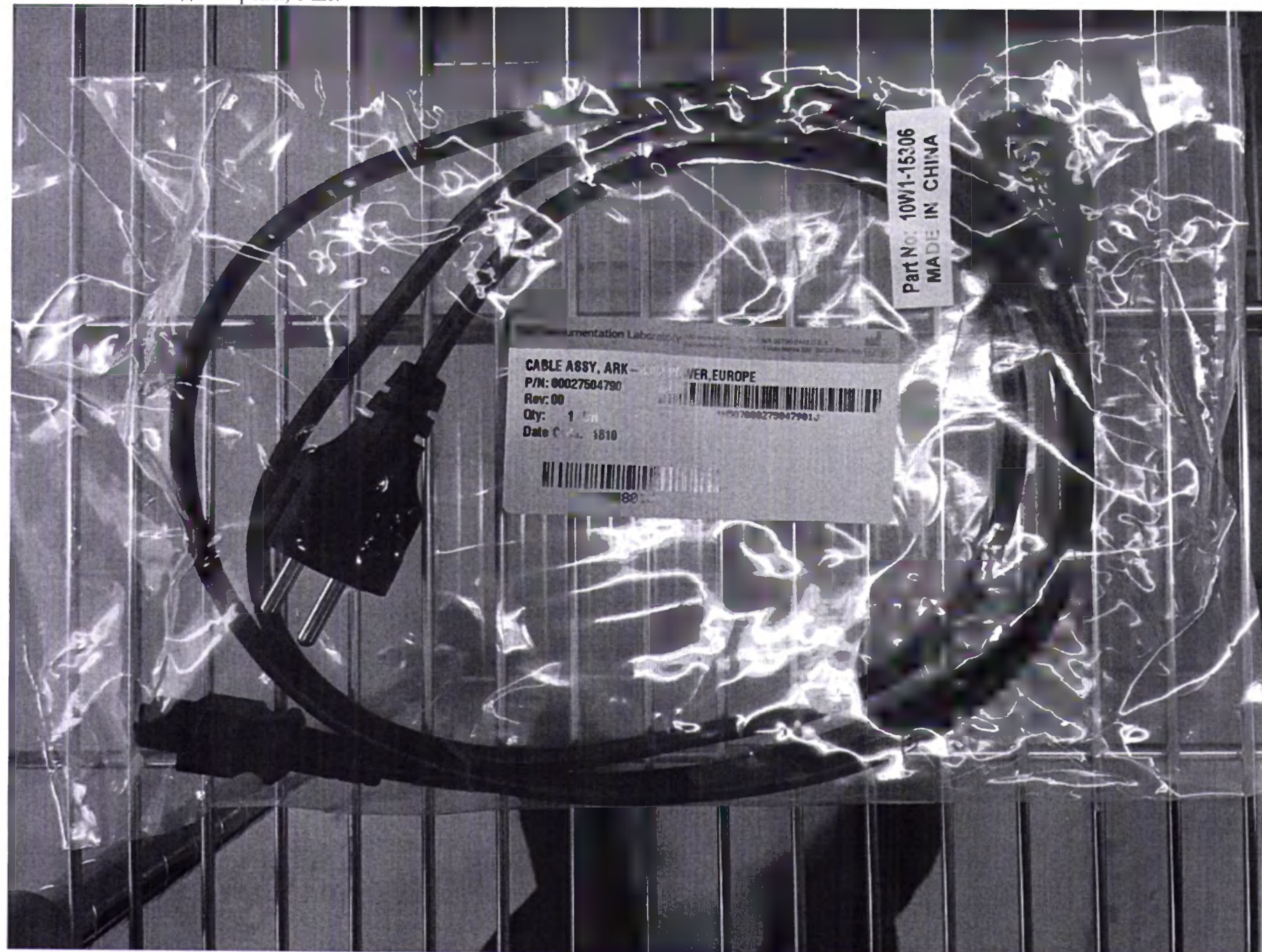
Напольный держатель, правая сейсмостойкая панель, 2 шт.



Кабель ARK-3382 для USA, 1 шт.



Кабель ARK-3382 для Европы, 1 шт.



Шайба, 8 шт.



Гроверная шайба, 8 шт.



00028904310/03

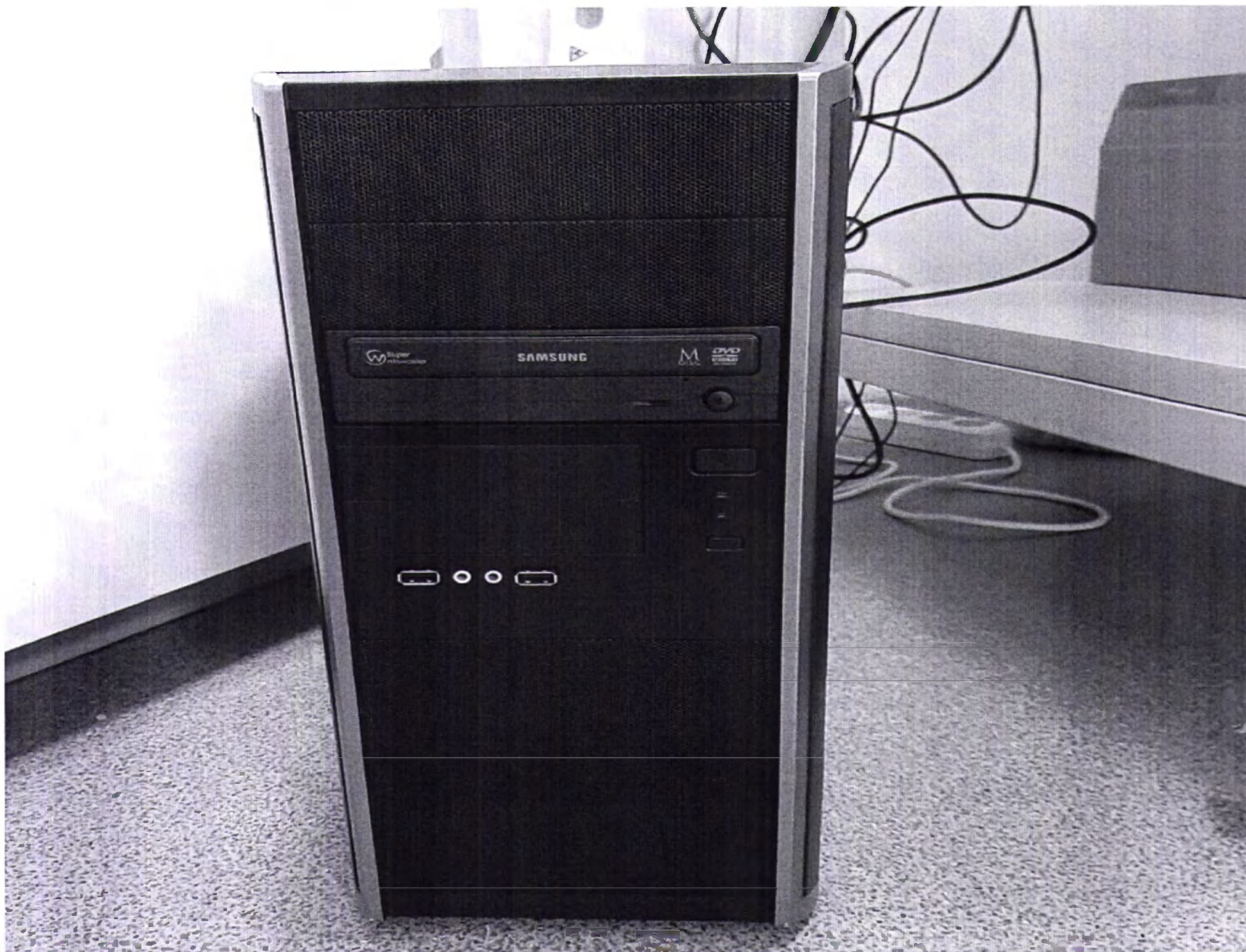


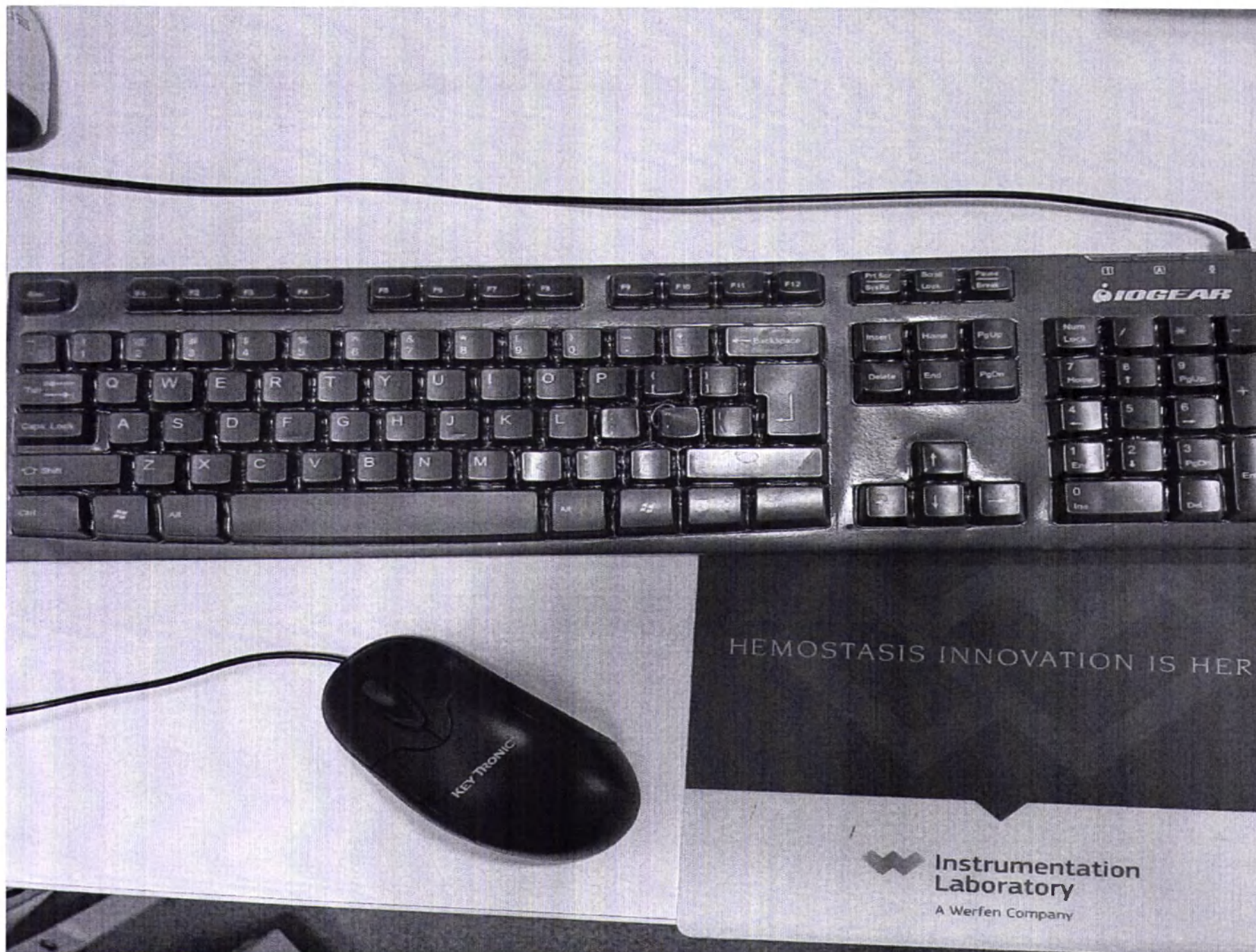
LDPE

Гайка, 8 шт.

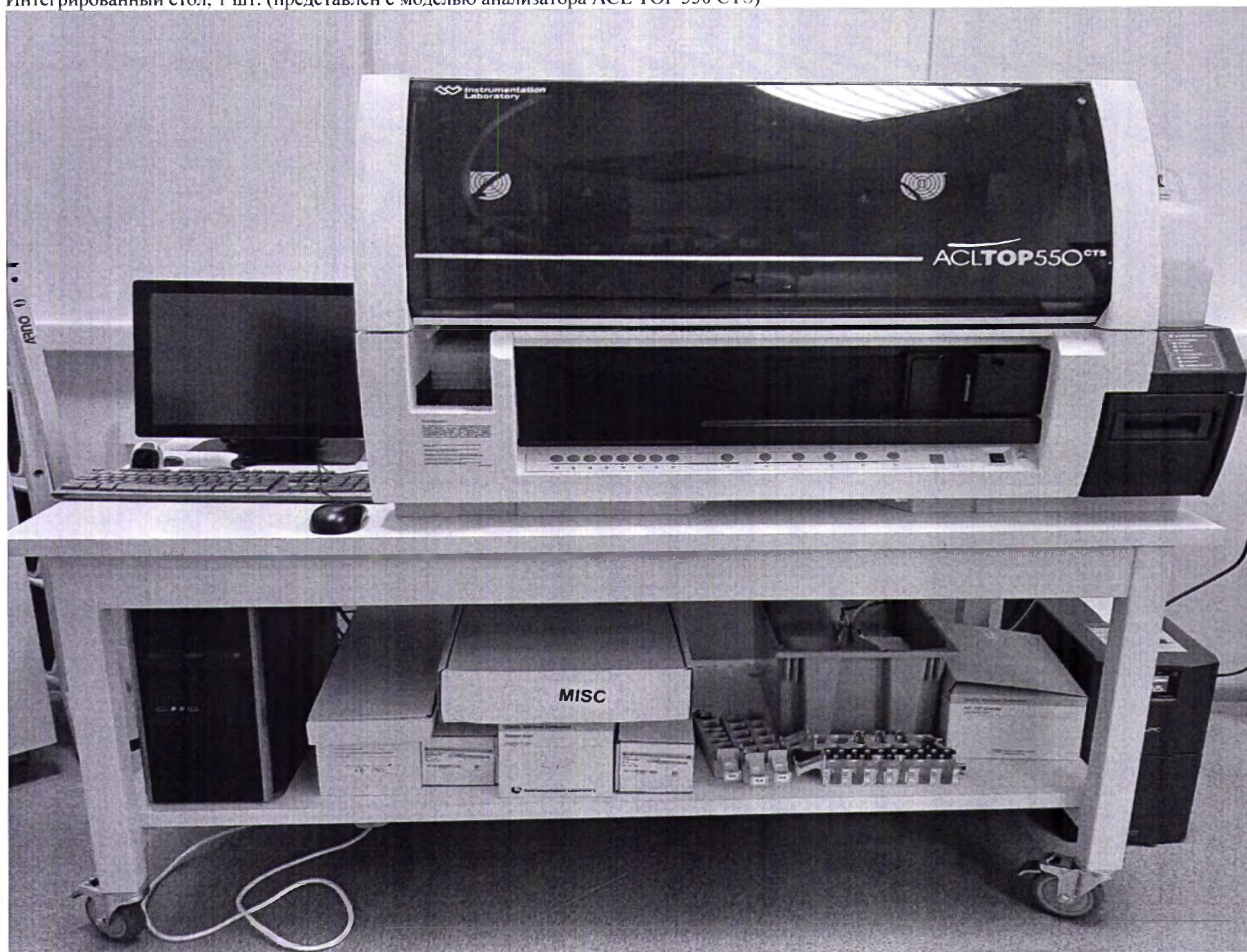




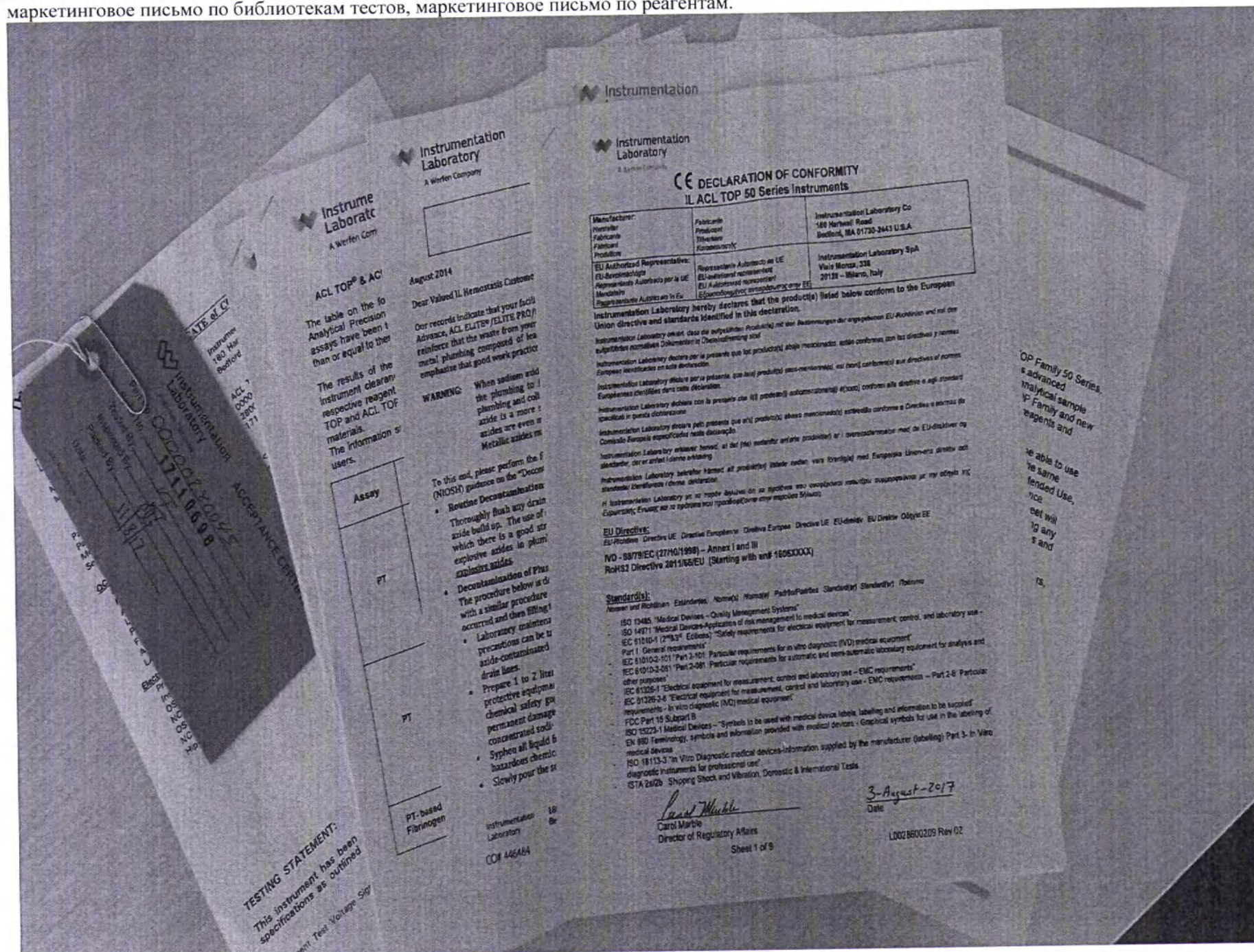


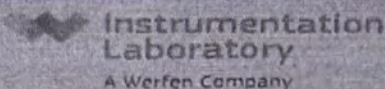


Интегрированный стол, 1 шт. (представлен с моделью анализатора ACL TOP 550 CTS)



Документация: декларация соответствия, сертификат соответствия, спецификация точности измерений, письмо-уведомление про Азид натрия, маркетинговое письмо по библиотекам тестов, маркетинговое письмо по реагентам.





February, 2016

ACL TOP Family 50 Series with Software Release V6.1.0, Parameters P-18.1.00 and User Manual (On Line Help) V6.1.0

Dear Valued ACL TOP™ Customer,

Welcome to the ACL TOP Family 50 Series of Analyzers. The ACL TOP Family 50 Series are the newest members of the ACL TOP Family: the best-in-class analyzers for the hemostasis laboratory. These high performance consolidated workstations are for routine and specialty assays: Clotting, Chromogenic and Latex-Immunoassay with pre-analytical sample integrity checks and advanced audit trail and accreditation support tools. They are part of Instrumentation Laboratory's commitment to develop and introduce products that meet the needs of today's demanding hemostasis laboratory. The ACL TOP Family 50 Series is configured with Software V6.1.0, Parameters P-18.1.00, and User Manual (On Line Help) V6.1.0 and available to select regions worldwide.

The ACL TOP Family 50 Series includes the following analyzers:

ACL TOP 350 CTS	Part Number: 00000280065
ACL TOP 550 CTS	Part Number: 00000280045
ACL TOP 750	Part Number: 00000280015
ACL TOP 750 CTS	Part Number: 00000280055
ACL TOP 750 LAS	Part Number: 00000280035

All models of the ACL TOP Family 50 Series offer:

- Same quality results
- Same comprehensive reagent portfolio
- Same powerful and intuitive software
- Same features and usability
- Same assay-specific sample checks
- Same advanced lab accreditation support tools

Software Version 6.1.0 with Parameters P-18.1.00 includes the following parameter files:

- Liquid Anti-Xa [Anti-Xa]
- Antithrombin Liquid [AT LIQ]
- APCR V with APC [APCR V+]
- APCR V without APC [APCR V-]
- APTT Syn Phospholip [APTT-SP]
- APTT SynthASII [APTT-SS]
- D-Dimer HS 500 [DDHS 500]
- D-Dimer HS [DDHS]
- D-Dimer [DD]
- Factor II-RP [FII-RP]
- Factor II- ReadiPlasTin [FIIRead]
- Factor II-RP-8 [FII-RP-8]
- Factor IX-SS [FIX-SS]
- Factor V ReadiPlasTin [FVRead]
- Factor V-RP-8 [FVRP-8]
- Factor VIII-SS [FVIII-SS]
- Factor VIII-SS with normal VWF [F8vf-SS]
- Factor VII-RP [FVII-RP]
- Factor VII-RP-8 [FVII-RP-8]
- Factor VII ReadiPlasTin [FVIIRead]
- Factor V-RP [FV-RP]
- Factor X HS Plus [FX-HS+]
- Factor X-RP [FX-RP]
- FX ReadiPlasTin [FXRead]
- Factor XI-SS [FXI-SS]
- Factor XII-SS [FXII-SS]
- Factor VIII-SP [FVIII-SP]
- Factor IX-SP [FIX-SP]
- Factor XI-SP [FXI-SP]
- Factor XII-SP [FXII-SP]
- Fib RecombiPlasTin [Fib-RP]



**Instrumentation
Laboratory**

A Werfen Company

November, 2014

Dear Valued ACL TOP 50 customer,

Instrumentation Laboratory is pleased to announce the launch of the new ACL TOP Family 50 Series. The ACL TOP Family 50 Series offer low- to high- volume hemostasis laboratories advanced automation of routine to specialty assays with the added benefit of integrated pre-analytical sample integrity checks, and advanced laboratory accreditation support tools. The ACL TOP Family and new ACL TOP Family 50 Series will be able to use the same comprehensive portfolio of reagents and produce the same quality results.

Since the new ACL TOP Family 50 Series evolved from the ACL TOP Family, you will be able to use the same comprehensive portfolio of HemosIL reagents, calibrators and controls using the same assigned values as listed on the insert sheets for the ACL TOP Family. In addition, the Intended Use, Reagent Storage/Stability, Limitations/Interfering Substances, Expected Values, Performance Characteristics, and any other instrument specific claims on any HemosIL reagent insert sheet will apply to both the ACL TOP Family and the ACL TOP Family 50 Series. Therefore, when using any HemosIL reagent on the ACL TOP Family 50 Series analyzer, please use the assigned values and claims listed on the insert sheet for the ACL TOP Family.

IL is committed to delivering innovative and practical solutions to meet the needs of our customers. The features of the new ACL TOP Family 50 Series will minimize the risk of errors and enhance quality assurance leading to better patient care. Thank you for choosing IL as a partner in Hemostasis testing.

Please contact your local representative if you have any questions.

Sincerely,

Catherine Quirbach Ph.D.

Group Product Manager, Hemostasis Reagents
Instrumentation Laboratory

CON446005

00027503098 R00

180 Hartwell Road, Bedford MA 01730 781-861-0710 www.il.us.com



**Instrumentation
Laboratory**
A Werfen Company

**IL HEMOSTASIS SYSTEMS
URGENT SAFETY NOTIFICATION**

August 2014

Dear Valued IL Hemostasis Customer:

Our records indicate that your facility has in use one or more IL Hemostasis Systems: ACL TOP® Family, ACL Futura/ACL Advance, ACL ELITE®/ELITE PRO/8/9/10000, ACL Classic (100-7000) and ACL AcuStar. This notification is intended to reinforce that the waste from your IL Hemostasis System contains sodium azide that may potentially form explosives in metal plumbing composed of lead, brass, tin, copper or zinc or containing solder in the plumbing system and to emphasize that good work practices should be followed to mitigate the risk of explosion.

WARNING: When sodium azide preservative in reagents is disposed down the drain, it can react with the metals in the plumbing to form insoluble metallic azides, such as copper and lead azide, which settle in the plumbing and collect in traps, threads, etc. These metallic azides are highly explosive. For example, lead azide is a more sensitive primary explosive than nitroglycerine and copper azide and other metallic azides are even more explosive and are considered too sensitive to be used commercially as explosives. Metallic azides may explode if subjected to friction, heat, shock or by reaction with other chemicals.

To this end, please perform the following steps taken directly from the National Institute of Occupational Safety and Health (NIOSH) guidance on the "Decontamination Procedures for Azide Contaminated Plumbing" (1976):

• **Routine Decontamination:**

Thoroughly flush any drain used for waste disposal with copious amounts of water several times a day to prevent azide build up. The use of copper- and lead-free lines between the point of discharge of azide and the nearest pipe in which there is a good stream of water, or the use of azide-free reagents, may prevent future accumulation of explosive azides in plumbing. **NOTE: These measures will NOT decontaminate plumbing already containing explosive azides.**

• **Decontamination of Plumbing Containing Explosive Azides:**

The procedure below is designed to decontaminate a drain trap. Longer lengths of drain lines can be decontaminated with a similar procedure after plugging the drain below the point at which any azide contamination is likely to have occurred and then filling the entire length of pipe with 10% sodium hydroxide solution.

- Laboratory maintenance workers, especially plumbers, should be alerted to the azide hazard so that proper precautions can be taken. Violent explosions have resulted when plumbers have attempted to penetrate blocked azide-contaminated drainage systems with a flexible metal probe (snake) or to cut or saw azide-contaminated drain lines.
- Prepare 1 to 2 liters of 10% sodium hydroxide solution (100 g NaOH per liter of water). Wear appropriate protective equipment when preparing and handling this corrosive material including gloves, protective clothing, chemical safety goggles and face shield. Contact with eyes or skin will cause severe burns and may cause permanent damage. Carefully read and follow the manufacturer's safety instructions and instructions for diluting concentrated sodium hydroxide or sodium hydroxide solid in water.
- Syphon all liquid from the trap and drain using a soft rubber or plastic hose. Use proper precautions against any hazardous chemicals which may be present.
- Slowly pour the sodium hydroxide solution into the trap.

Instrumentation
Laboratory 180 Hartwell Road
Bedford, MA 01730

Tel 781-861-0710

www.ilus.com

CO# 446484

Page 1 of 2

L0019014800 R03

ACL TOP® & ACL TOP Family 50 Series Analytical Precision Performance Requirements

The table on the following pages reflects the current ACL TOP and ACL TOP Family 50 Series Analytical Precision Performance Requirements. The released parameters for each of the noted assays have been tested by Instrumentation Laboratory, and the imprecision data generated is less than or equal to these requirements.

The results of the internal testing have been submitted to the respective governing bodies for instrument clearance where the reagent is sold, and is also published in the insert sheets of the respective reagent products. Those published values reflect the testing performed on specific ACL TOP and ACL TOP Family 50 Series instruments using specific lots of reagent, calibrator, and control materials.

The information supplied here can serve as a guide to ACL TOP and ACL TOP Family 50 Series users.

Assay	Reagent	Result Unit	Control	Within Run Imprecision (%CV)	Total Imprecision (%CV)
PT	PT-Fib HS + PT-Fibrinogen	Seconds	HemosIL® Normal Control	≤ 2.0	≤ 3.0
			HemosIL Normal Control 1	≤ 2.0	≤ 3.0
			HemosIL Low Abnormal Control	≤ 3.0	≤ 4.0
			HemosIL Abnormal Control 2	≤ 3.0	≤ 4.0
			HemosIL High Abnormal Control	≤ 5.0	≤ 8.0
			HemosIL Abnormal Control 3	≤ 5.0	≤ 8.0
PT	RecombiPlasTin 2G ReadiPlasTin	Seconds	HemosIL® Normal Control	≤ 3.0	≤ 3.0
			HemosIL Normal Control 1	≤ 3.0	≤ 3.0
			HemosIL Low Abnormal Control	≤ 4.0	≤ 4.0
			HemosIL Abnormal Control 2	≤ 4.0	≤ 4.0
			HemosIL High Abnormal Control	≤ 5.0	≤ 8.0
			HemosIL Abnormal Control 3	≤ 5.0	≤ 8.0
PT-based Fibrinogen	PT-Fib HS + PT-Fibrinogen	mg/dL	HemosIL Normal Control	≤ 10.0	≤ 12.0
			HemosIL Normal Control 1	≤ 10.0	≤ 12.0



**Instrumentation
Laboratory**

A Werfen Company

For North America Customers Only

September 19, 2016

Dear Valued ACL TOP Family 50 Series customer,

When using any HemosIL reagent on the ACL TOP Family 50 Series analyzer, please use the assigned values and the claims listed on the insert sheet for the ACL TOP Family. Since the ACL TOP Family 50 Series evolved from the ACL TOP Family, you will be able to use the same comprehensive portfolio of HemosIL reagents, calibrators and controls. The claims for Intended Use, Reagent Storage/Stability, Limitations/Interfering Substances, Expected Values on a HemosIL reagent insert sheet will apply for both the ACL TOP Family and the ACL TOP Family 50 Series.

In addition, Instrumentation Laboratory performed additional precision and method comparison studies to achieve 510k clearance. While the HemosIL labeling is being updated, the corresponding Precision and Method Comparison data for ACL TOP 50 Series from the current 510k cleared assays are listed in this letter for your reference.

Please share this information with your laboratory staff and retain a copy of this letter for your records. Thank you for choosing IL as a partner in Hemostasis testing.

Please contact your local representative if you have any questions.

Sincerely,

Catherine Quirbach Ph.D.

Group Product Manager, Hemostasis Reagents
Instrumentation Laboratory

Instrumentation Laboratory
 Part No. 00000280045
 Serial No. 17110698
 Tested By: [Signature]
 Inspected By: [Signature]
 Passed By: [Signature]
 Date: 11/8/17

Instrumentation Laboratory
 ACCEPTANCE CERTIFICATE

CATE of COMPLIANCE

Instrumentation Laboratory
 180 Hartwell Road
 Bedford, MA US 01730

ACL TOP 550 CTS SYSTEM
 00000280045
 2800-45 ACL TOP 550 CTS
 17110698

V = 1.7 %	0.7	PASS
V = 3.2 %	1.2	PASS
V = 1.7 %	1.2	PASS
V = 3.0 %	2.6	PASS
V = 3.0 %	1.2	PASS
V = 6.0 %	1.4	PASS
V = 2.3 %	1.1	PASS
V = 10.0 %	6.8	PASS
V = 0.200 Ohm	0.070	PASS
V = 2 MOhm	734	PASS
0.1 .. 1000.0 μ A	524.1	PASS
0.1 .. 500.0 μ A	265.3	PASS
0.1 .. 1000.0 μ A	530.4	PASS
0.1 .. 500.0 μ A	268.7	PASS
2.00 .. 10.00 mA	4.21	PASS

TESTING STATEMENT:

This instrument has been certified to meet all applicable electrical and analytical specifications as outlined in Instrumentation Laboratory's final test and QC procedures.

Instrument Test Voltage Signature: JNUON

Date: 11/03/2017

QC Signature: SYI

Date: 11/07/2017

CO # 464252

Sheet 1 of 1

Part No. 00028786200 Rev 1B

CE DECLARATION OF CONFORMITY **IL ACL TOP 50 Series Instruments**

Manufacturer: Hersteller Fabricante Fabricant Produttore	Fabricante Producent Tilvirkare Κατασκευαστής	Instrumentation Laboratory Co 180 Hartwell Road Bedford, MA 01730-2443 U.S.A.
EU Authorized Representative: EU-Besolmächtigter Representante Autorizado por la UE Mandataire Rappresentante Autorizzato in Eu	Representante Autorizado na UE EU-authorized representative EU Auktoriserad representant Εξουσιοδομημένος αντιπρόσωπος στην ΕΕ	Instrumentation Laboratory SpA Viale Monza, 338 20128 - Milano, Italy

Instrumentation Laboratory hereby declares that the product(s) listed below conform to the European Union directive and standards identified in this declaration.

Instrumentation Laboratory erklärt, dass die aufgeführten Produkt(e) mit den Bestimmungen der angegebenen EU-Richtlinien und mit den aufgeführten normativen Dokumenten in Übereinstimmung sind.

Instrumentation Laboratory déclare par la présente que les produits(s) ci-dessous mentionnés, sont conformes aux directives et normes européennes identifiées dans cette déclaration.

Instrumentation Laboratory dichiara con la presente che il(i) prodotto(i) sottoelencato(i) è(sono) conforme alla direttiva e agli standard specificati in questa dichiarazione.

Instrumentation Laboratory declara pela presente que o(s) produto(s) abaixo mencionado(s) está(ão) conforme a Directiva e normas da Comissão Europeia especificadas nesta declaração.

Instrumentation Laboratory erklærer hermed, at det (de) nedenfor anførte produkt(er) er i overensstemmelse med de EU-direktiver og standarder, der er anført i denne erklæring.

Instrumentation Laboratory bekräftar härmed, att produkt(er) listade nedan, vara förenliga med Europeiska Union-ens direktiv och standarder identifierade i denna deklaration.

Η Instrumentation Laboratory με το παρόν δηλώνει ότι τα προϊόντα που αναφέρονται κατωτέρω συμμορφούνται με την οδηγία της Ευρωπαϊκής Ένωσης και τα πρότυπα που προσδιορίζονται στην παρούσα δήλωση.

EU Directive:
EU-Richtlinie Directive UE Directive Européenne Direttiva Europea Directiva UE EU-direktiv EU Direktiv Οδηγία ΕΕ

IVD - 98/79/EC (27/10/1998) - Annex I and III
RoHS2 Directive 2011/65/EU (Starting with an# 1606XXX)

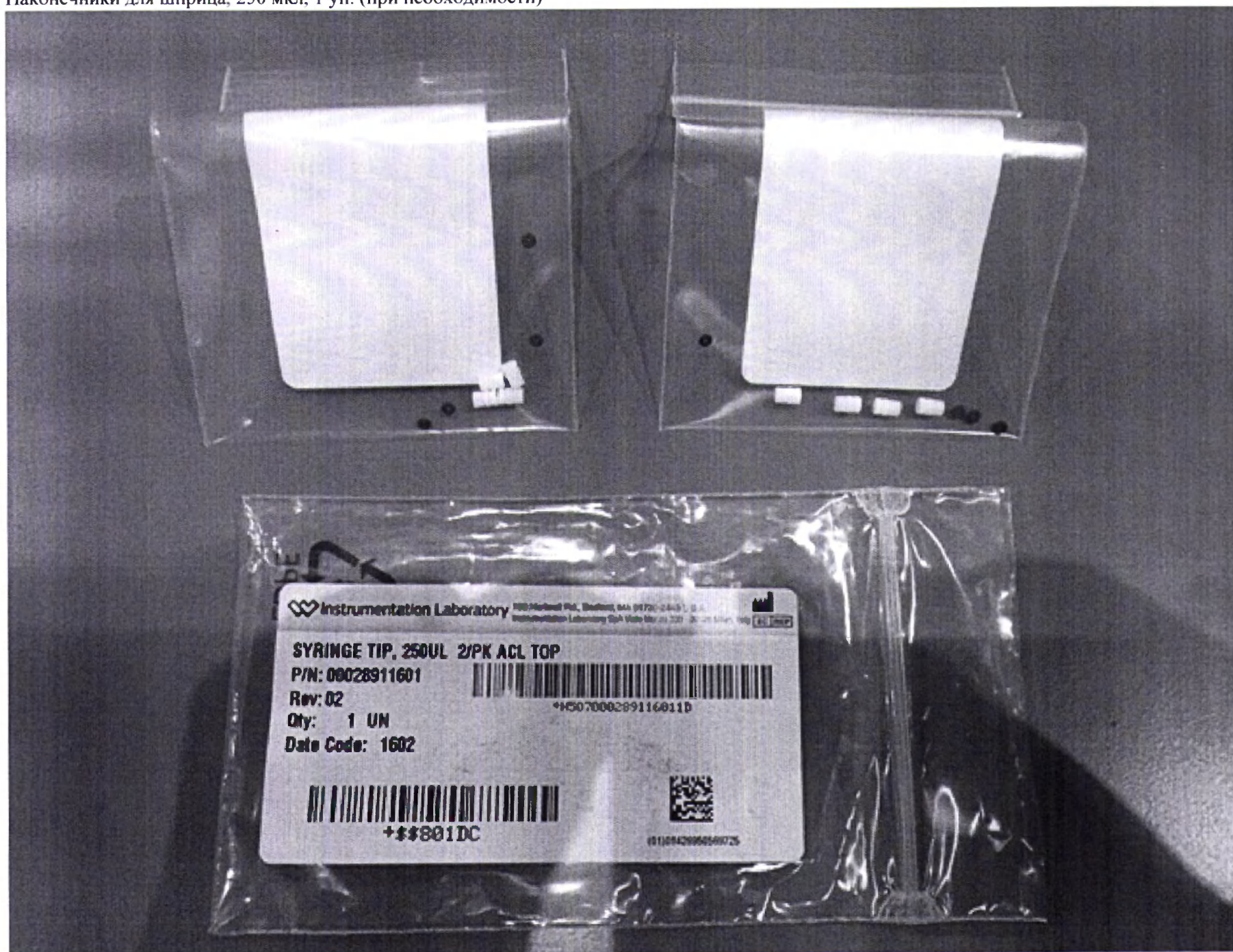
Standard(s):
Normen und Richtlinien Estándar(es) Norme(s) Norma(e) Padrão/Padrões Standard(er) Standard(er) Πρότυπα

- ISO 13485, "Medical Devices - Quality Management Systems"
- ISO 14971 "Medical Devices-Application of risk management to medical devices"
- IEC 61010-1 (2nd & 3rd Editions) "Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements"
- IEC 61010-2-101 "Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment"
- IEC 61010-2-081 "Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes"
- IEC 61326-1 "Electrical equipment for measurement, control and laboratory use - EMC requirements"
- IEC 61326-2-6 "Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment"
- FCC Part 15 Subpart B
- ISO 15223-1 Medical Devices - "Symbols to be used with medical device labels, labelling and information to be supplied"
- EN 980 Terminology, symbols and information provided with medical devices - Graphical symbols for use in the labelling of medical devices
- ISO 18113-3 "In Vitro Diagnostic medical devices-Information supplied by the manufacturer (labelling) Part 3- In Vitro diagnostic instruments for professional use"
- ISTA 2s/2b Shipping Shock and Vibration, Domestic & International Tests.

Carol Marble
Carol Marble
Director of Regulatory Affairs

3-August-2017
Date

Наконечники для шприца, 250 мкл, 1 уп. (при необходимости)



Трубка пробозаборника, 1 шт. (при необходимости)



Штативы для реагентов RG-RM, 6 шт./уп. (при необходимости)



Штативы для разбавителей DD-DF, 3 шт./уп. (при необходимости)



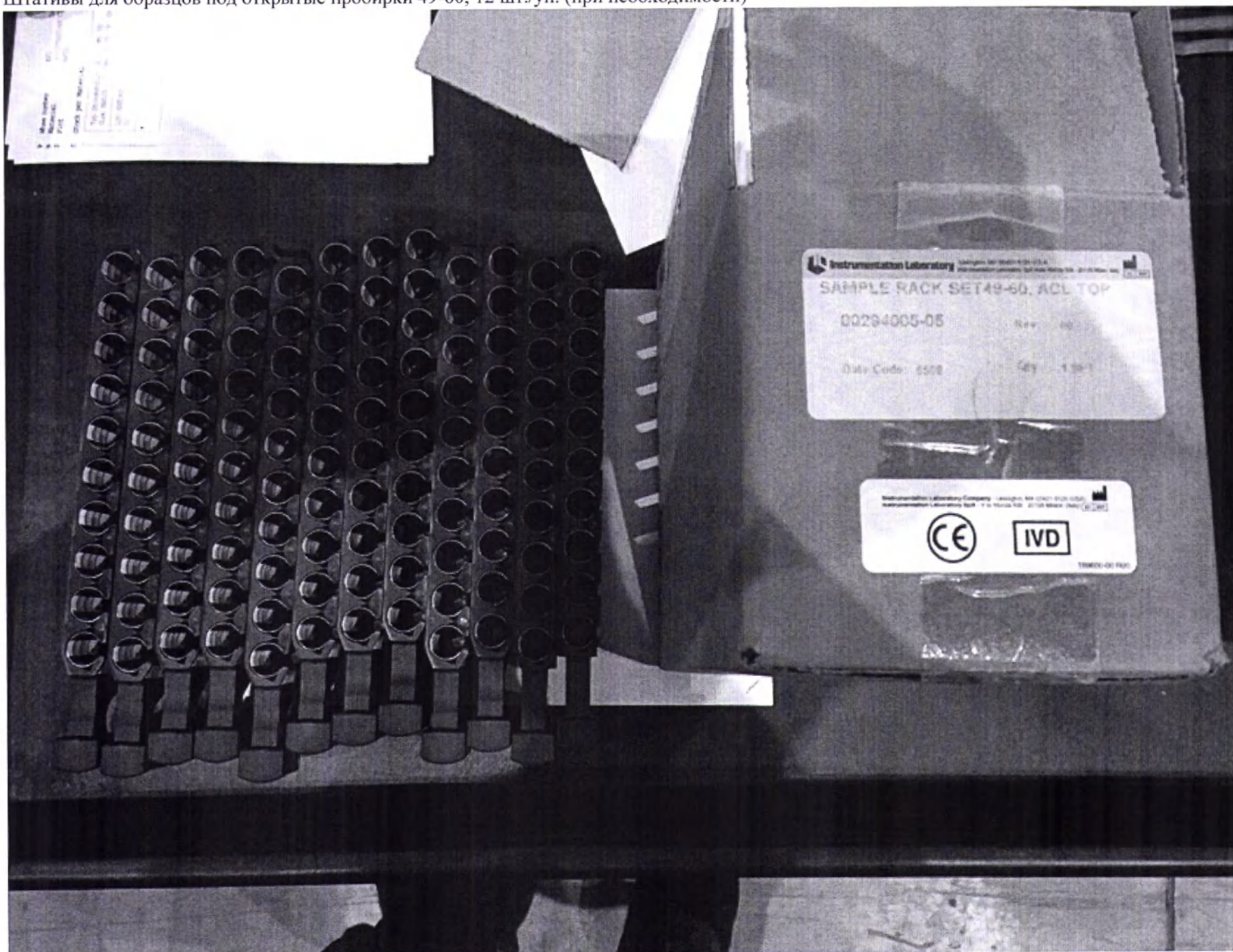
Штативы для образцов под открытые пробирки 25-36, 12 шт./уп. (при необходимости)



Штативы для образцов под открытые пробирки 37-48, 12 шт./уп. (при необходимости)



Штативы для образцов под открытые пробирки 49-60, 12 шт./уп. (при необходимости)



Штативы для образцов под открытые пробирки 61-72, 12 шт./уп. (при необходимости)



Штативы для образцов под открытые пробирки 73-84, 12 шт./уп. (при необходимости)



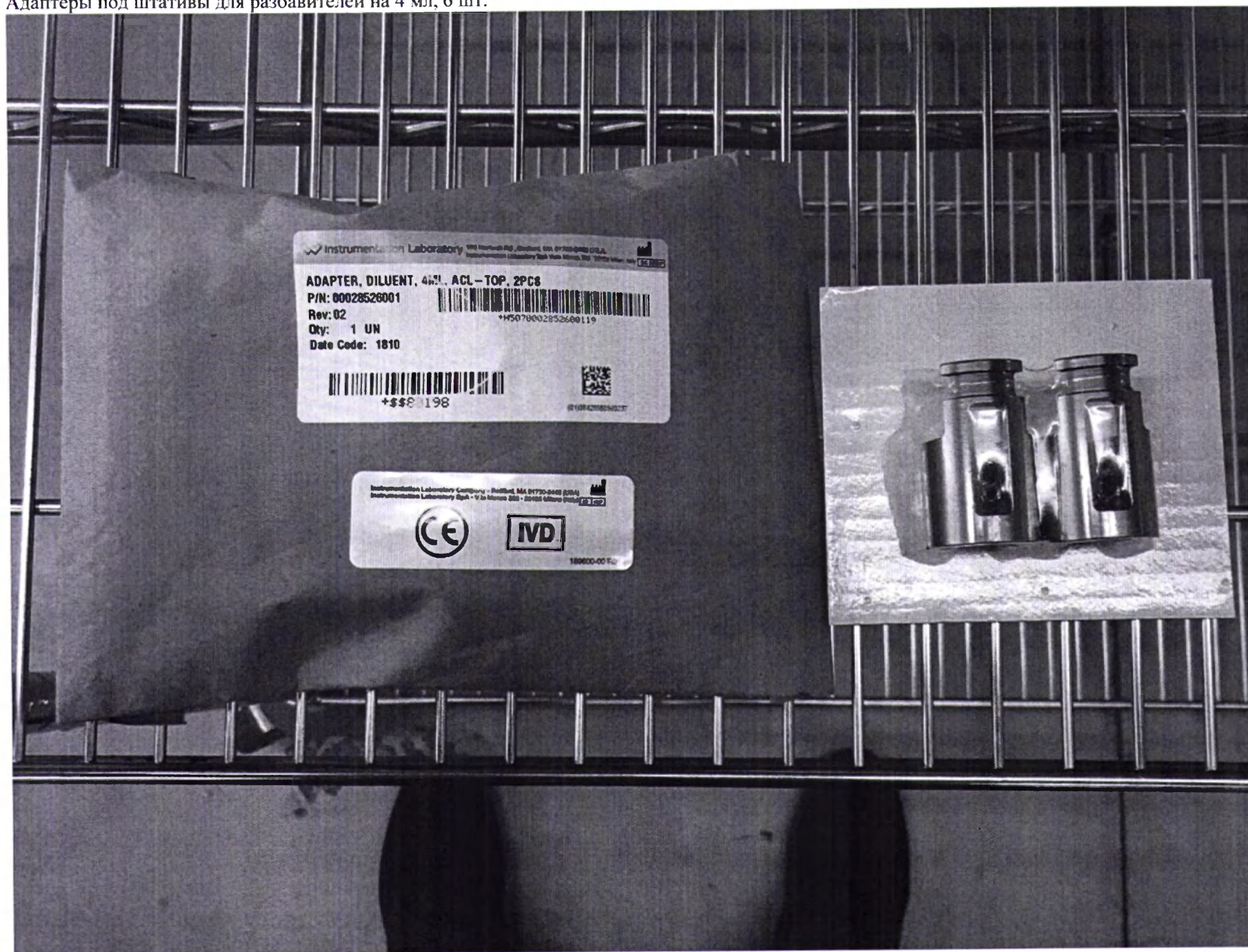
Штативы для образцов под открытые пробирки 85-96, 12 шт./уп. (при необходимости)



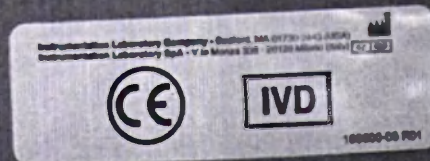
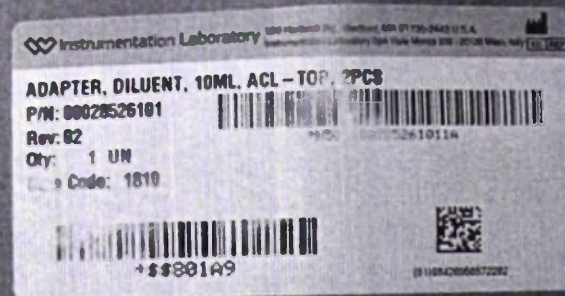
Подставка под 6 штативов для образцов, 1 шт.



Адаптеры под штативы для разбавителей на 4 мл, 6 шт.



Адаптеры под штативы для разбавителей на 10 мл, 6 шт.



Адаптеры под штативы для разбавителей на 20 мл, 6 шт.



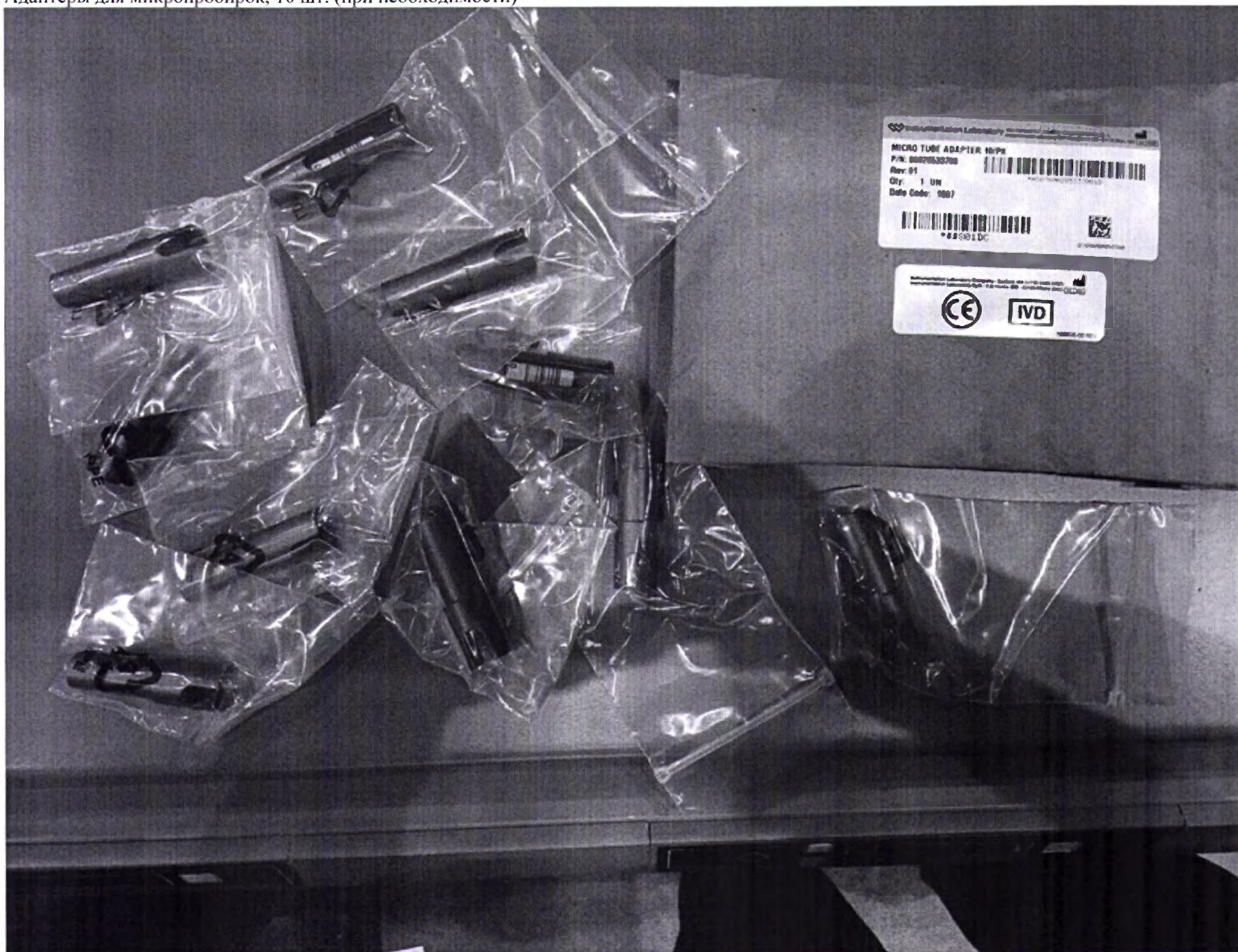
Адаптеры для аликвотных пробирок, 10 шт. (при необходимости)



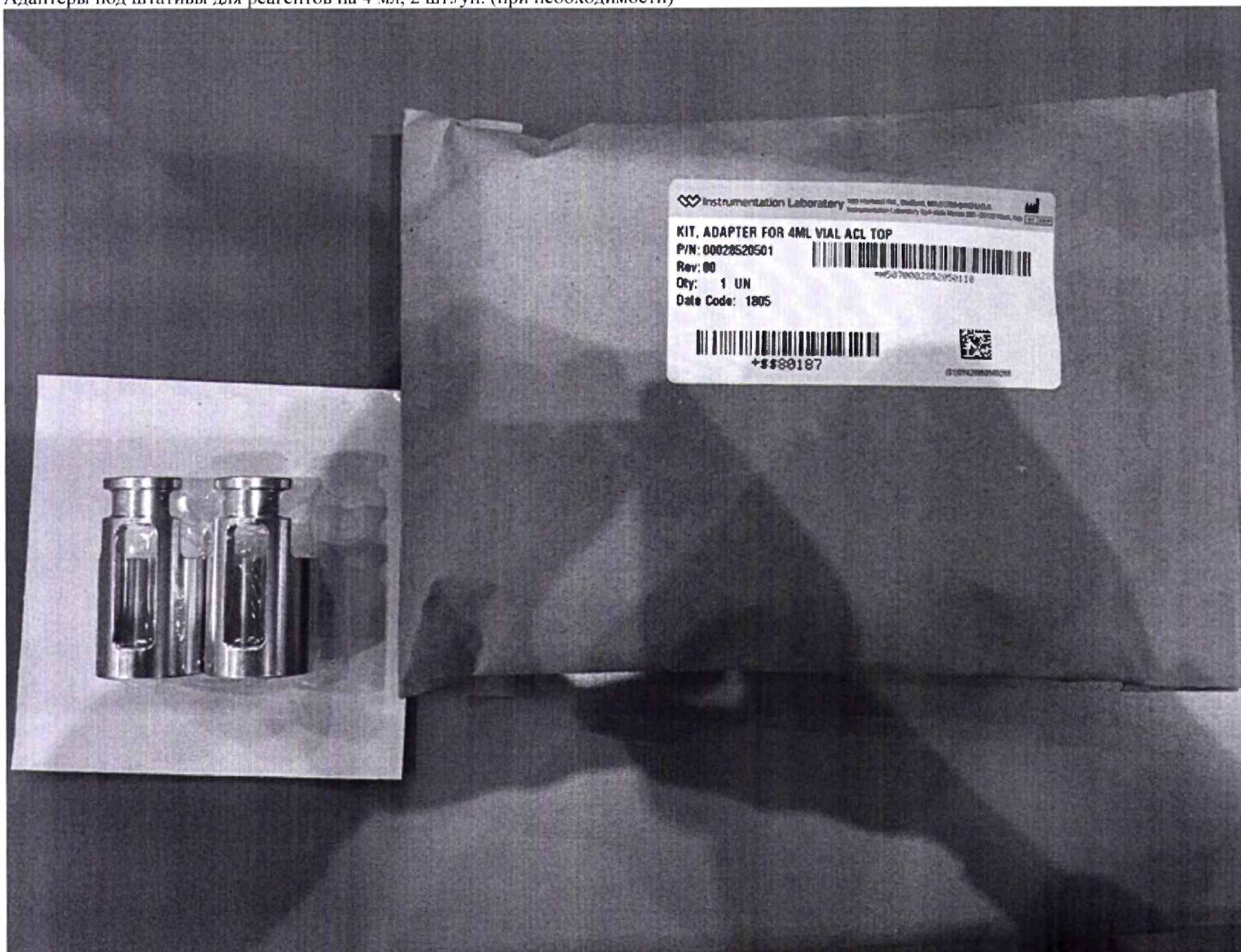
Адаптеры для педиатрических пробирок, 10 шт. (при необходимости)



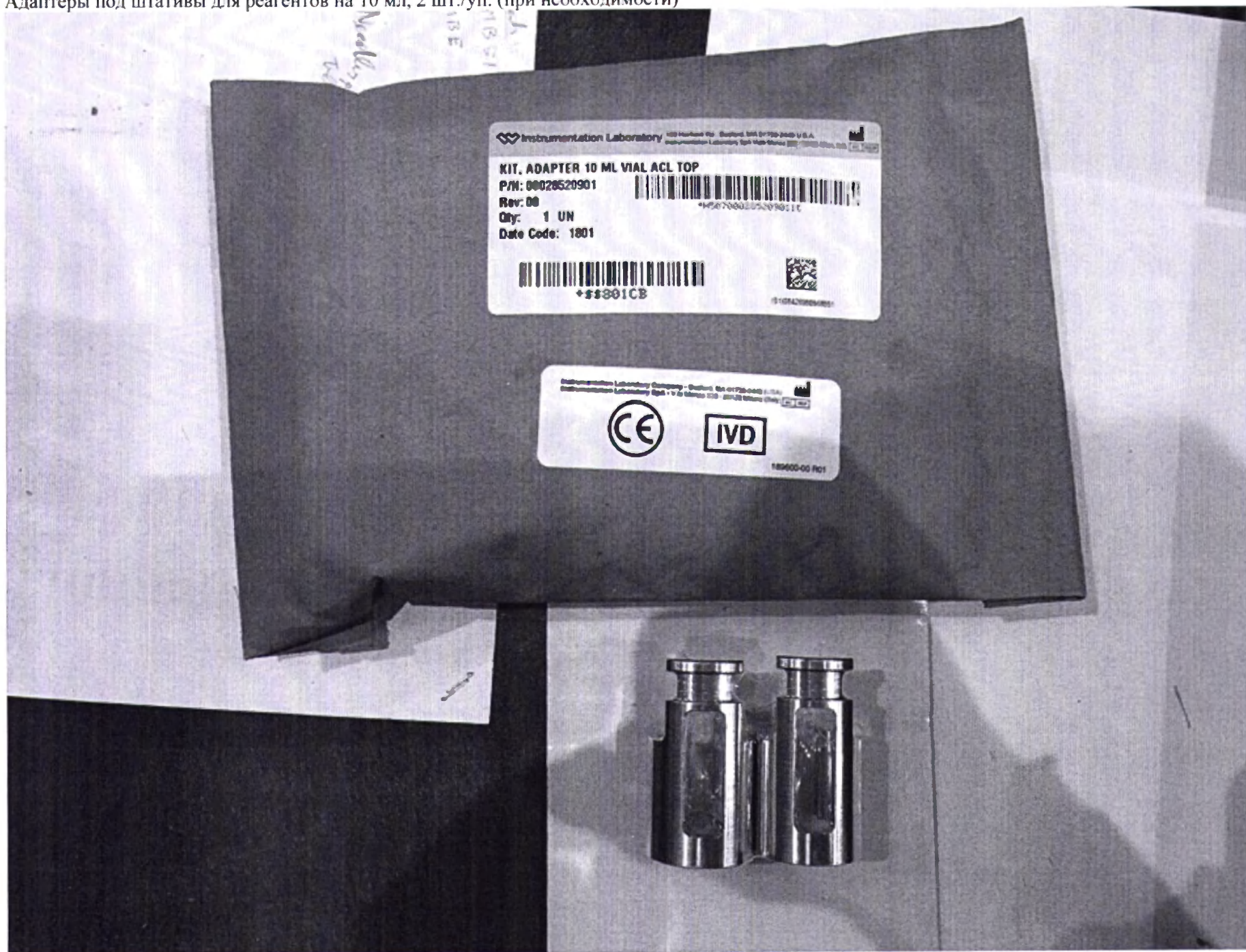
Адаптеры для микропробирок, 10 шт. (при необходимости)



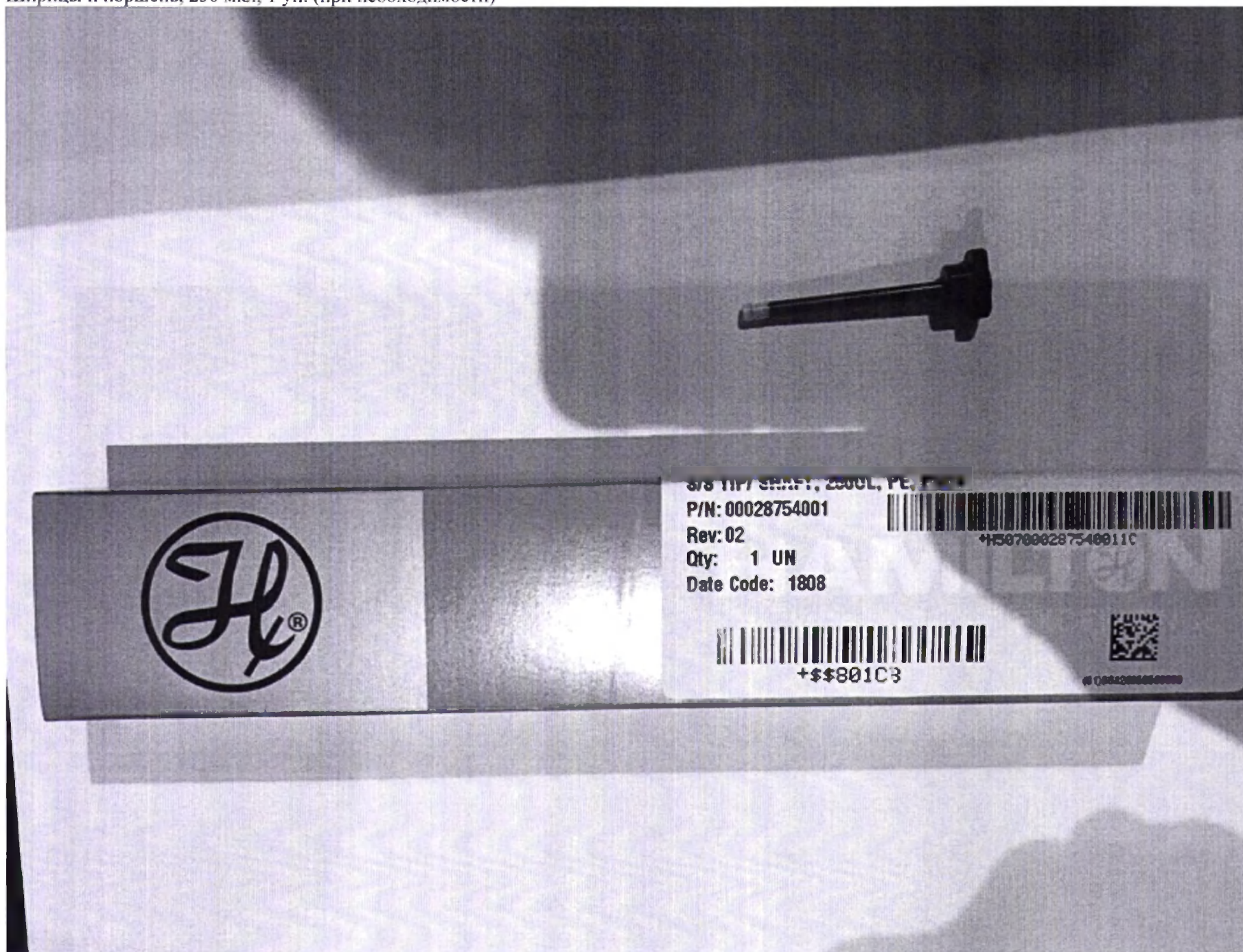
Адаптеры под штативы для реагентов на 4 мл, 2 шт./уп. (при необходимости)



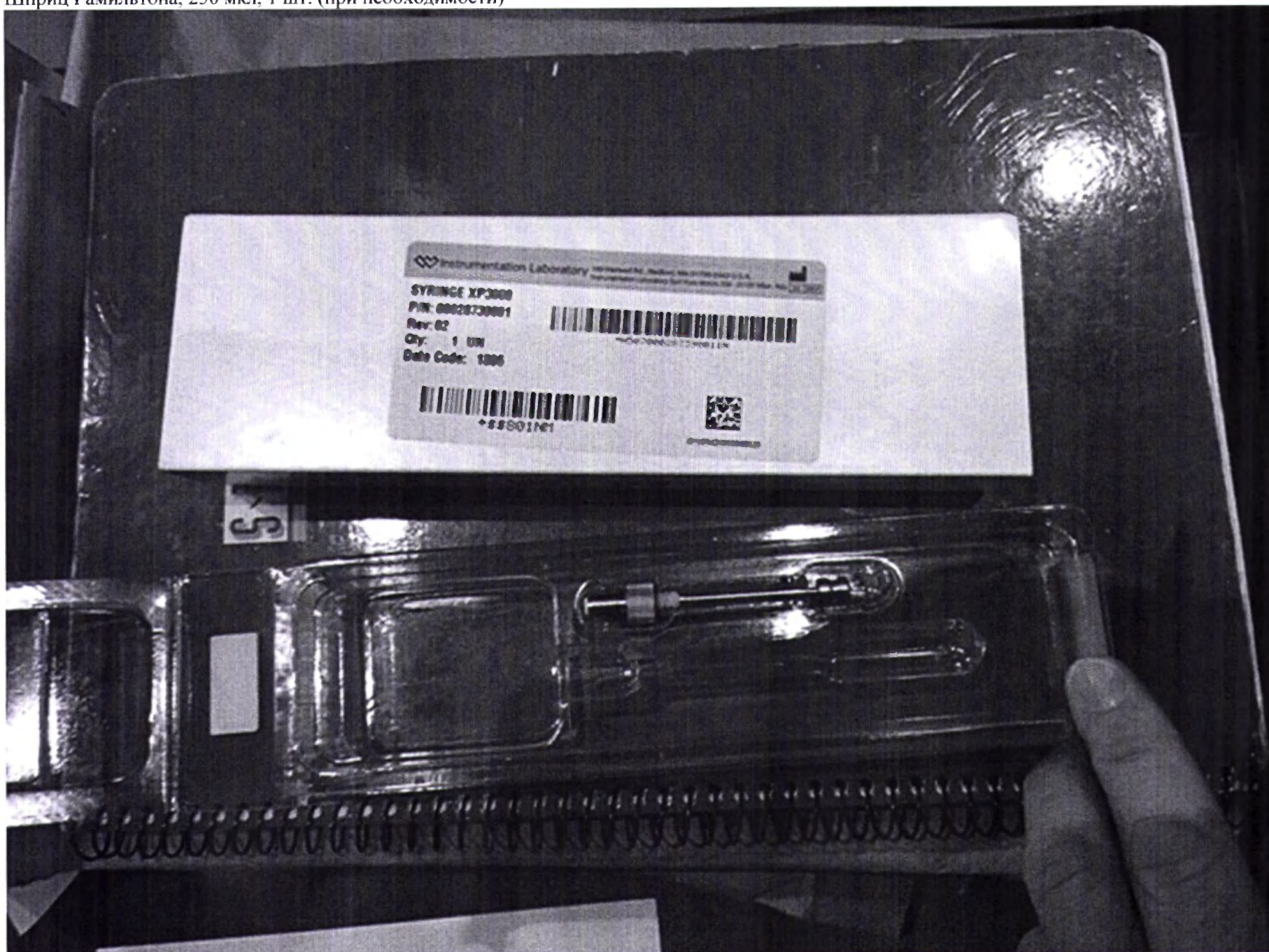
Адаптеры под штативы для реагентов на 10 мл, 2 шт./уп. (при необходимости)



Шприцы и поршень, 250 мкл, 1 уп. (при необходимости)



Шприц Гамильтона, 250 мкл, 1 шт. (при необходимости)

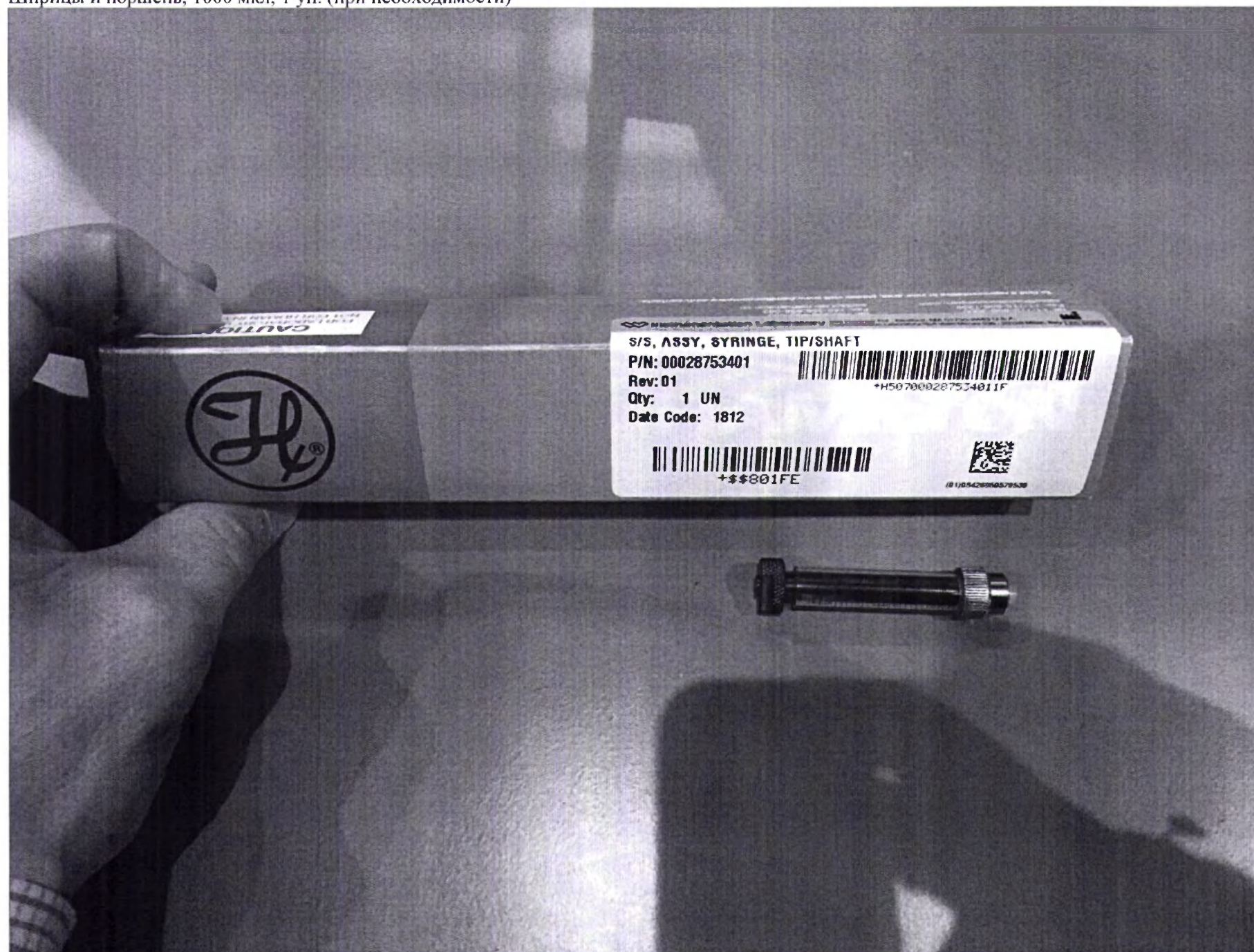


Syringe Drive Motor

Шприц PE PSD4, 250 мкл, 1 шт. (при необходимости)

Syringe

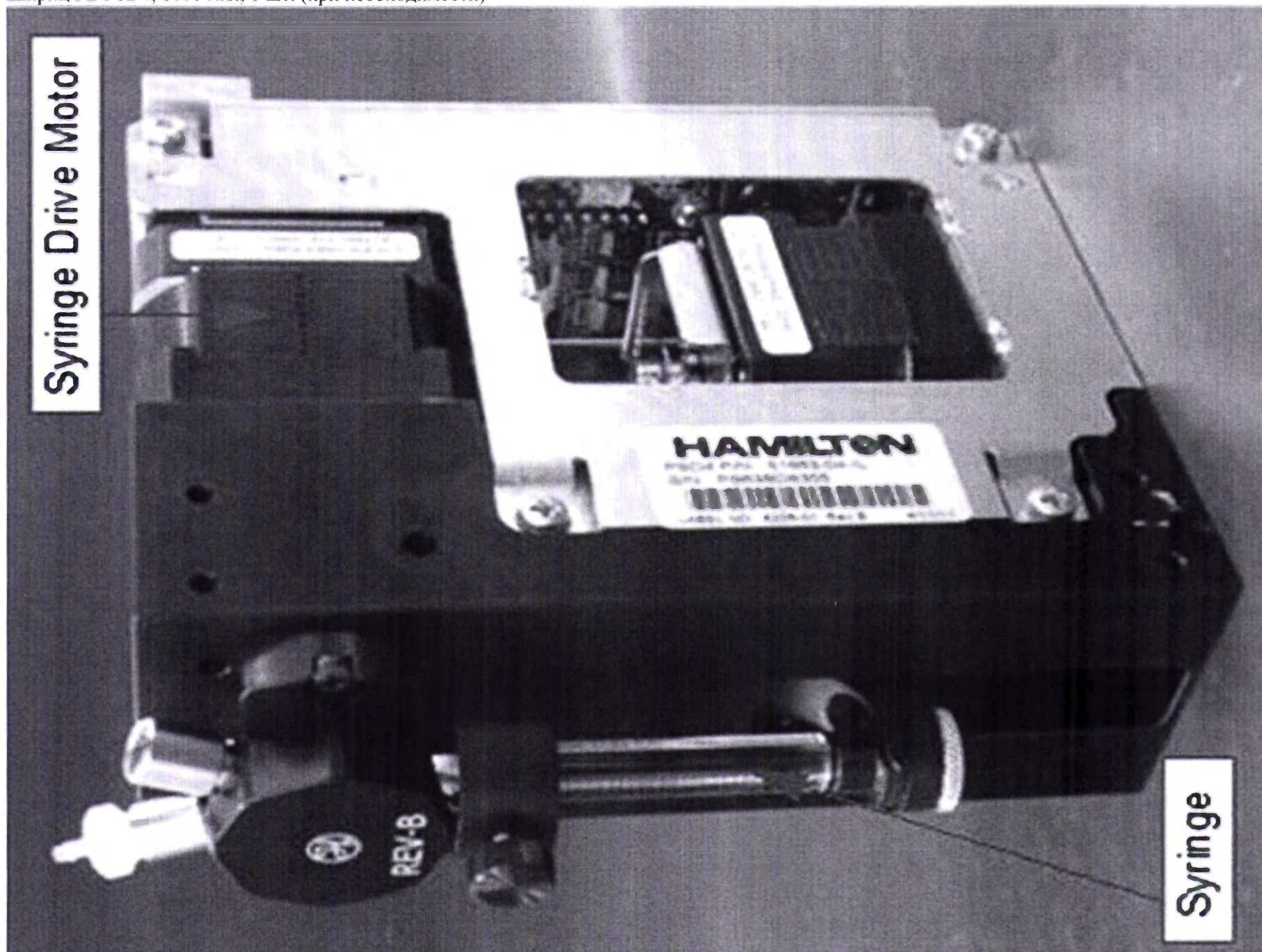
Шприцы и поршень, 1000 мкл, 1 уп. (при необходимости)



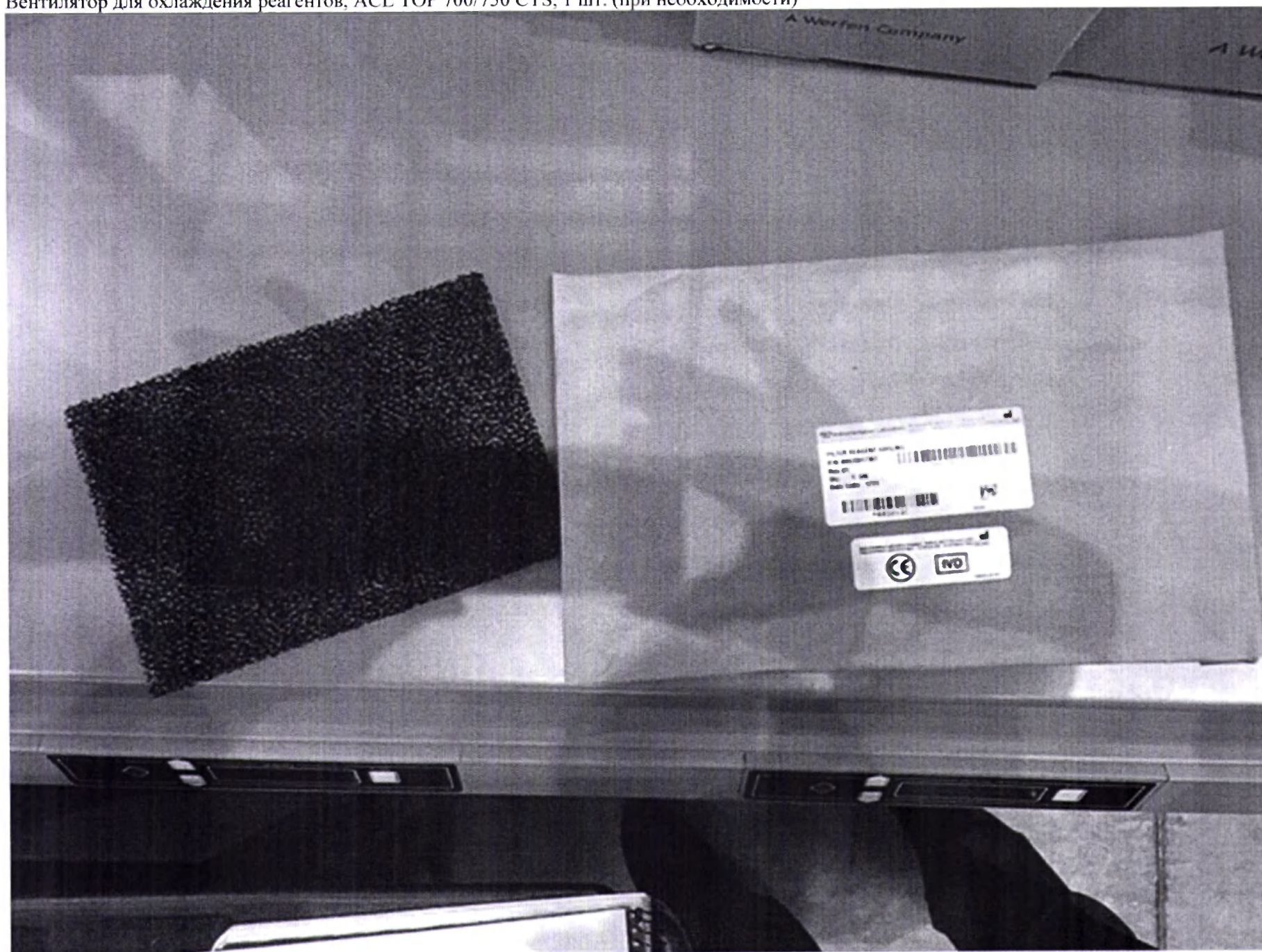
Поршень, 1 шт. (при необходимости)



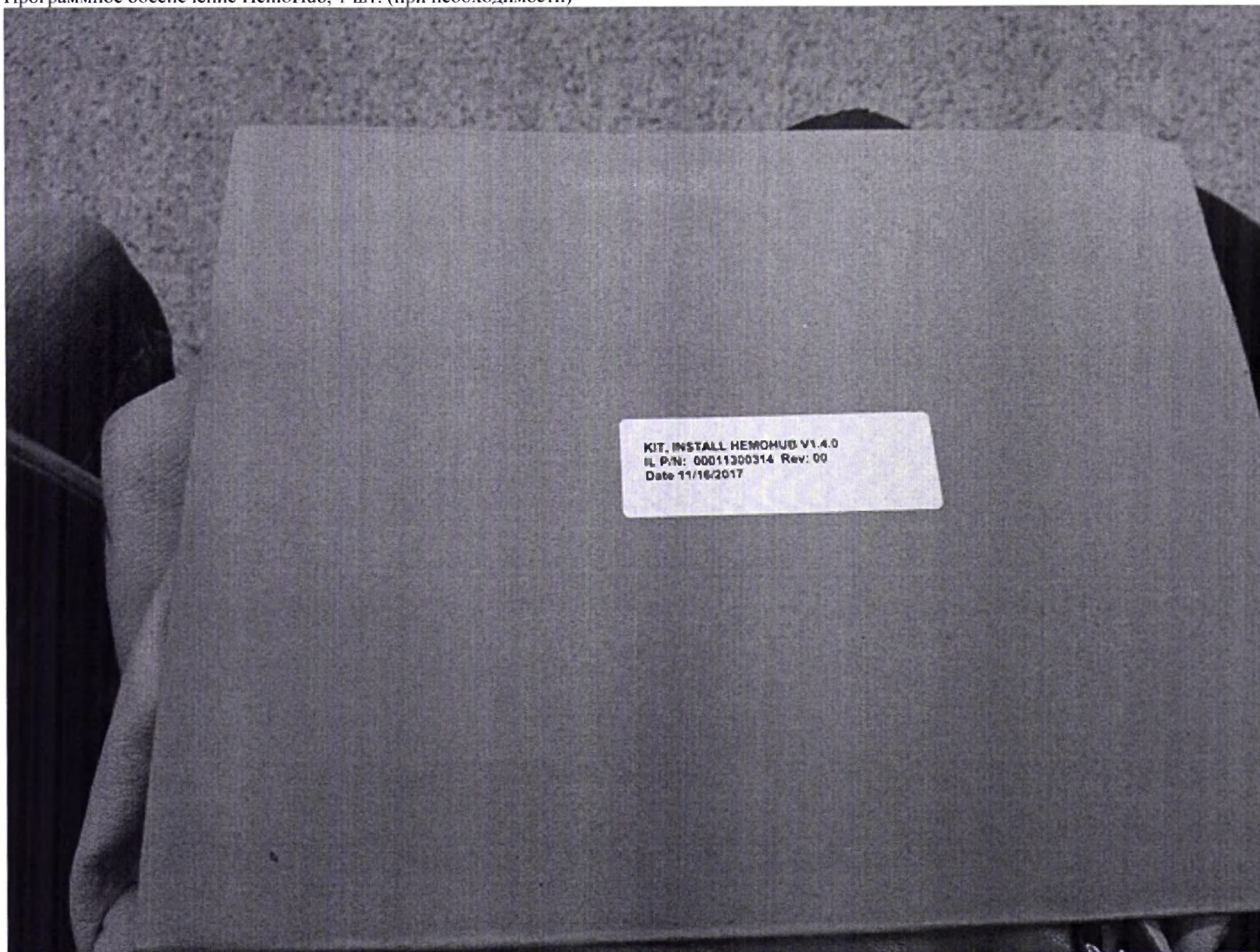
Шприц PE PSD4, 1000 мкл, 1 шт. (при необходимости)

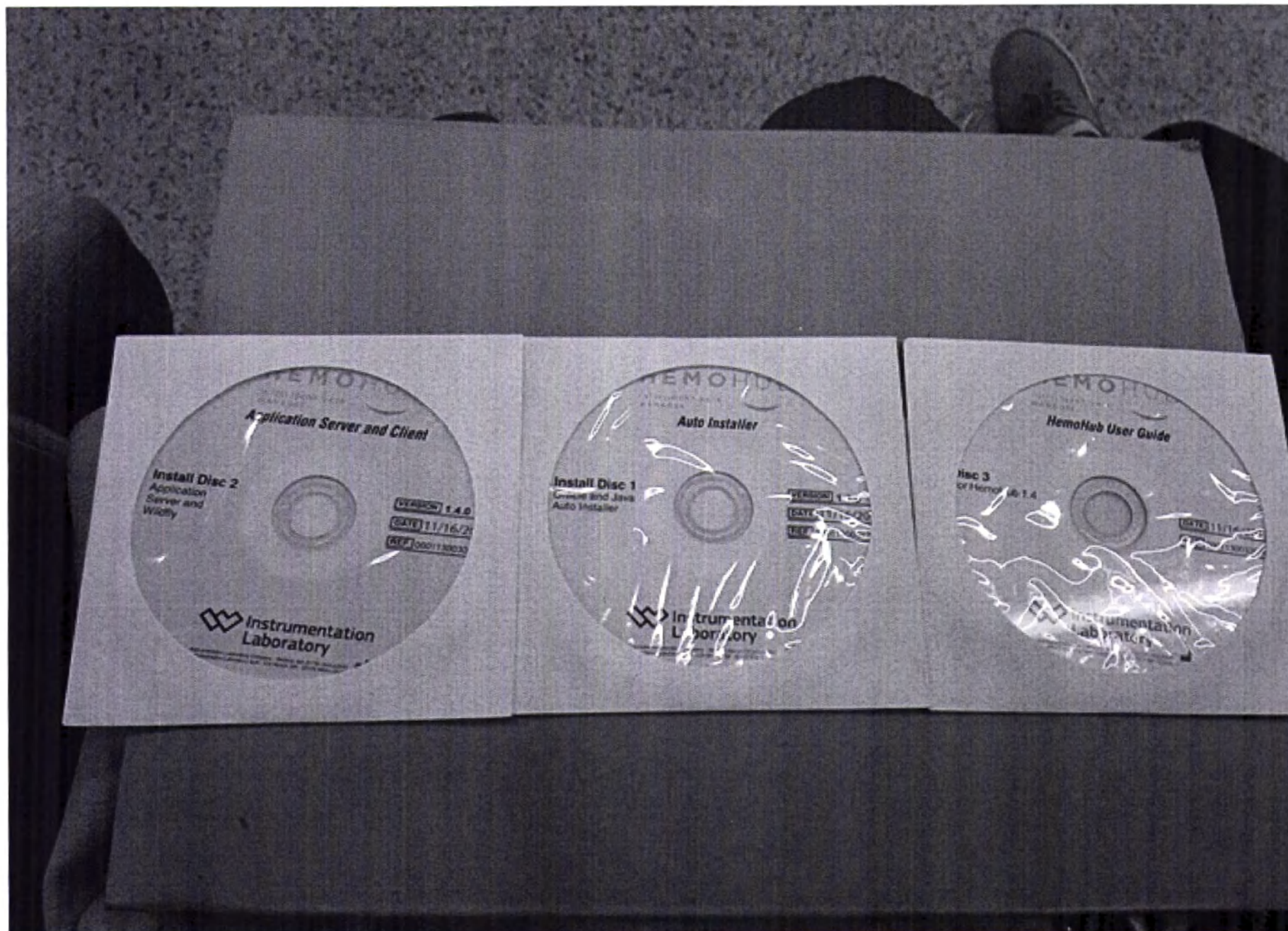


Вентилятор для охлаждения реагентов, ACL TOP 700/750 CTS, 1 шт. (при необходимости)

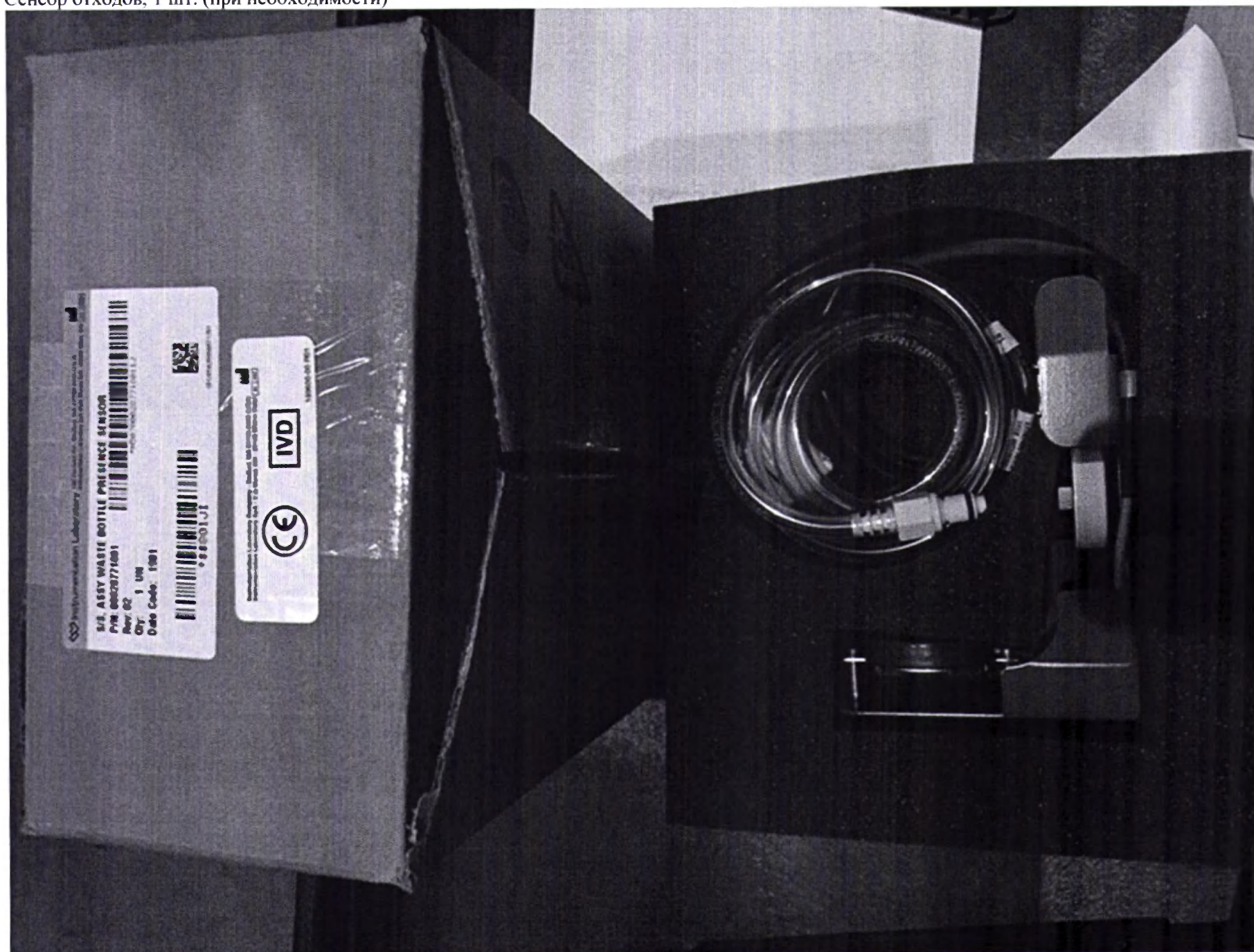


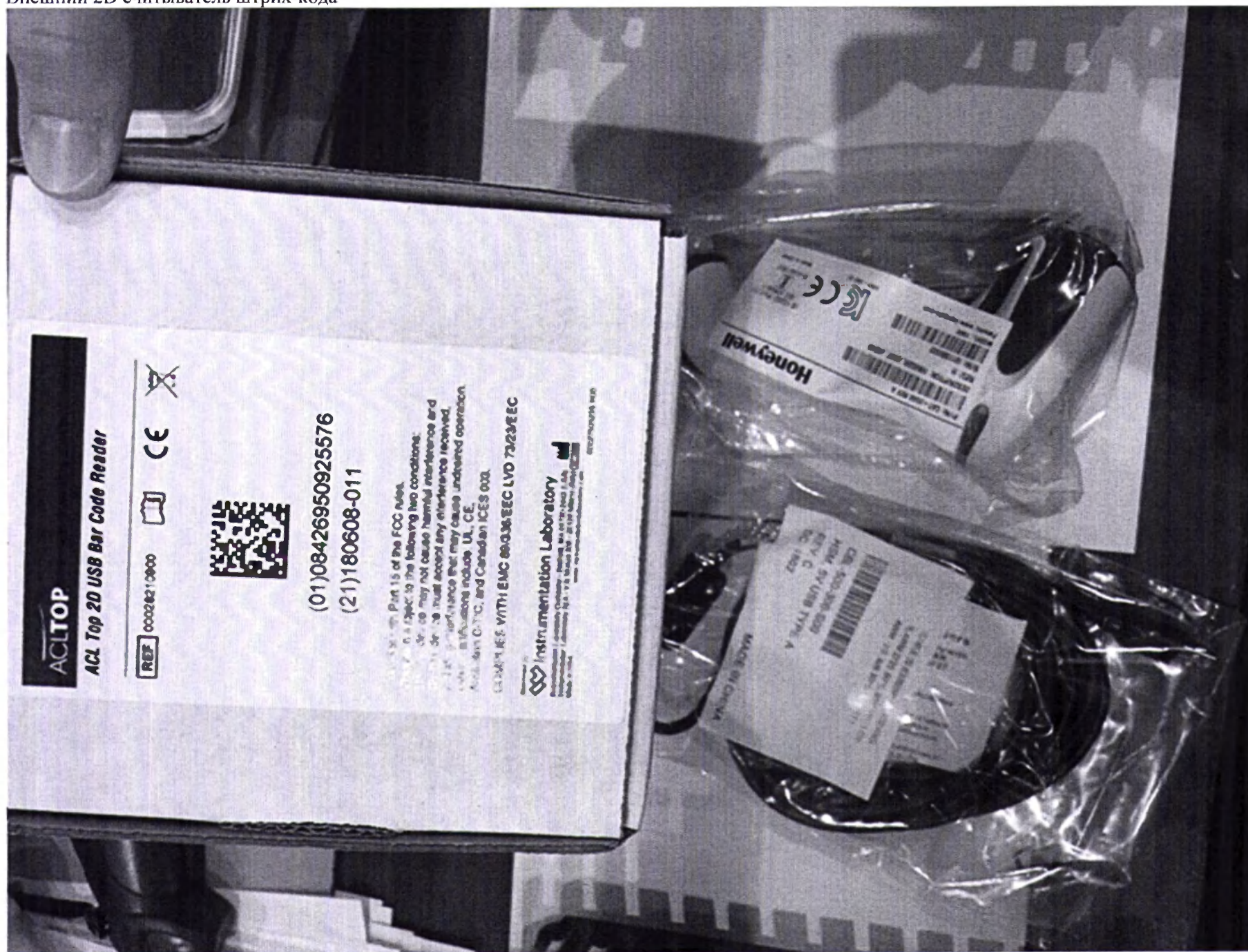
Программное обеспечение НетоHub, 1 шт. (при необходимости)





Сенсор отходов, 1 шт. (при необходимости)









Промышленности
39 метров

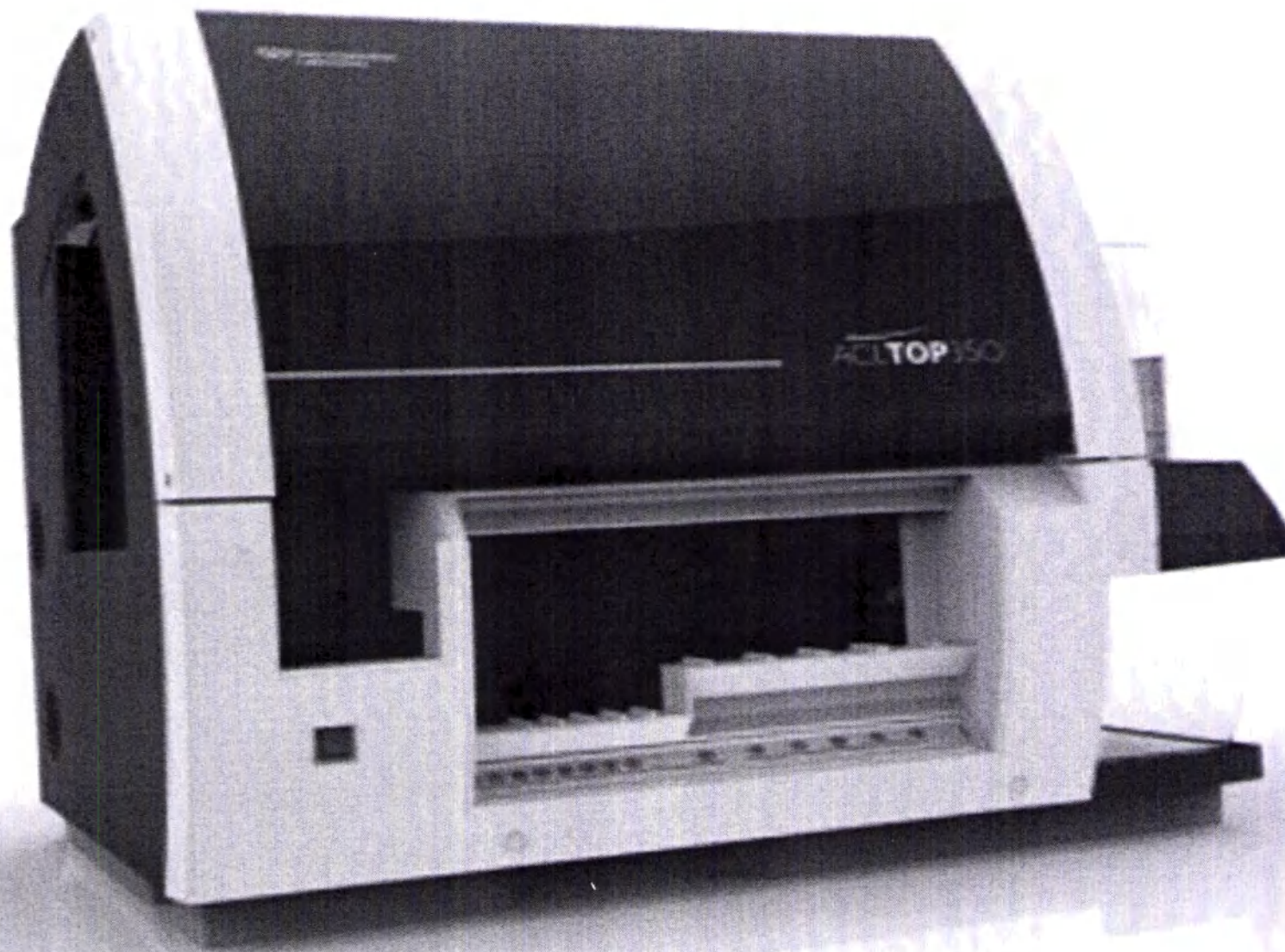


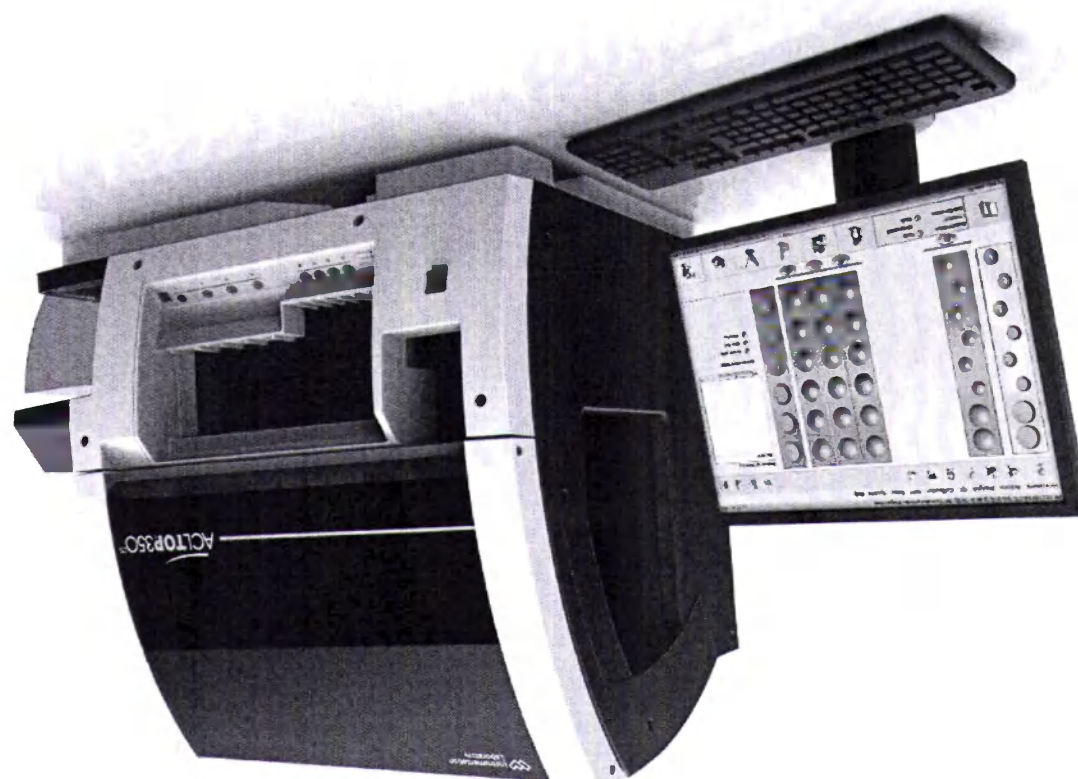
Иванов

ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ МЕДИЦИНСКОГО ИЗДЕЛИЯ

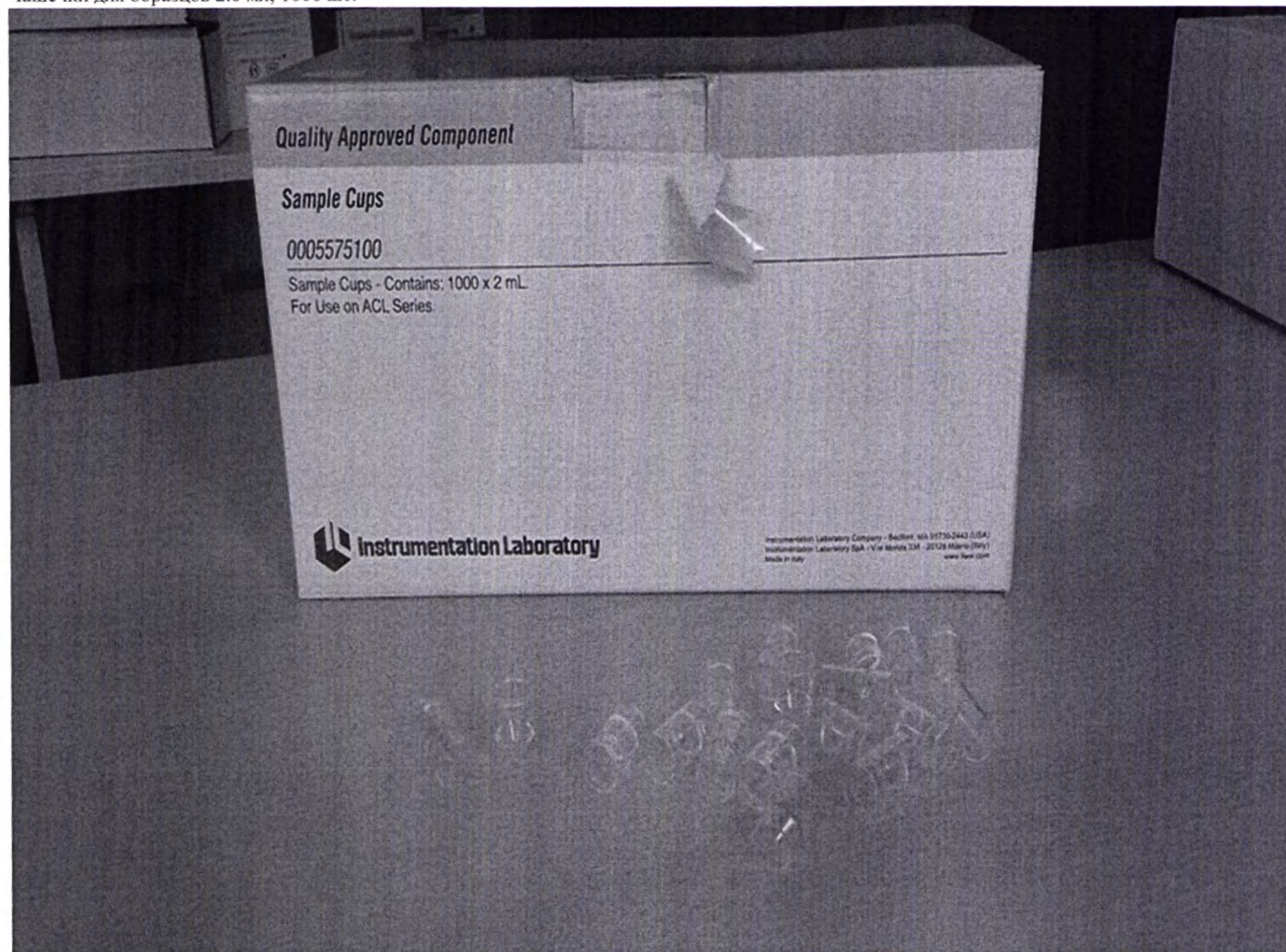
Анализатор автоматический коагулометрический для диагностики *in vitro* ACL TOP,
вариант исполнения ACL TOP 350 CTS

Анализатор

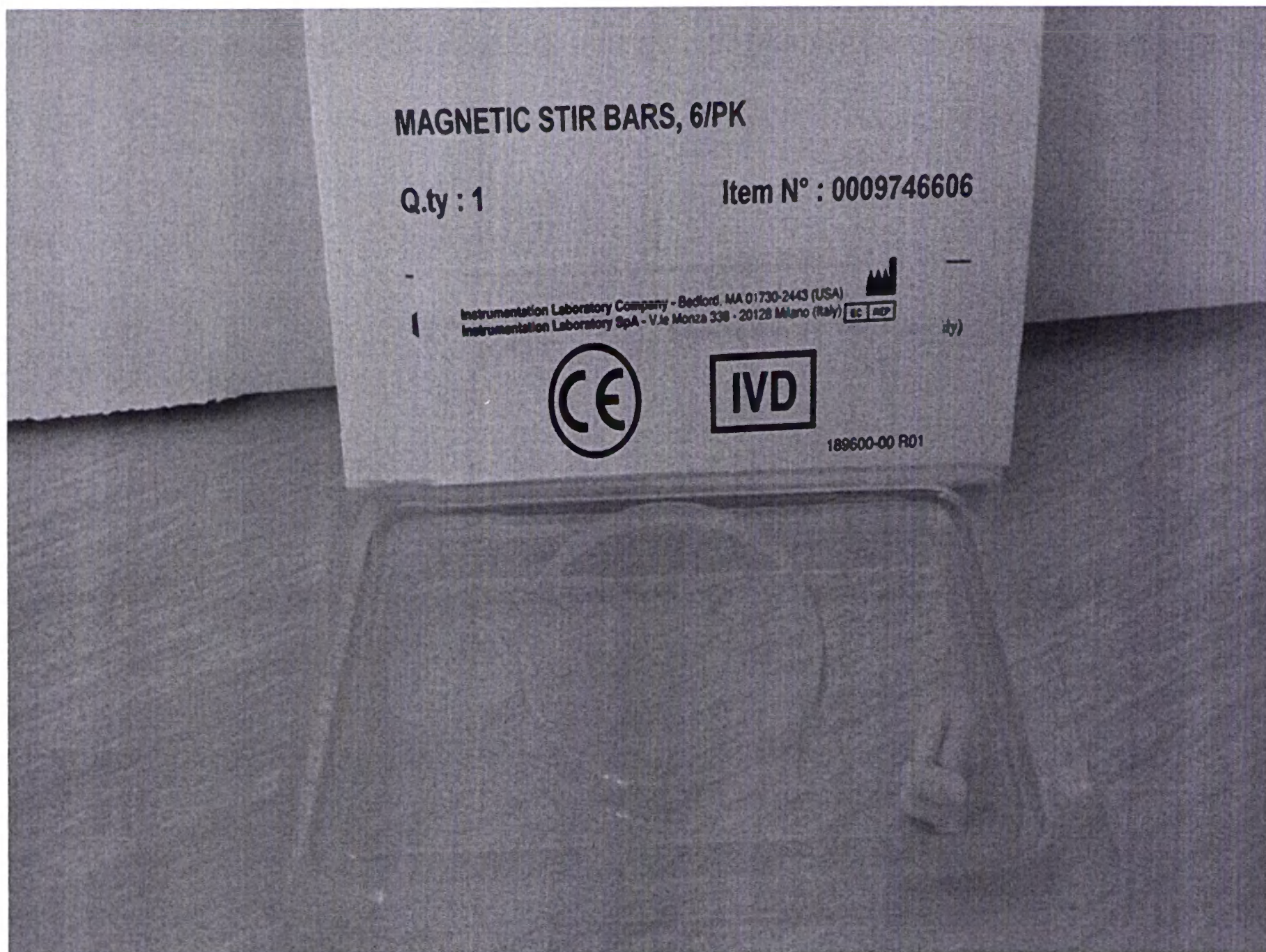




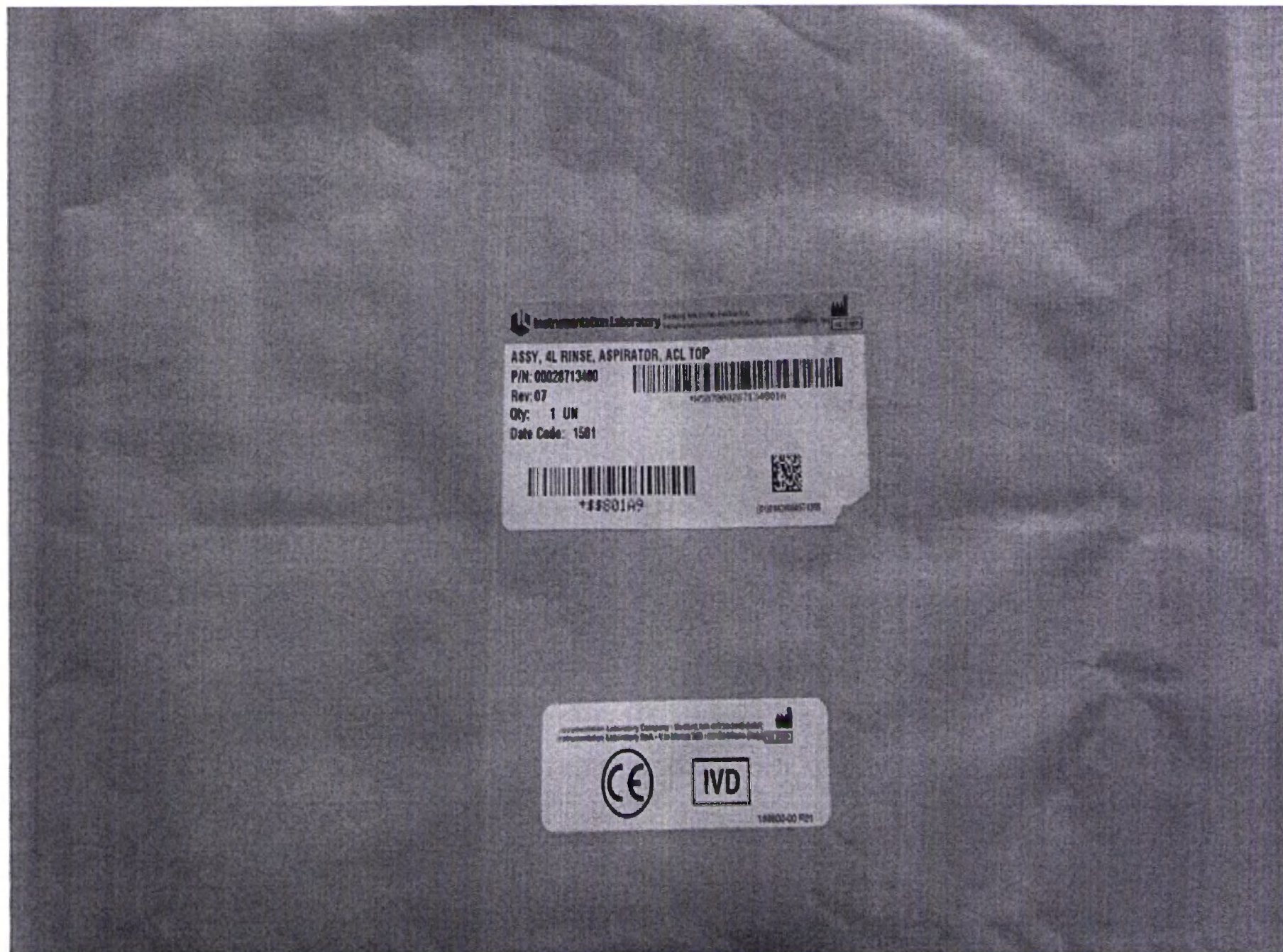
Чашечки для образцов 2.0 мл, 1000 шт.

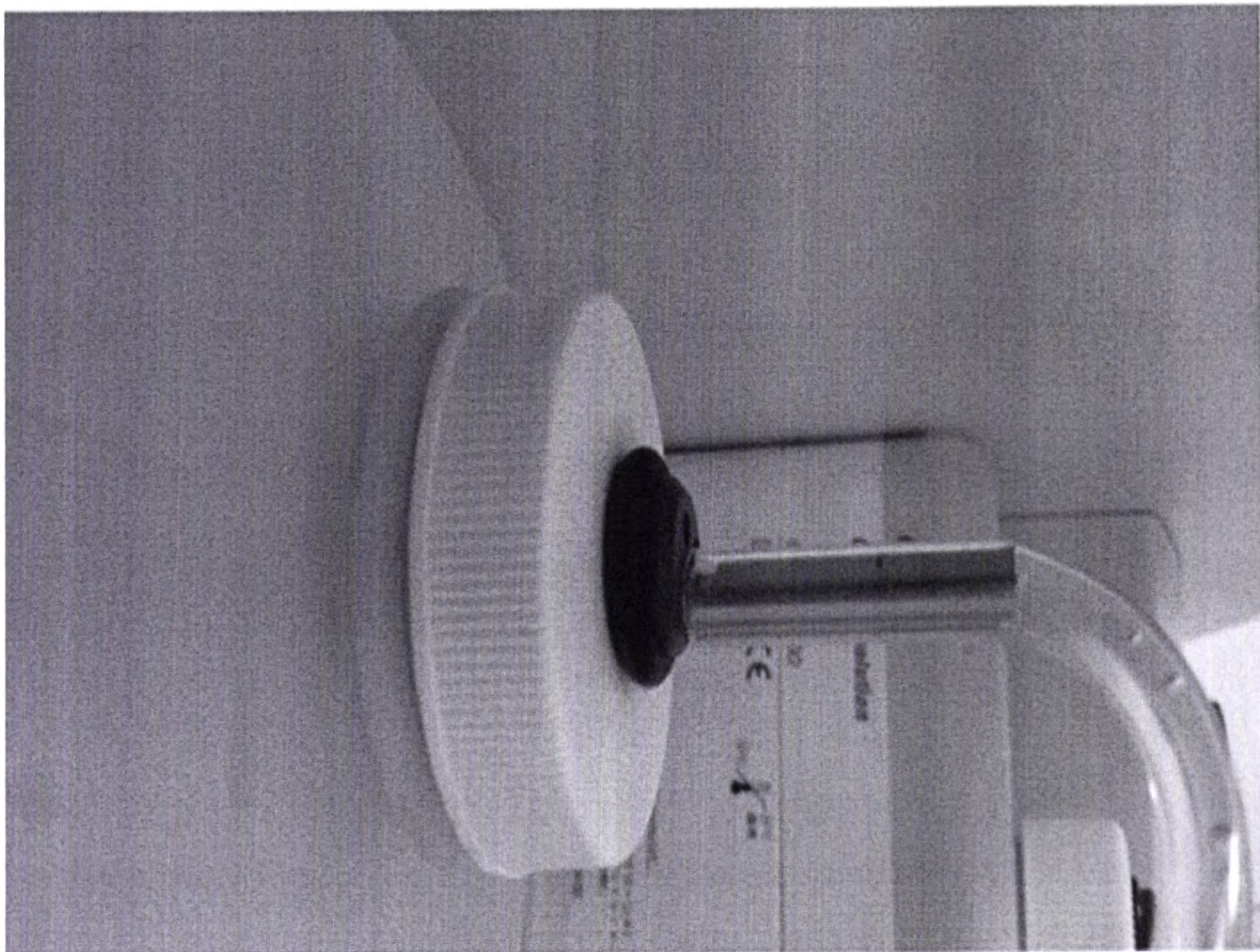


Магнитные мешалки, 6 шт.



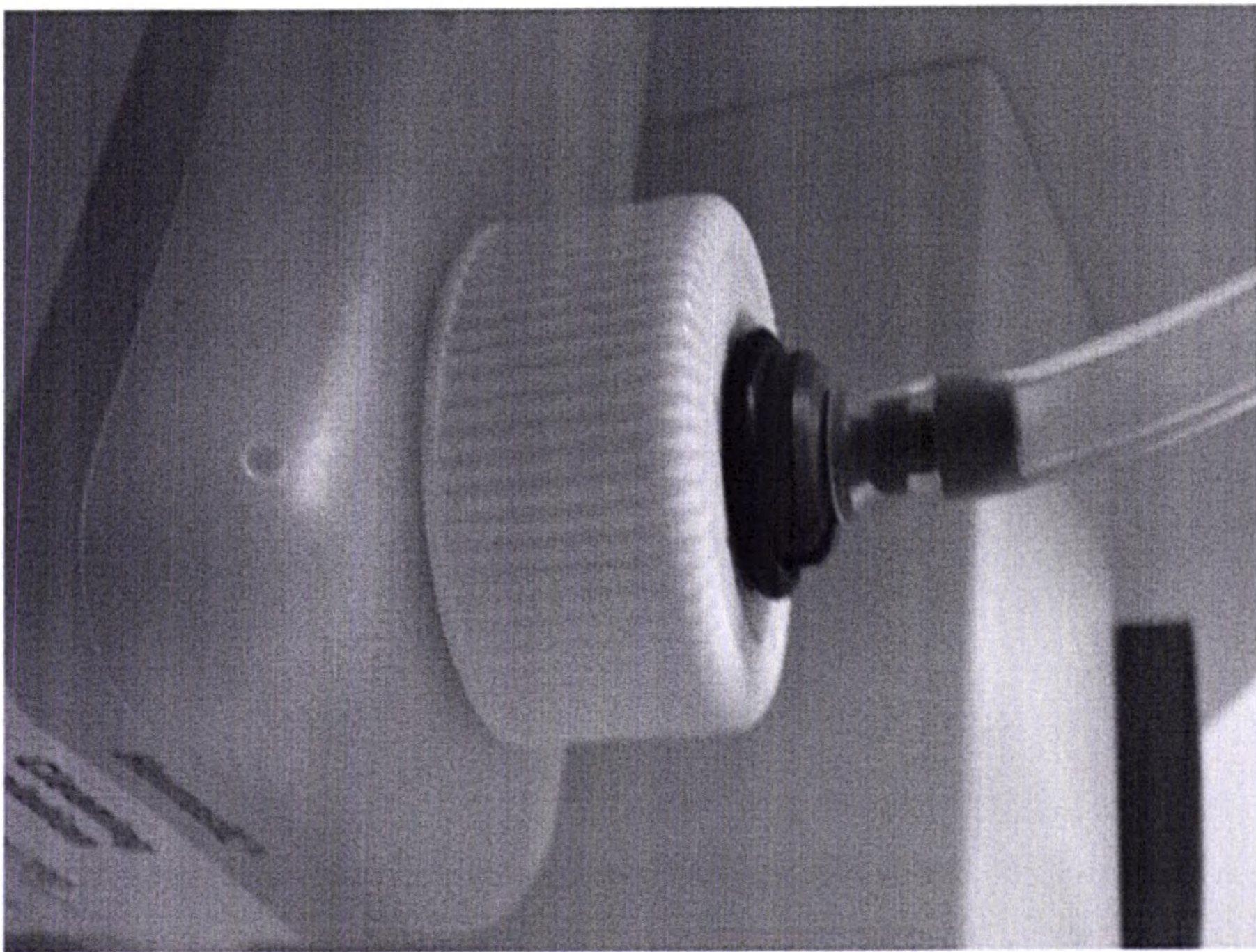
Аспиратор промывочного раствора 4 л для ACL TOP, 1 шт.



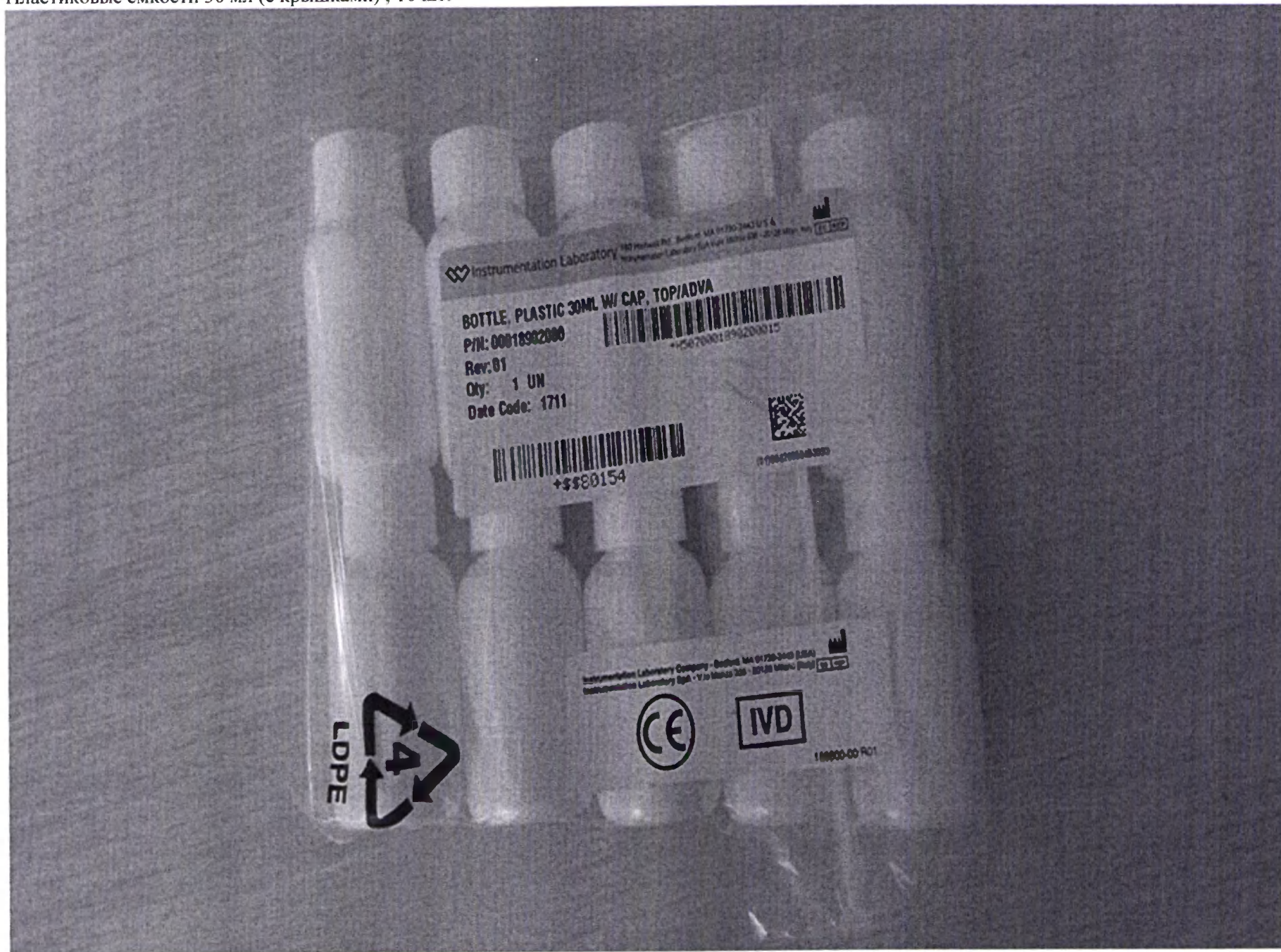


Аспиратор моющего раствора для ACL TOP, 1 шт.

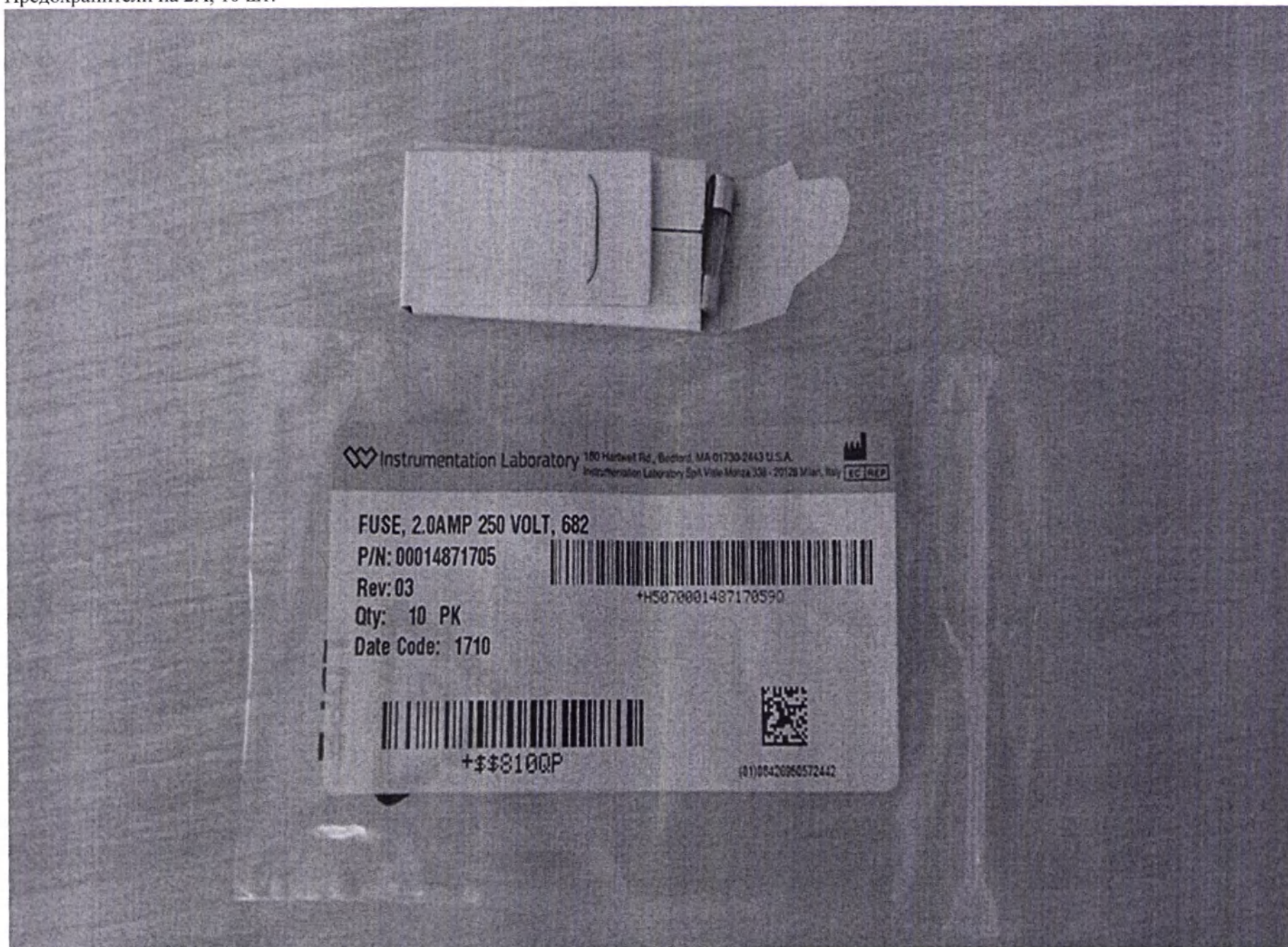




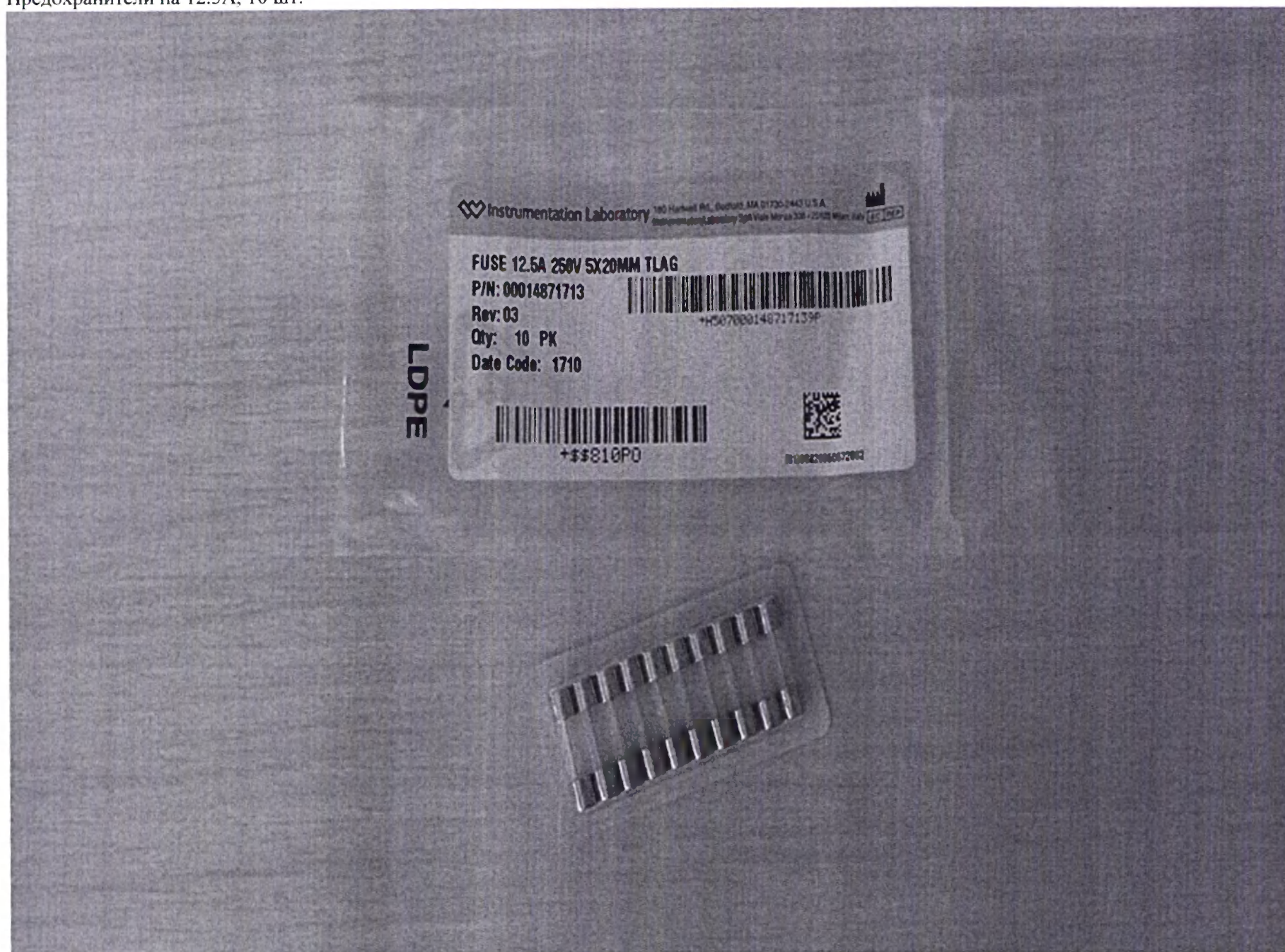
Пластиковые емкости 30 мл (с крышками) , 10 шт.



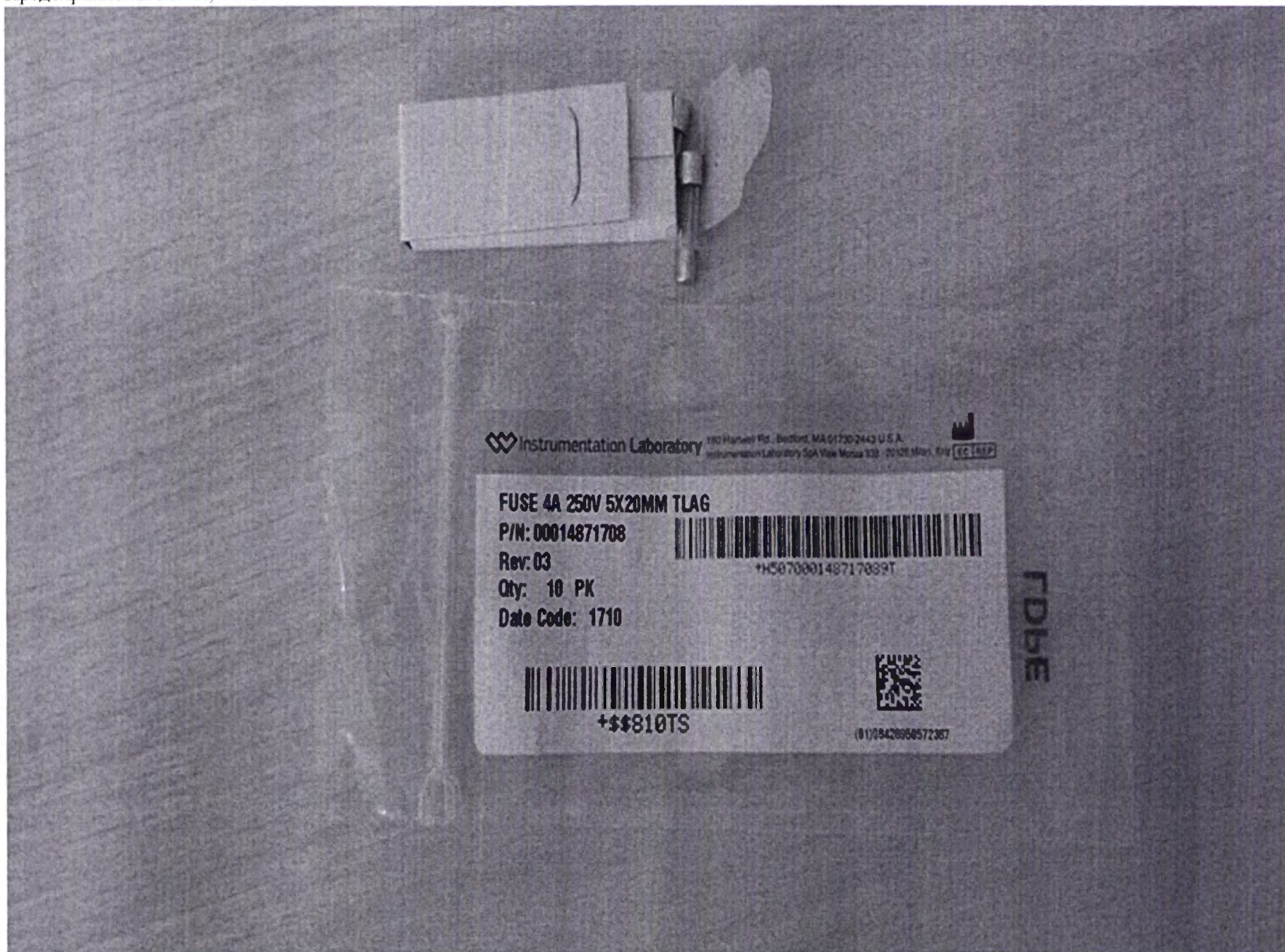
Предохранители на 2А, 10 шт.



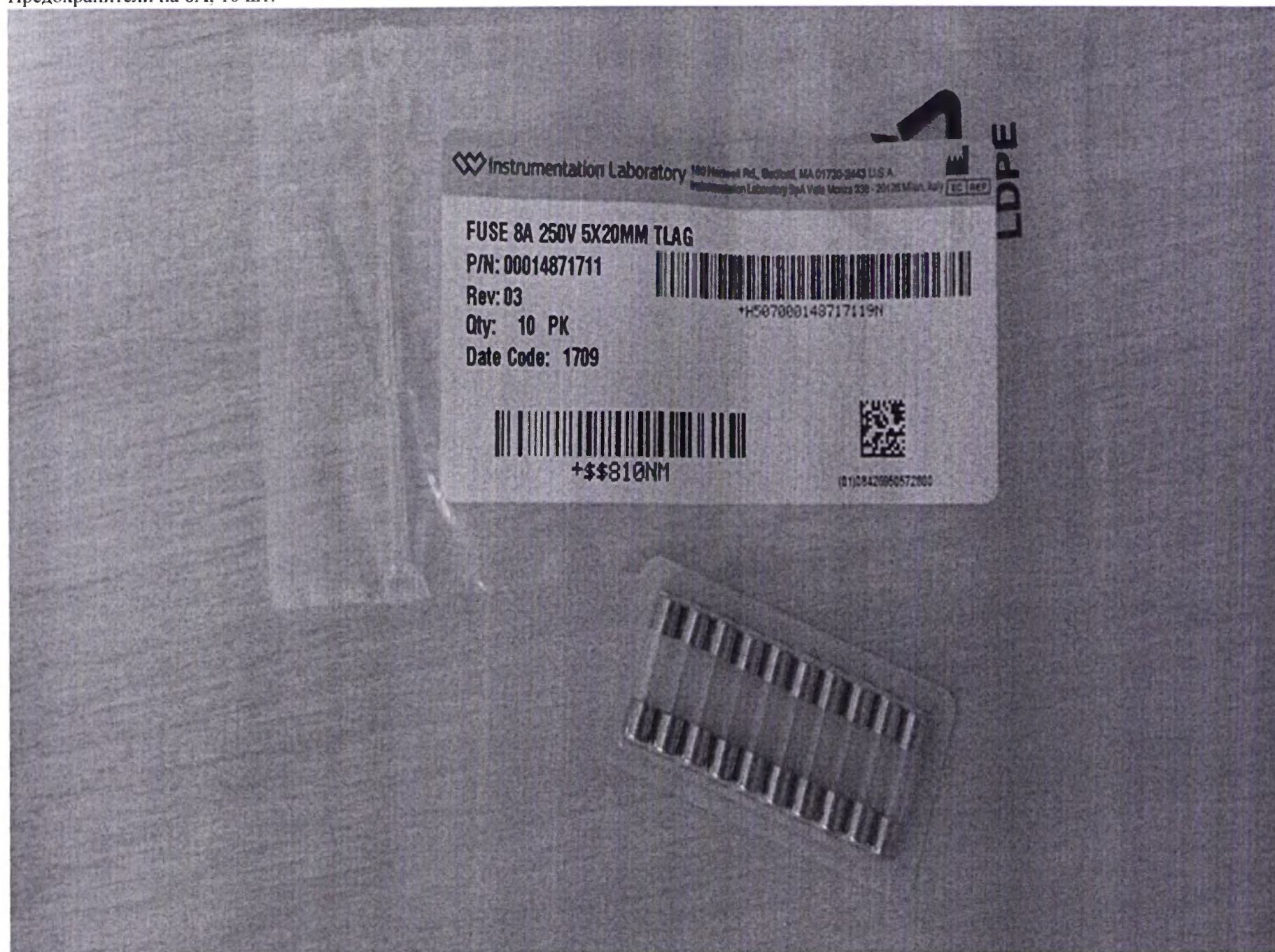
Предохранители на 12.5А, 10 шт.



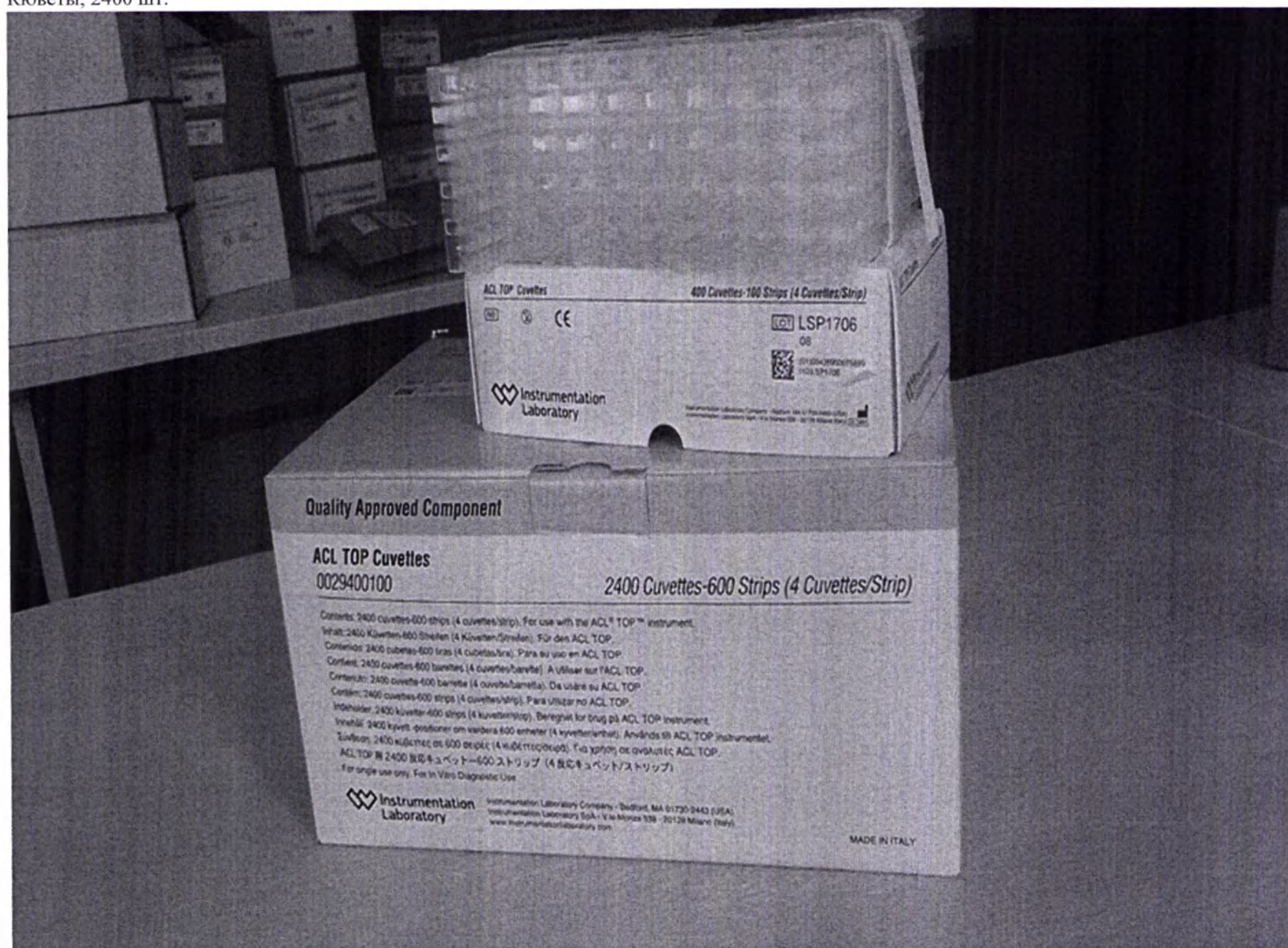
Предохранители на 4А, 10 шт.



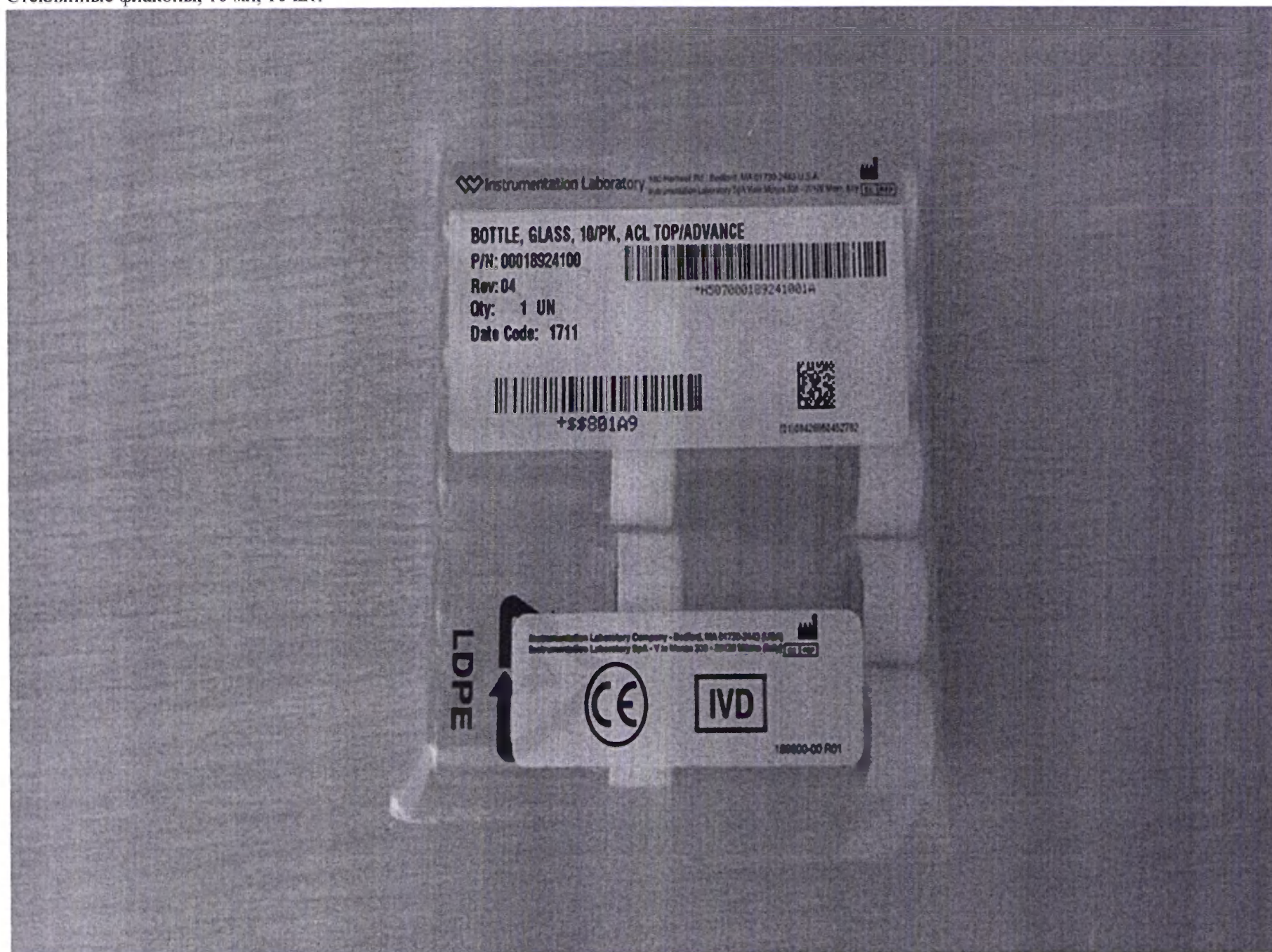
Предохранители на 8А, 10 шт.



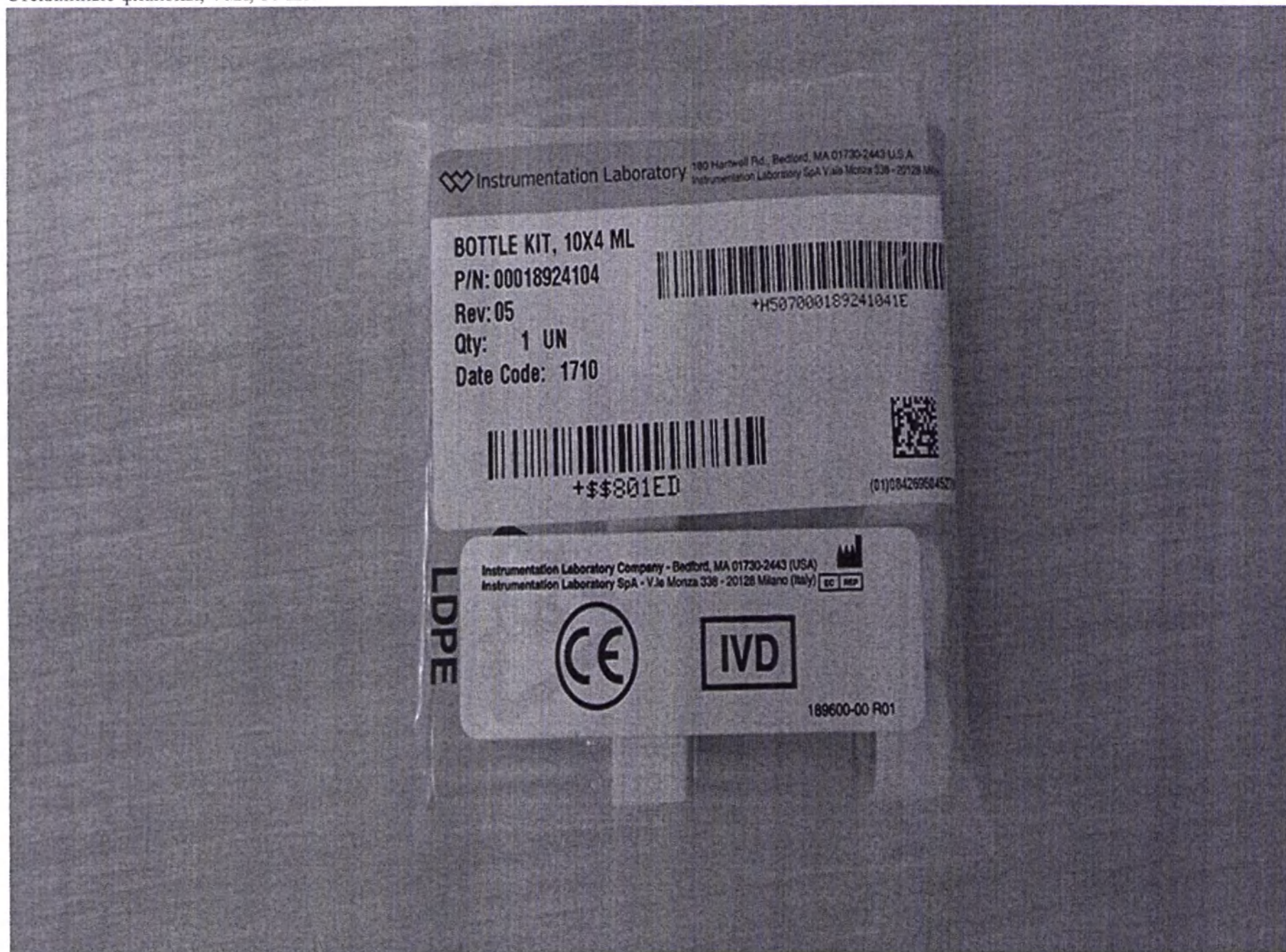
Кюветы, 2400 шт.



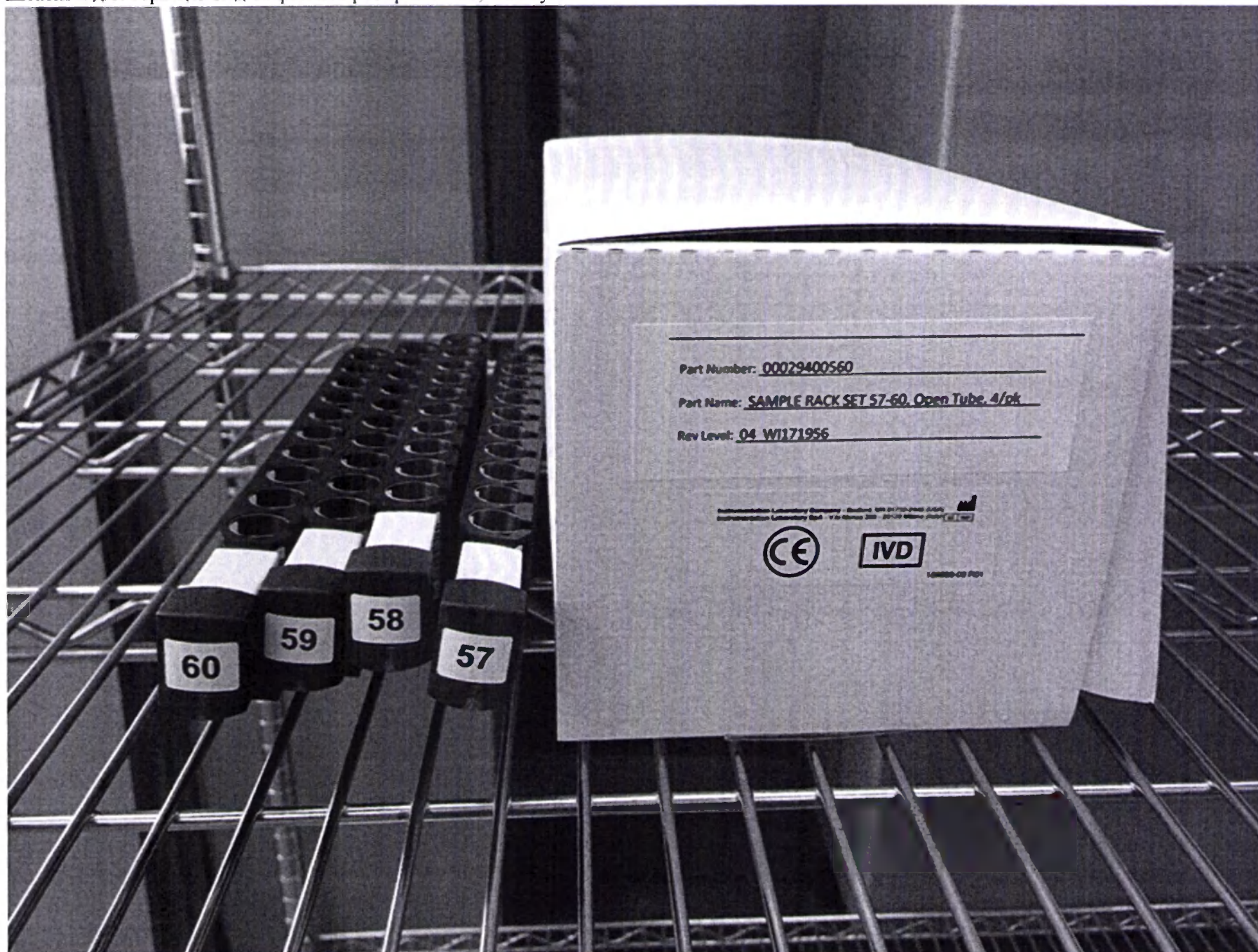
Стеклянные флаконы, 10 мл, 10 шт.



Стеклянные флаконы, 4 мл, 10 шт.



Штативы для образцов под открытые пробирки 57-60, 4 шт./уп.



Штативы для разбавителей DA, 1 шт./уп.



DILUENT RACK SET DA, ACL TOP 300
P/N: 00029400760
Rev: 01
Qty: 1 UN
Date Code: 1811



+H507000294007601D

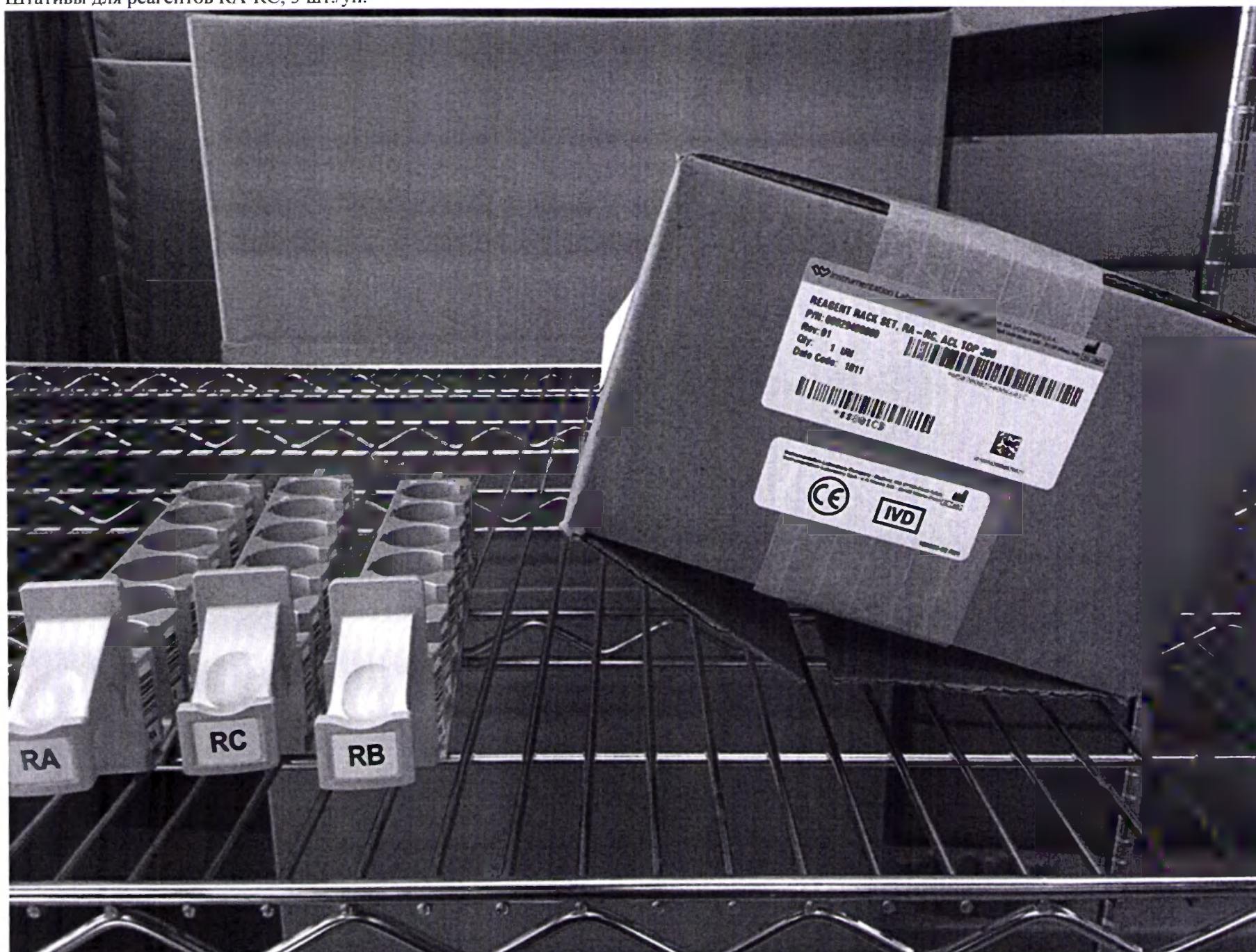


+\$801DC

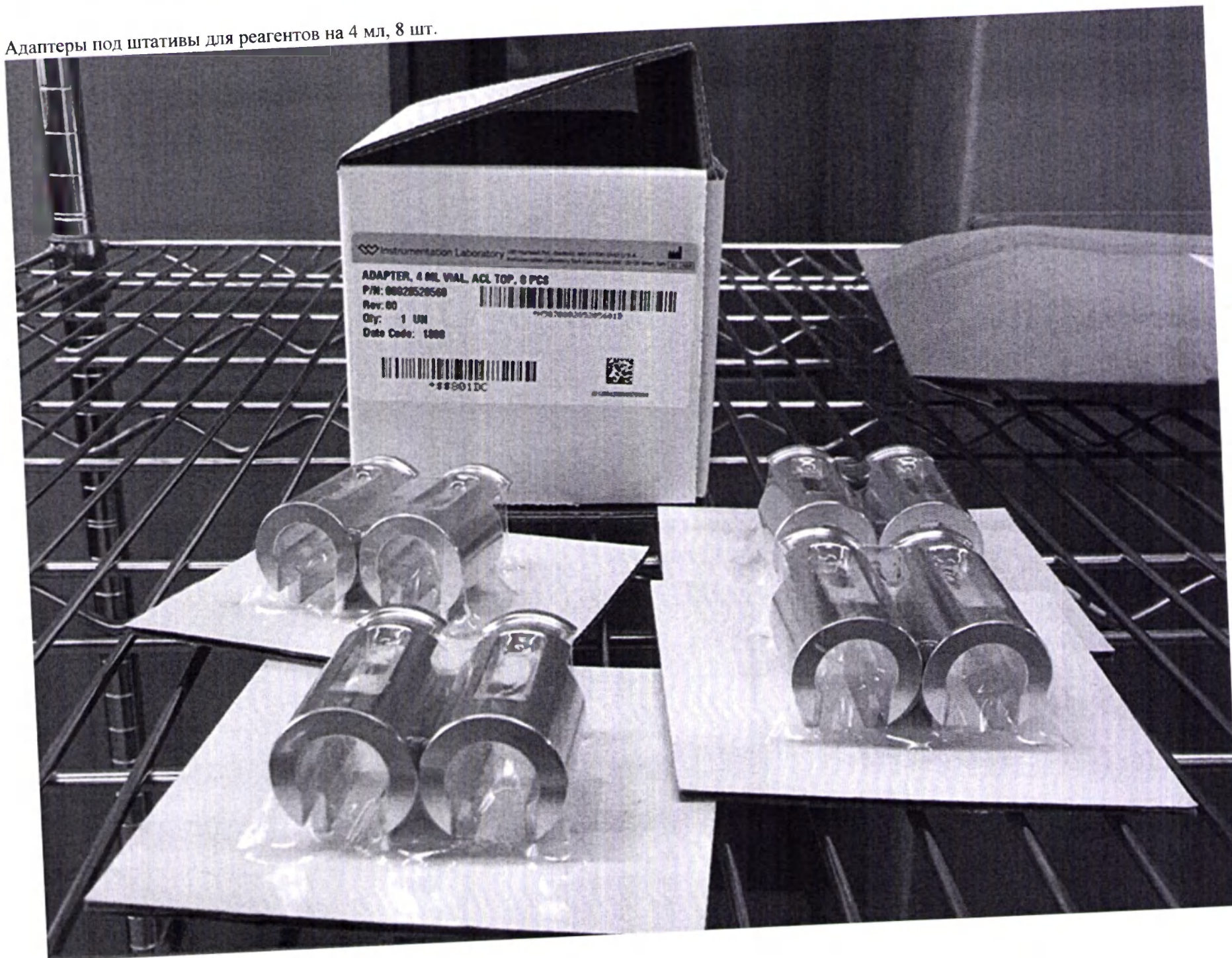


(01)00420000577102

Штативы для реагентов RA-RC, 3 шт./уп.



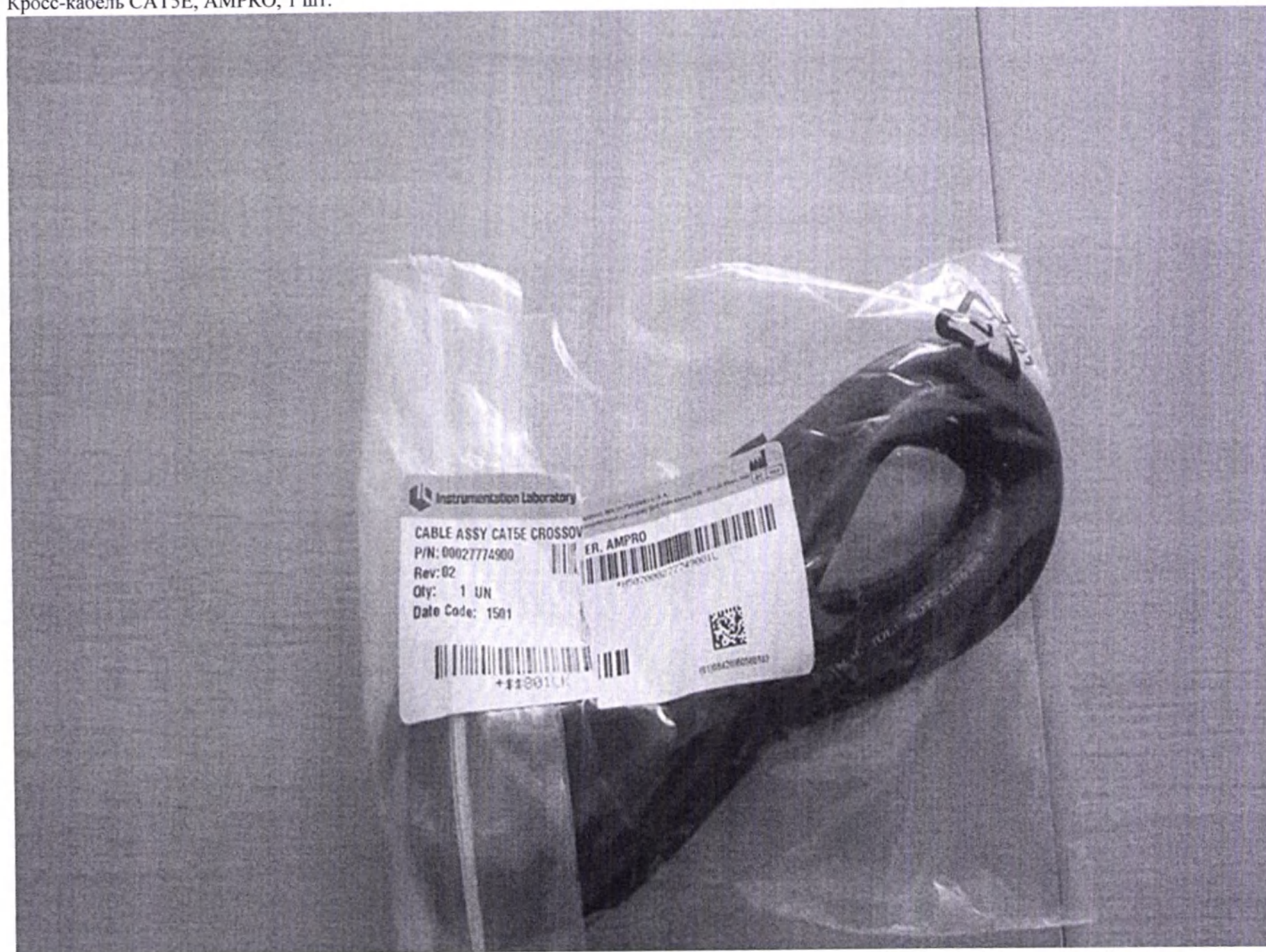
Адаптеры под штативы для реагентов на 4 мл, 8 шт.



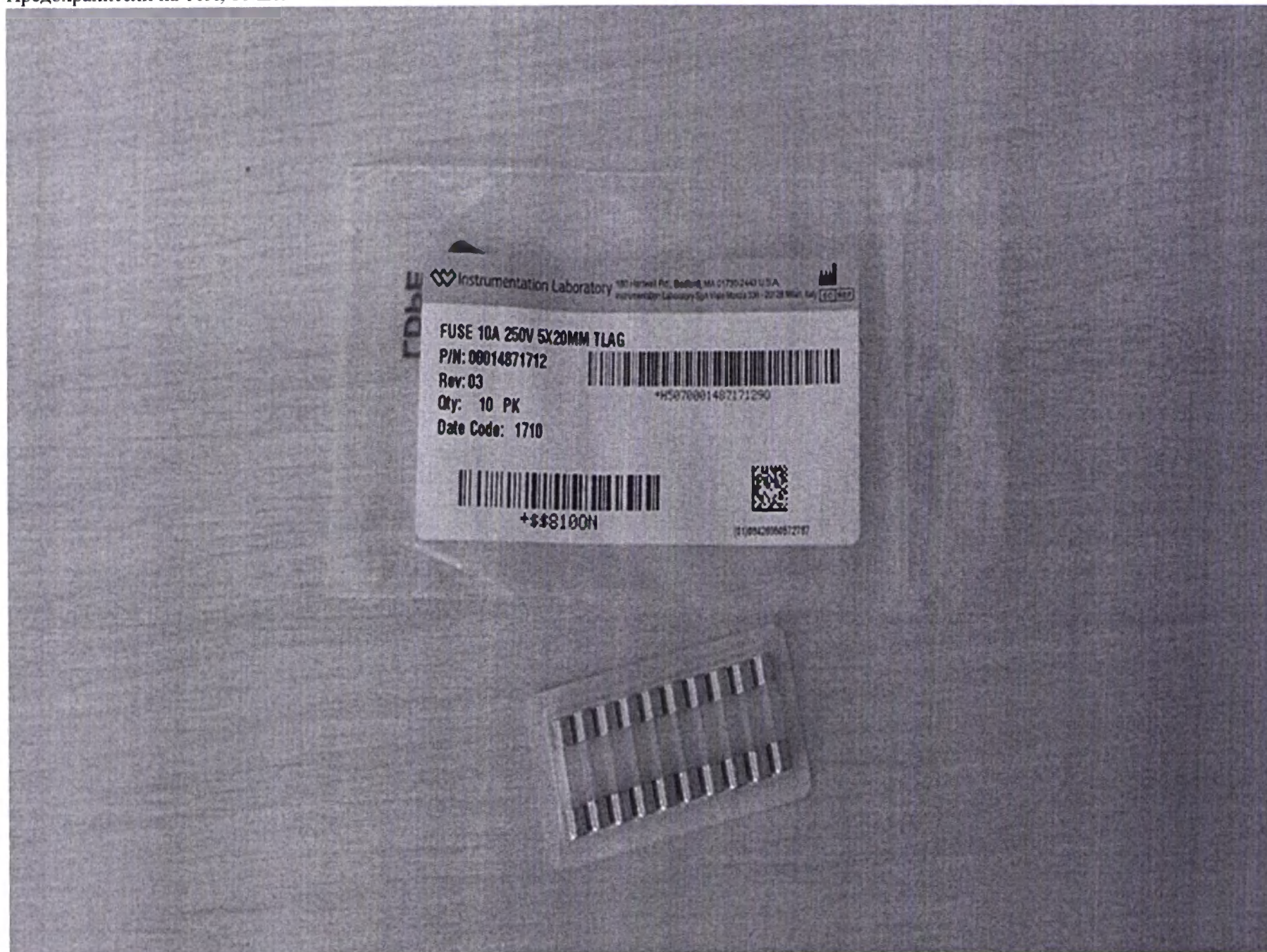
Адаптеры под штативы для реагентов на 10 мл, 8 шт.



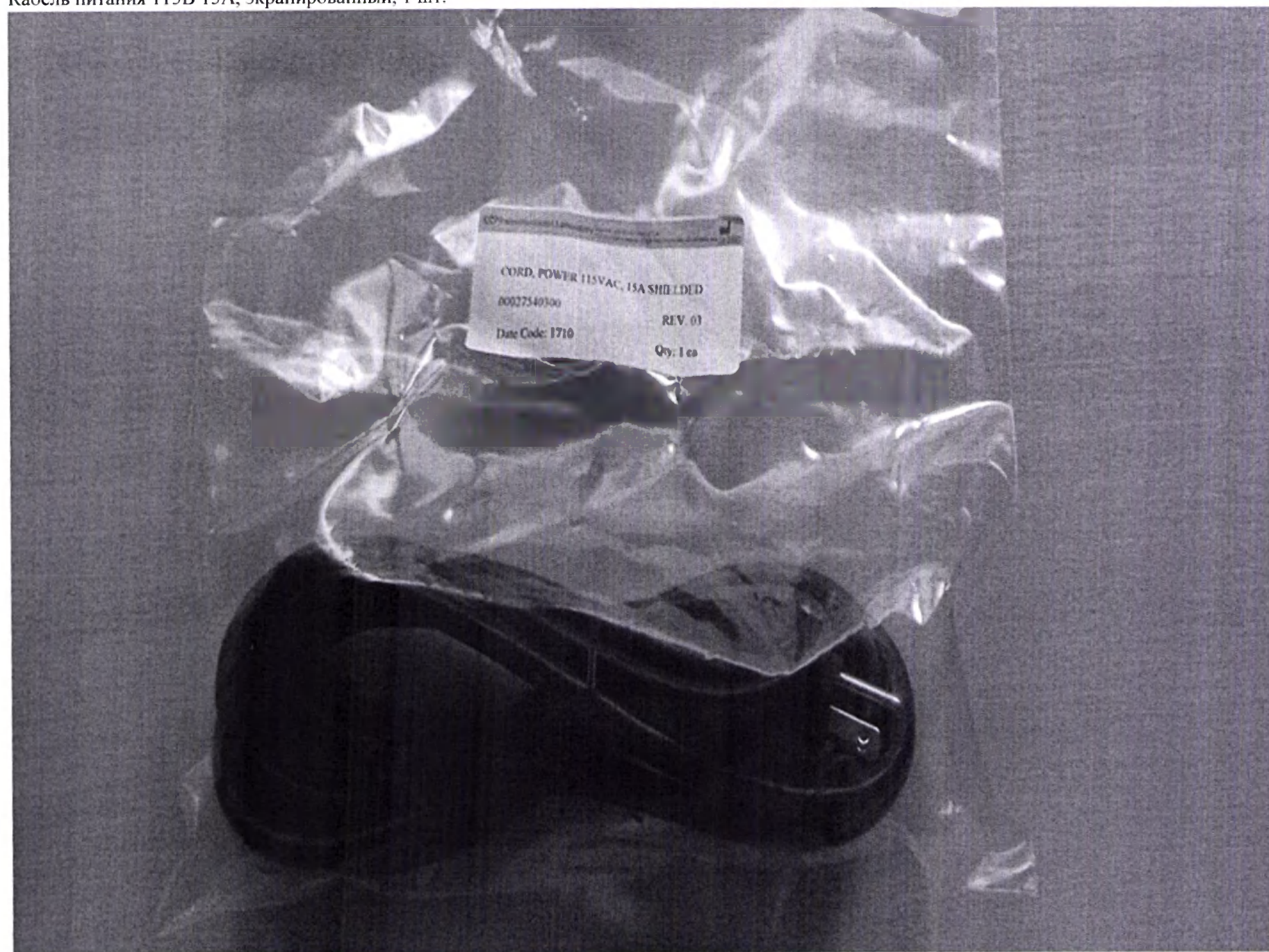
Кросс-кабель CAT5E, AMPRO, 1 шт.



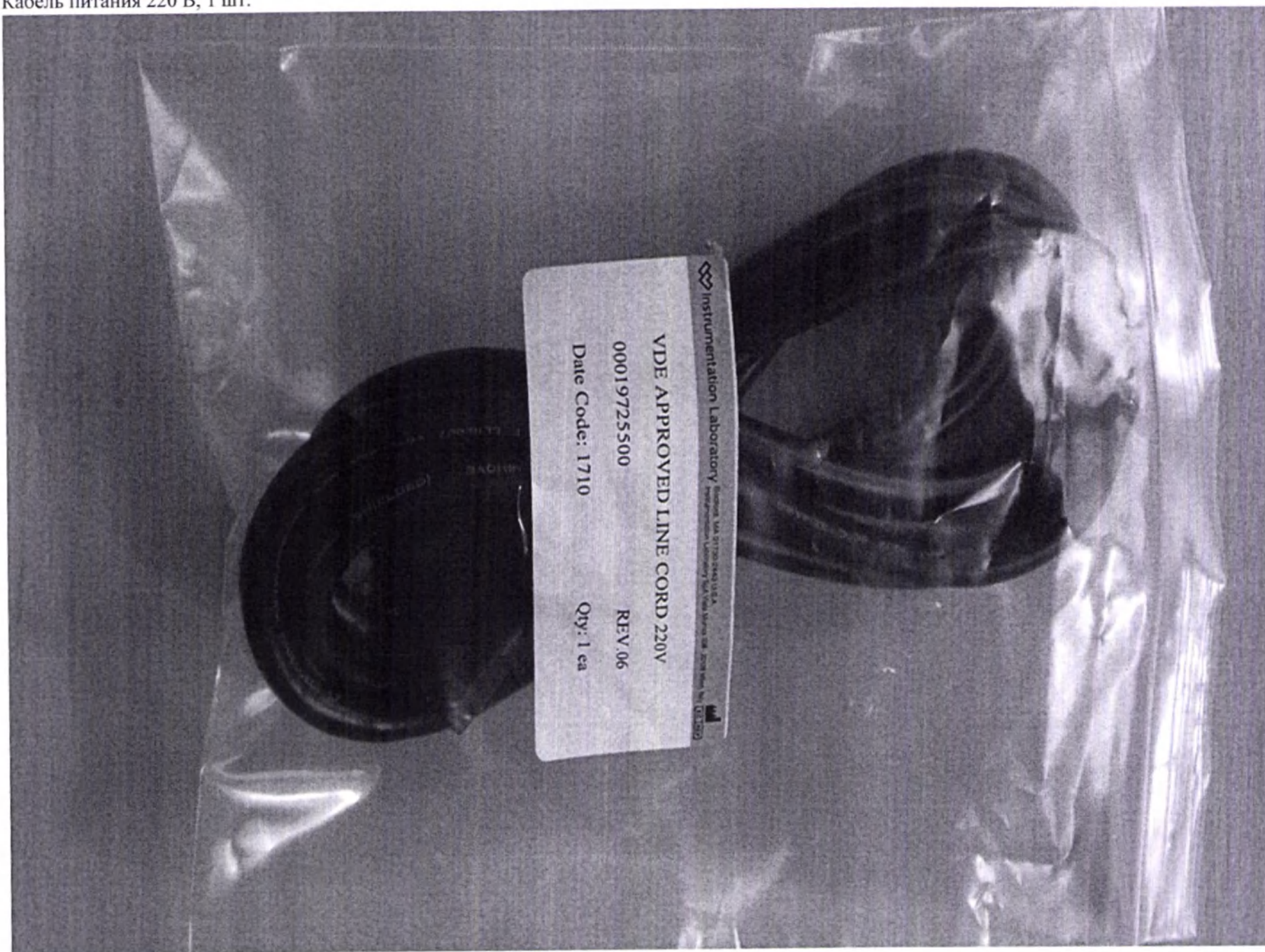
Предохранители на 10А, 10 шт.



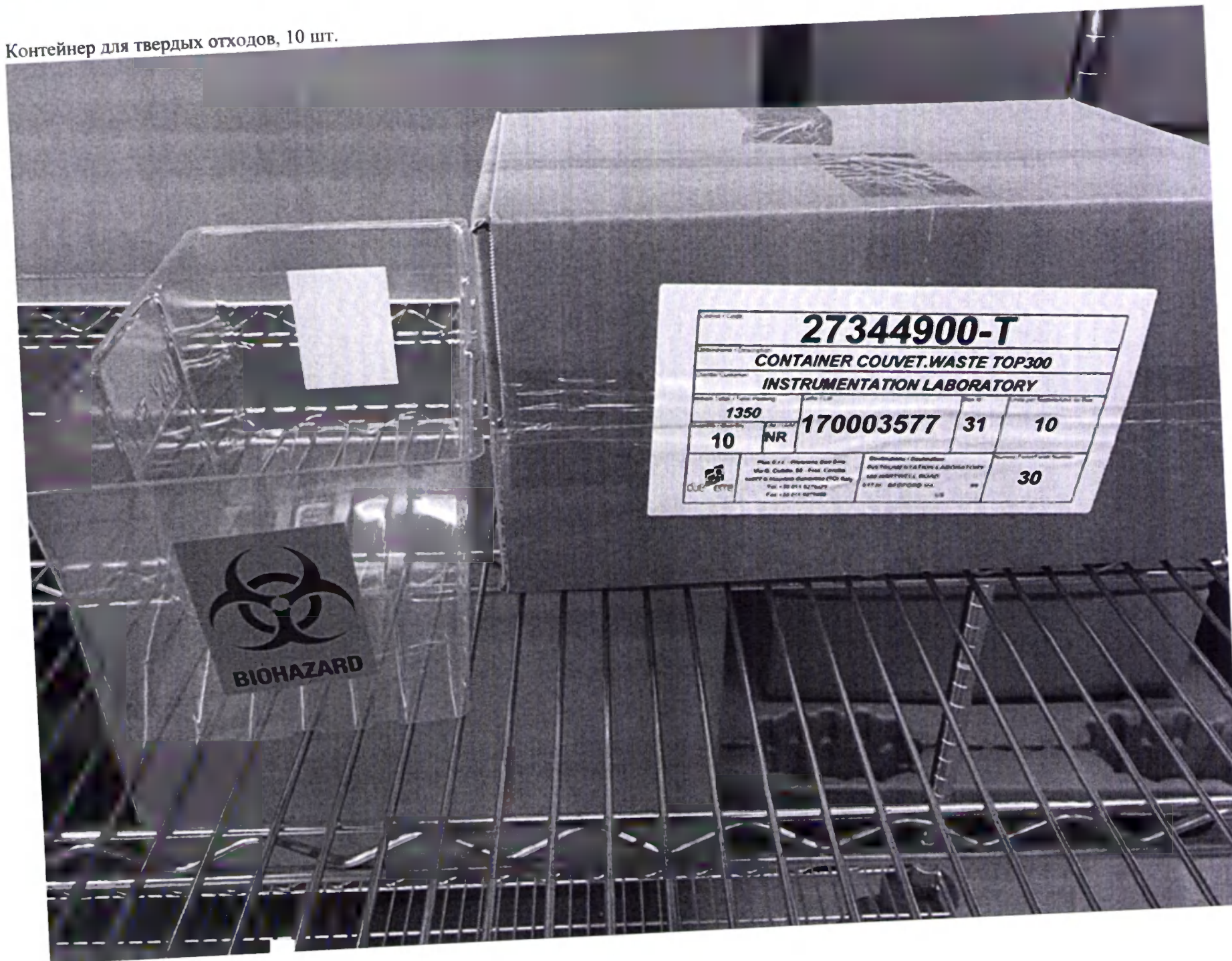
Кабель питания 115В 15А, экранированный, 1 шт.



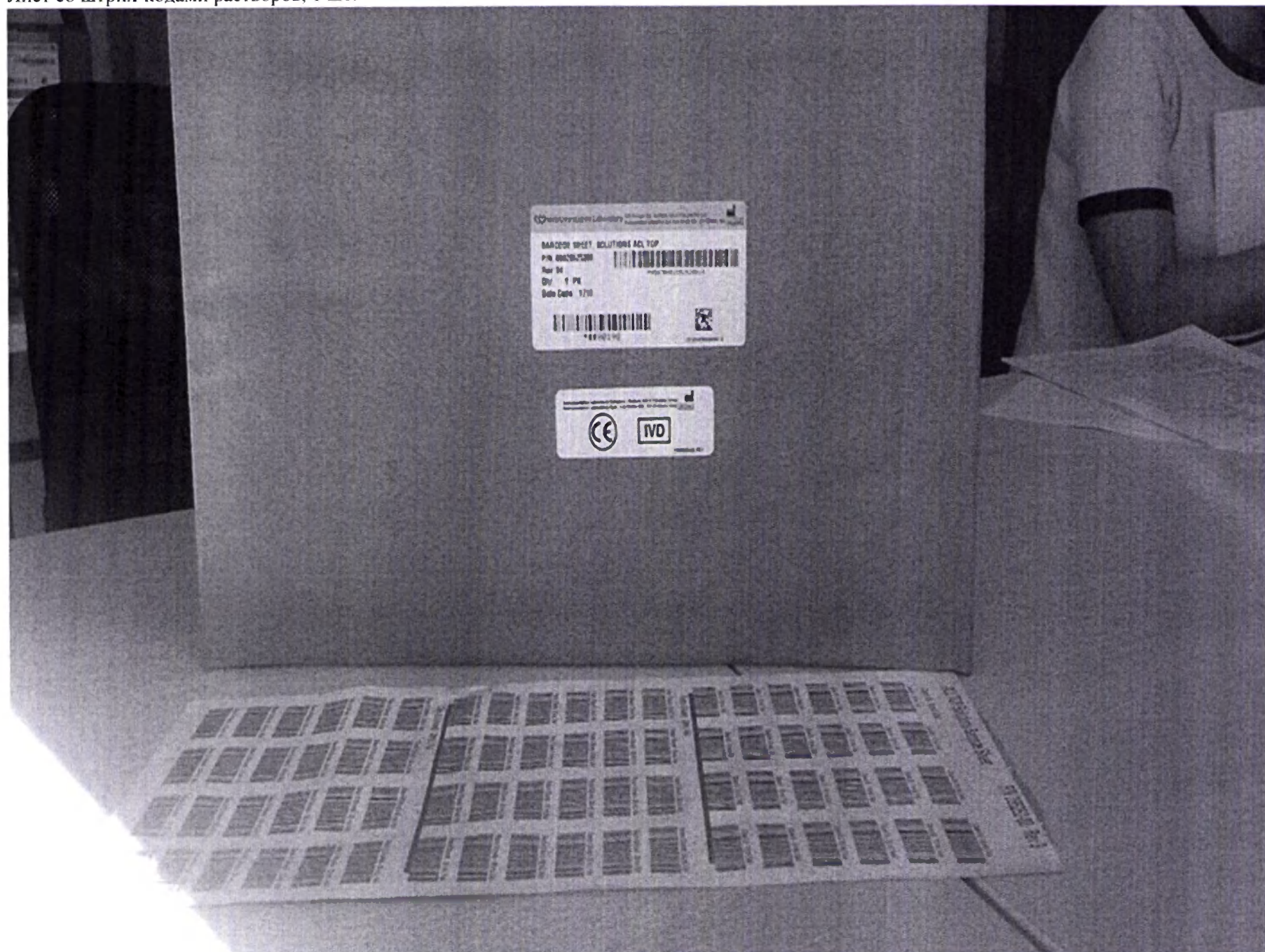
Кабель питания 220 В, 1 шт.



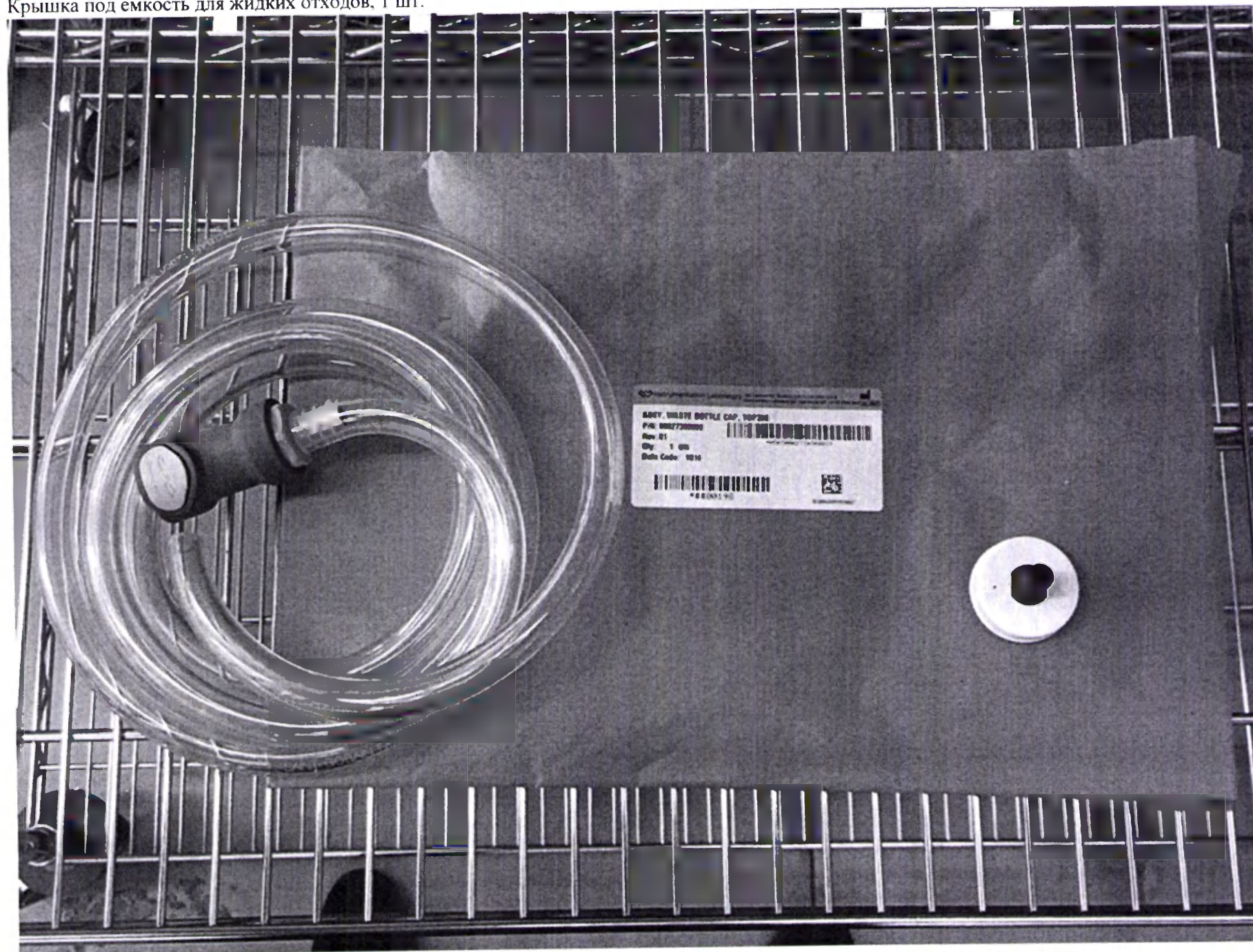
Контейнер для твердых отходов, 10 шт.



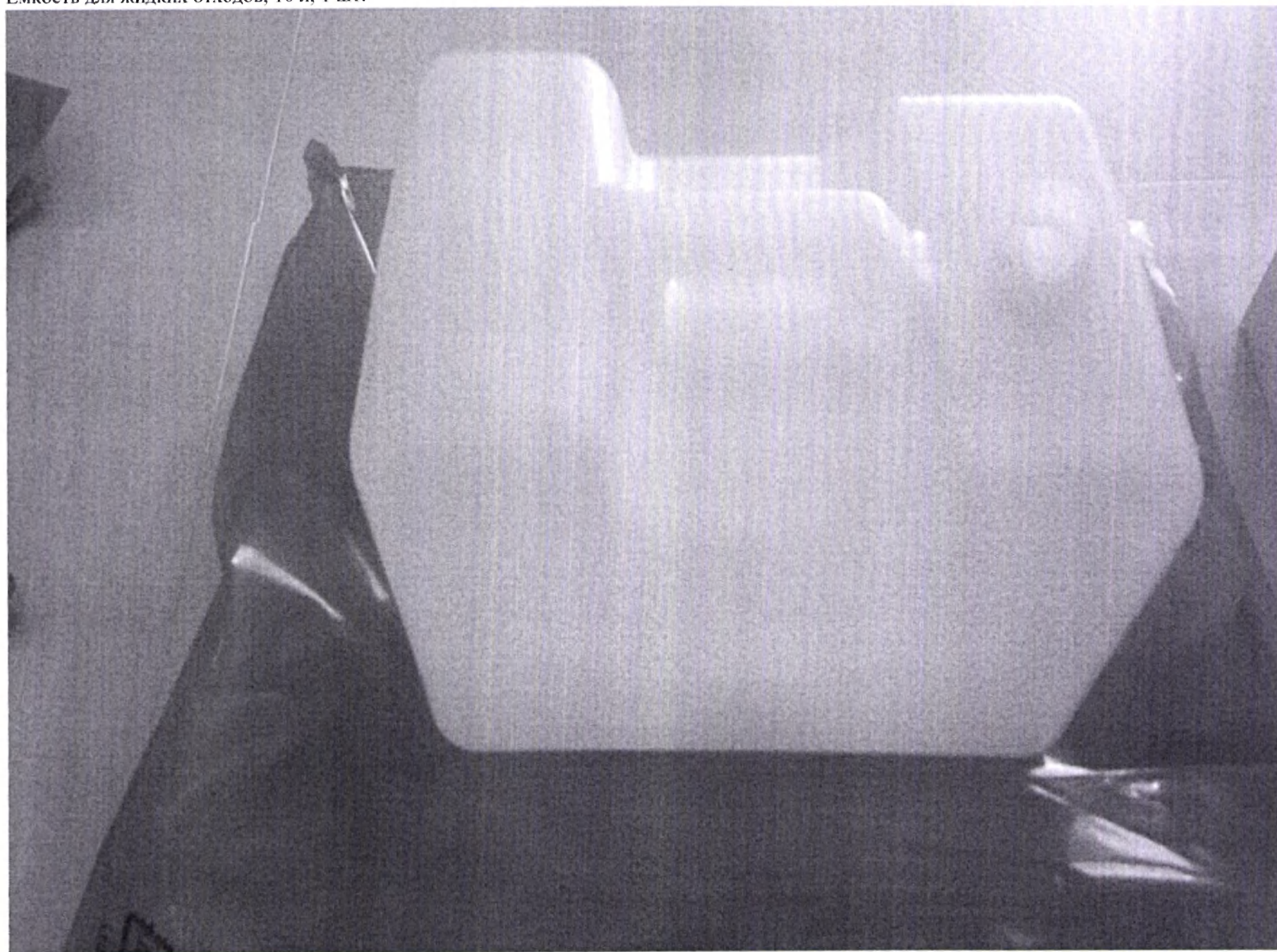
Лист со штрих-кодами растворов, 1 шт.

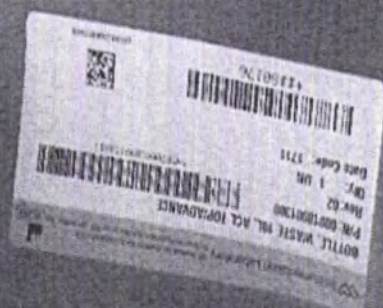


Крышка под емкость для жидких отходов, 1 шт.

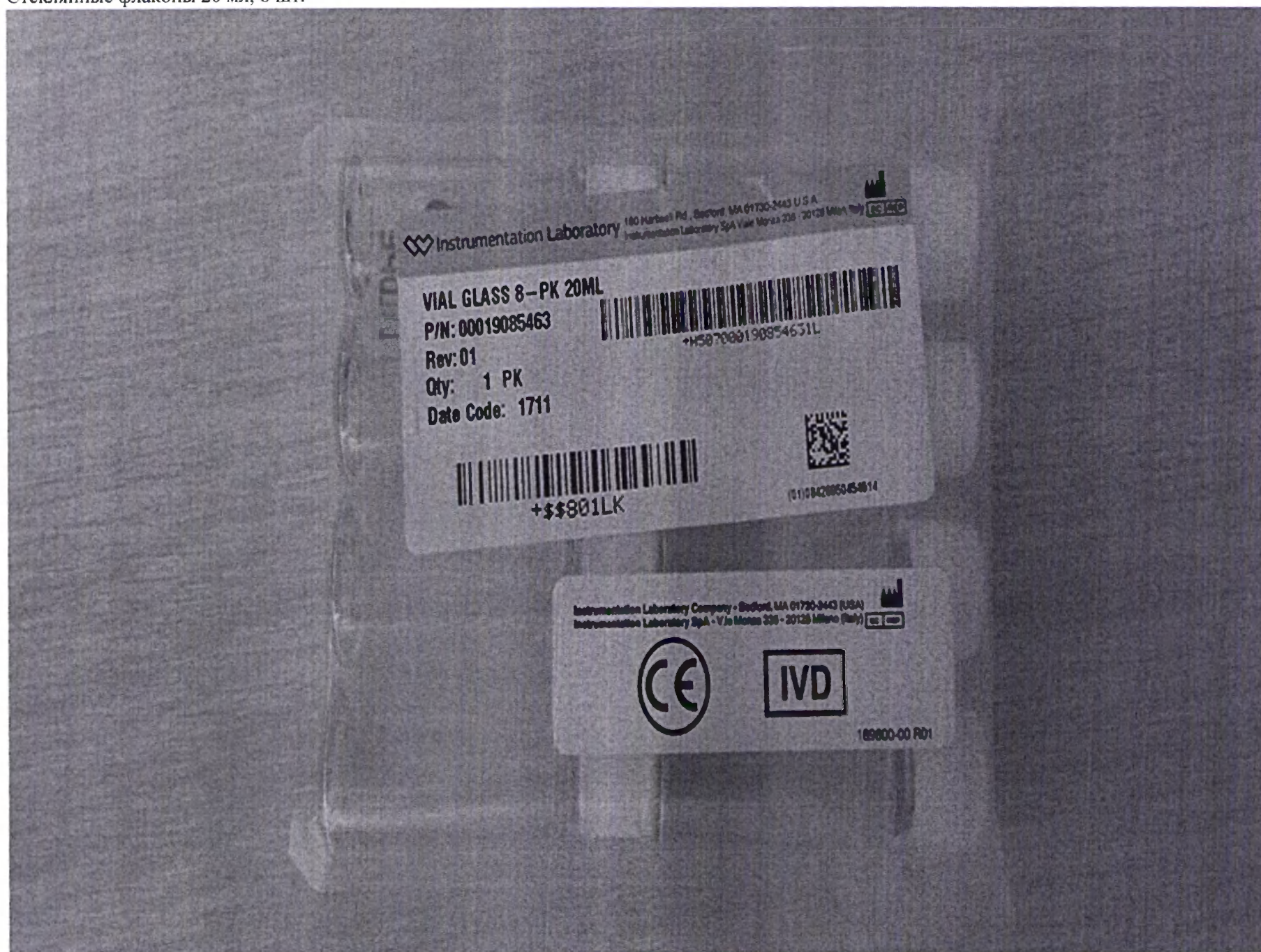


Емкость для жидких отходов, 10 л, 1 шт.

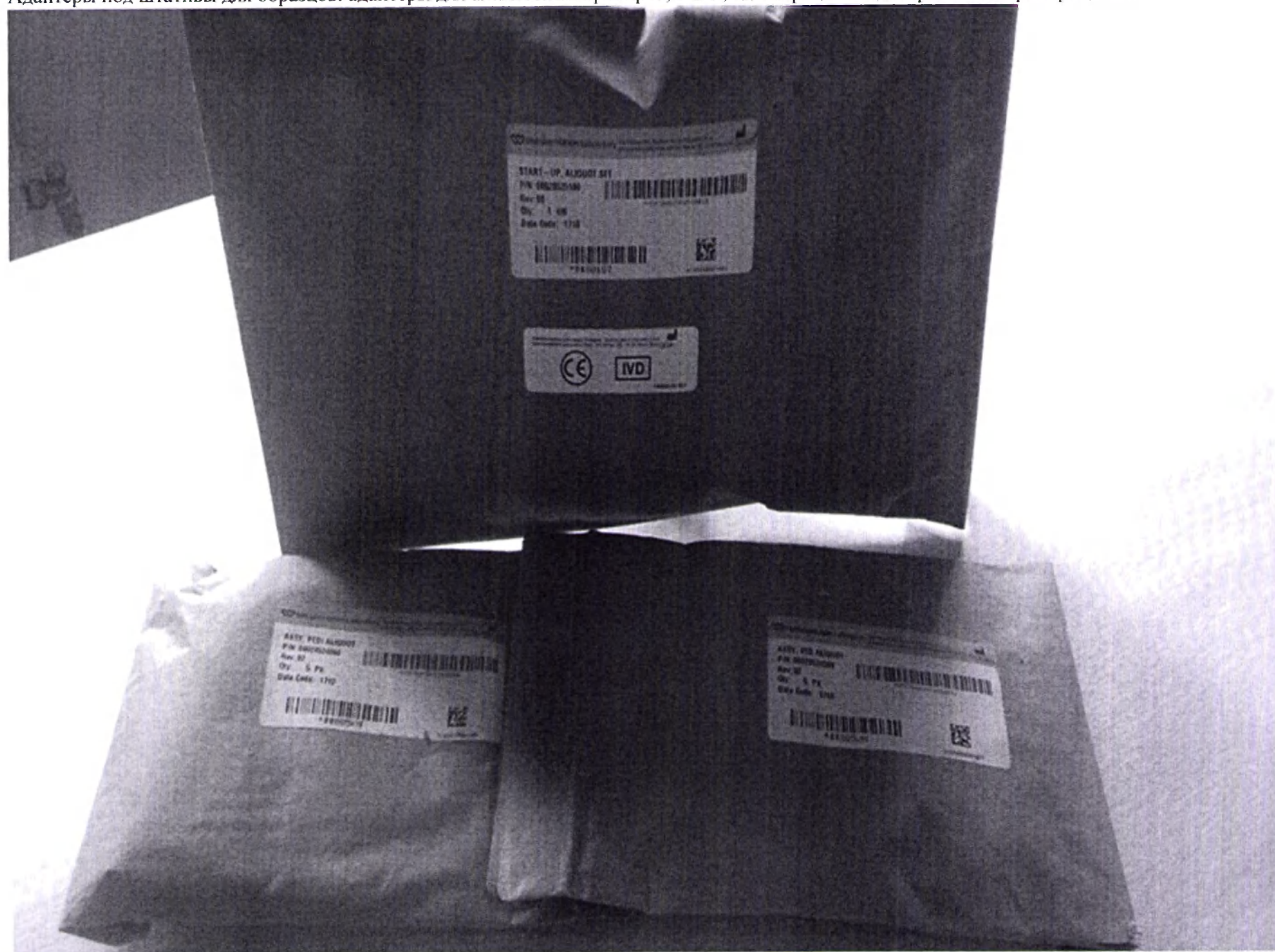




Стеклянные флаконы 20 мл, 8 шт.



Адаптеры под штативы для образцов: адаптеры для аликвотных пробирок, 5 шт.; адаптеры для педиатрических пробирок, 5шт.



Контейнер под емкость для жидких отходов, 10 л, 1 шт.



 **Instrumentation Laboratory** 180 Hartwell Rd., Bedford, MA 01730-2443 U.S.A.
Instrumentation Laboratory S.p.A. Viale Monza 338 - 20126 Milan, Italy 

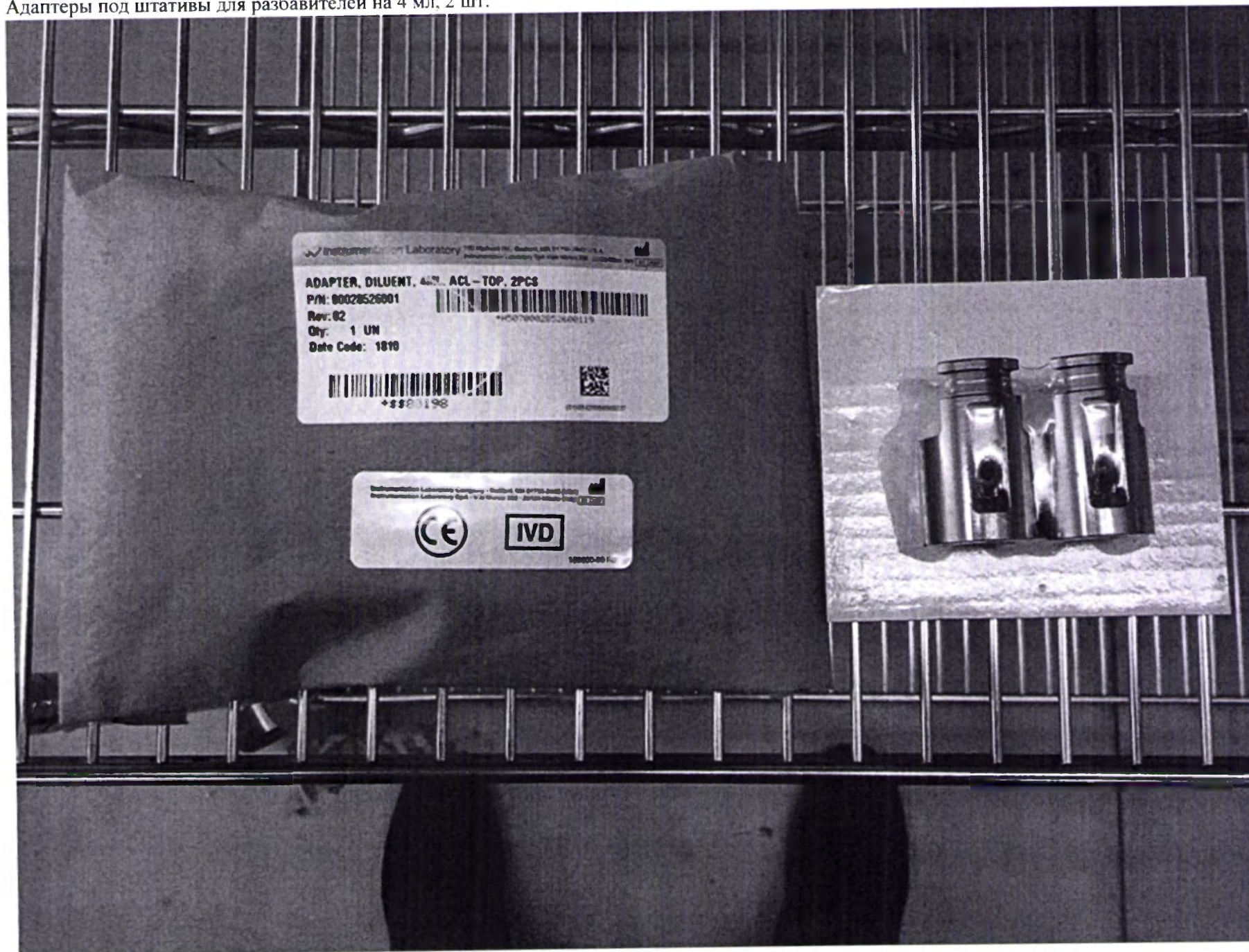
CONTAINER, 10L WASTE BOTTLE
P/N: 00028766600
Rev: 01
Qty: 1 UN
Date Code: 1711


+H507000287666001K

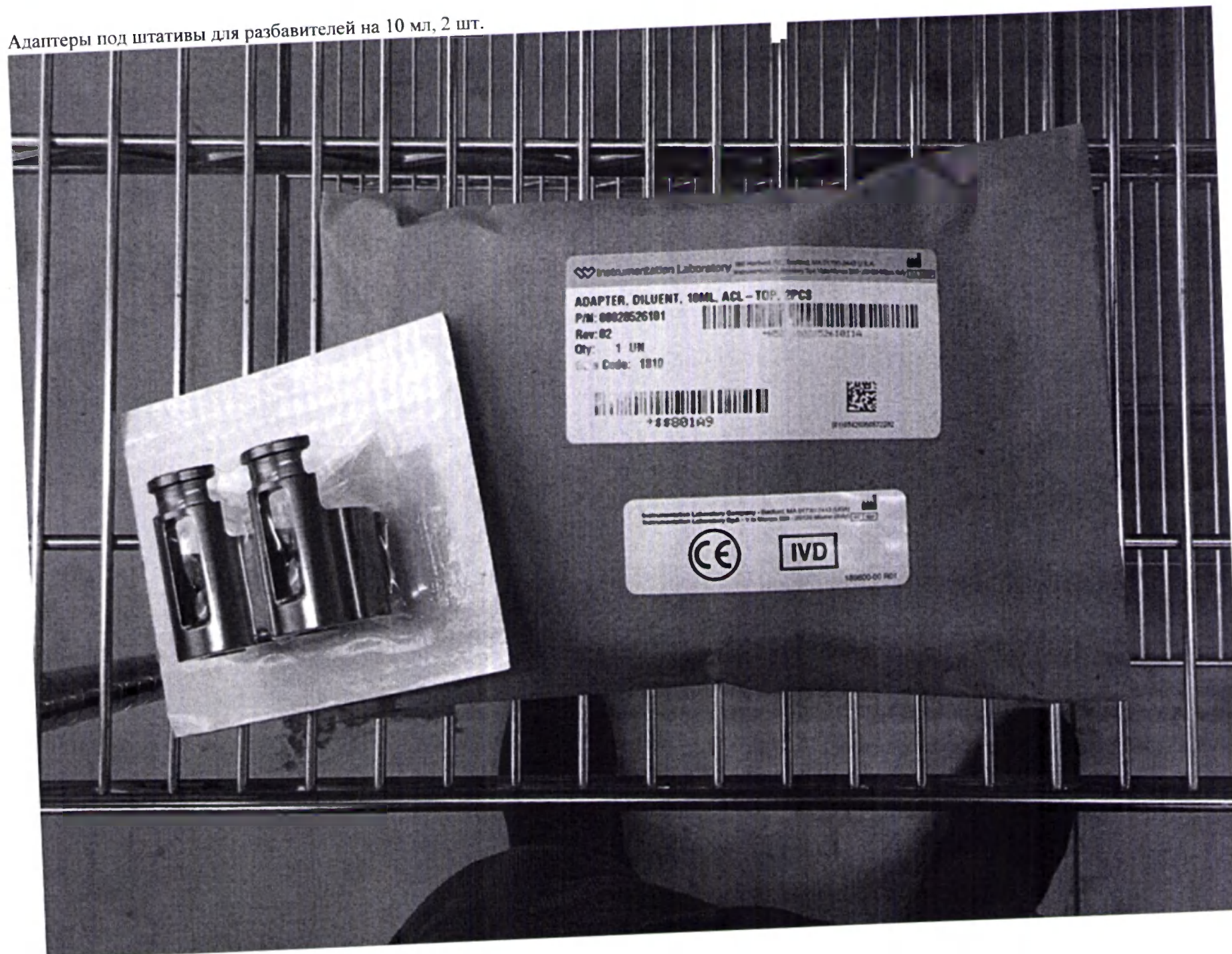

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(01)08426950567059

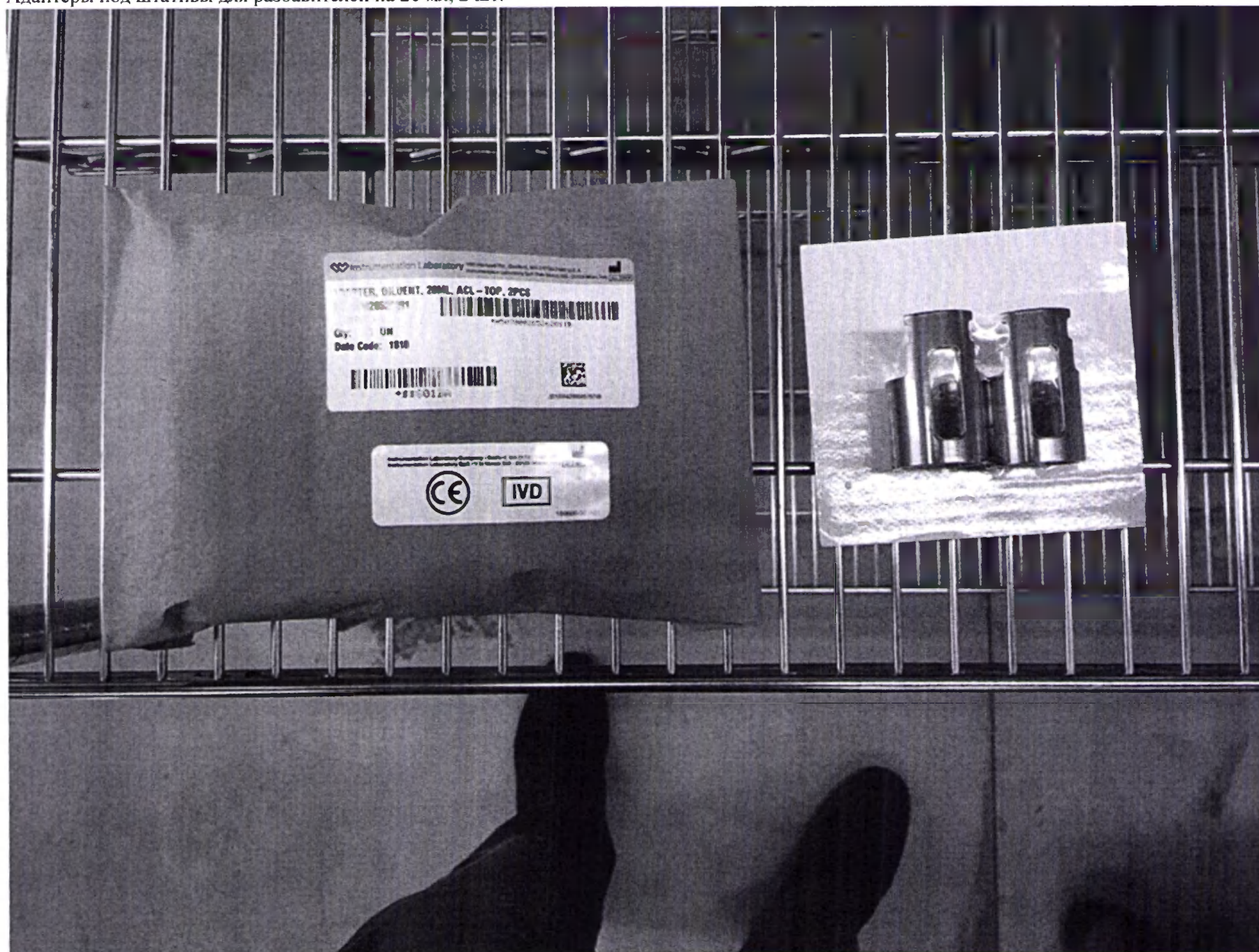
Адаптеры под штативы для разбавителей на 4 мл, 2 шт.



Адаптеры под штативы для разбавителей на 10 мл, 2 шт.



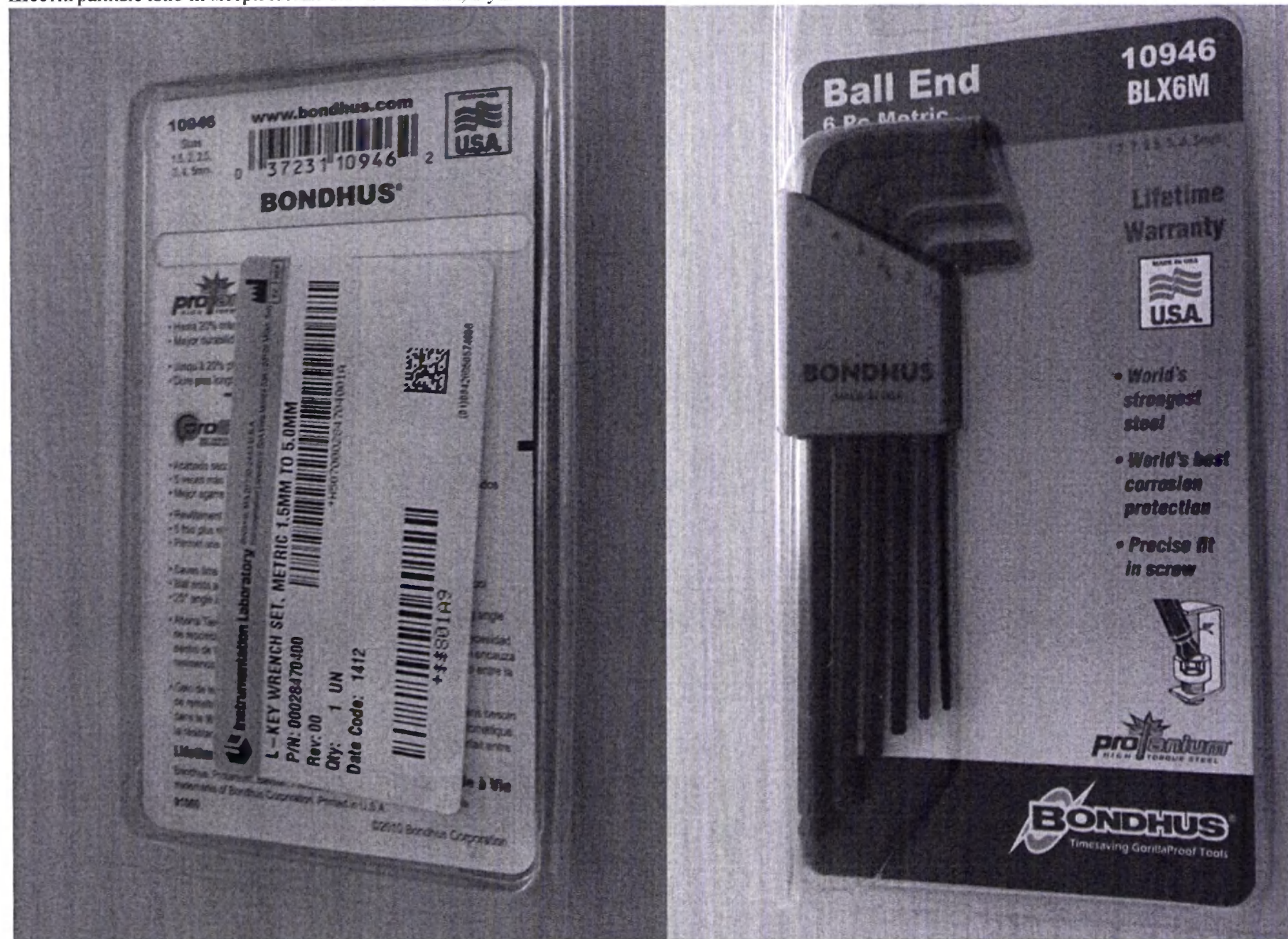
Адаптеры под штативы для разбавителей на 20 мл, 2 шт.



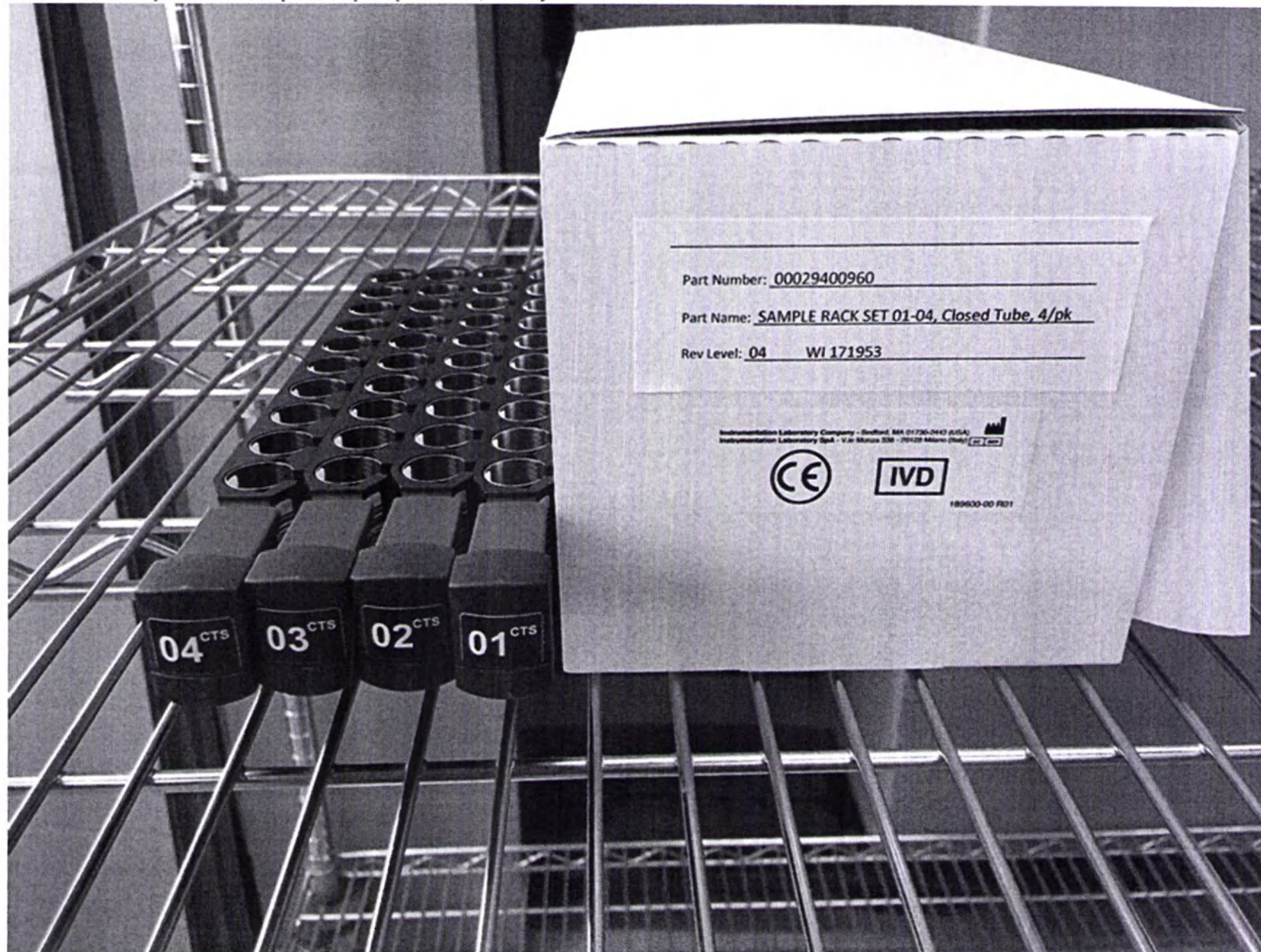
Фильтры CTS, 12 шт.



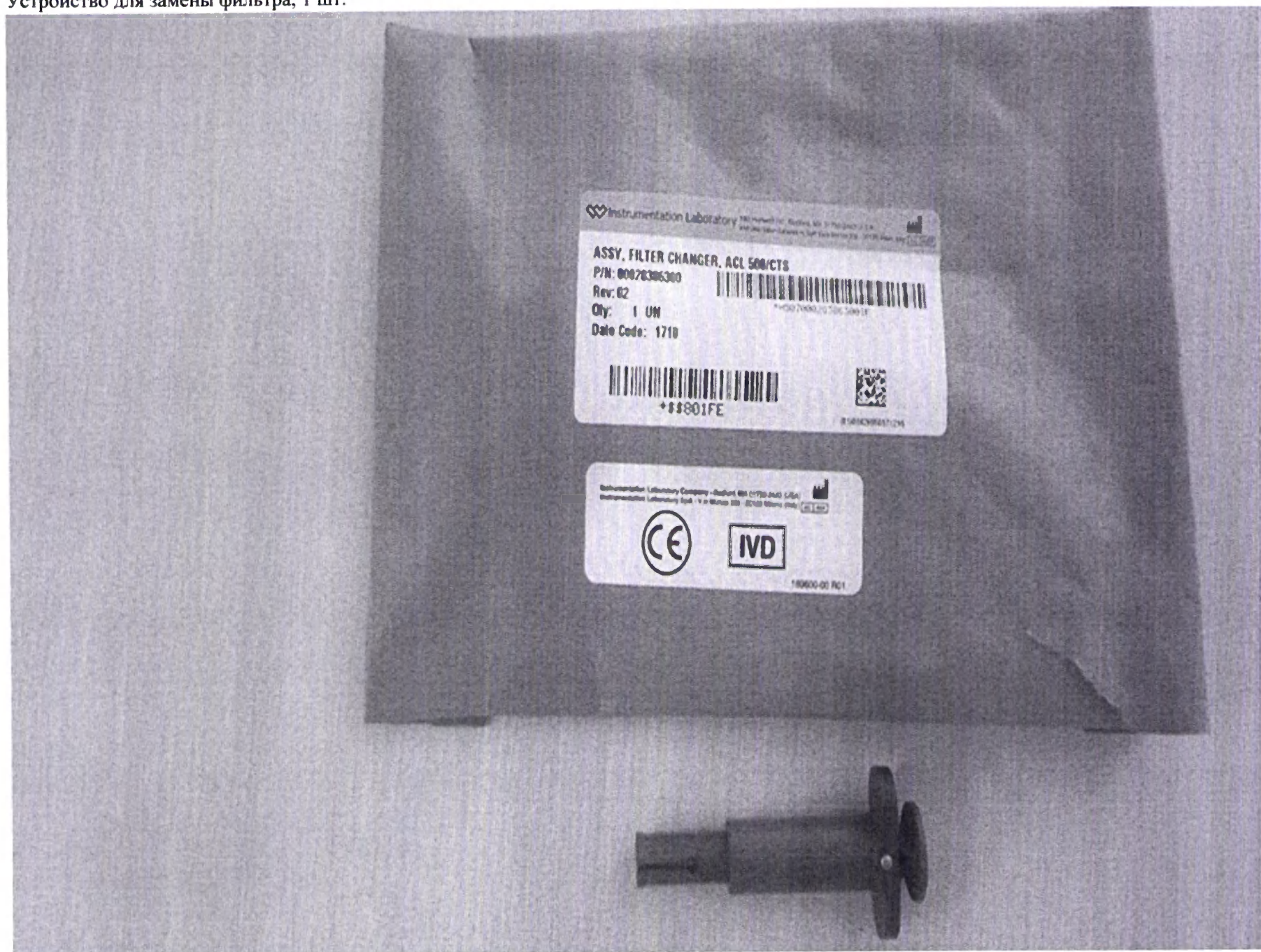
Шестигранные ключи метрические 1.5 мм - 5.0 мм, 1 уп.



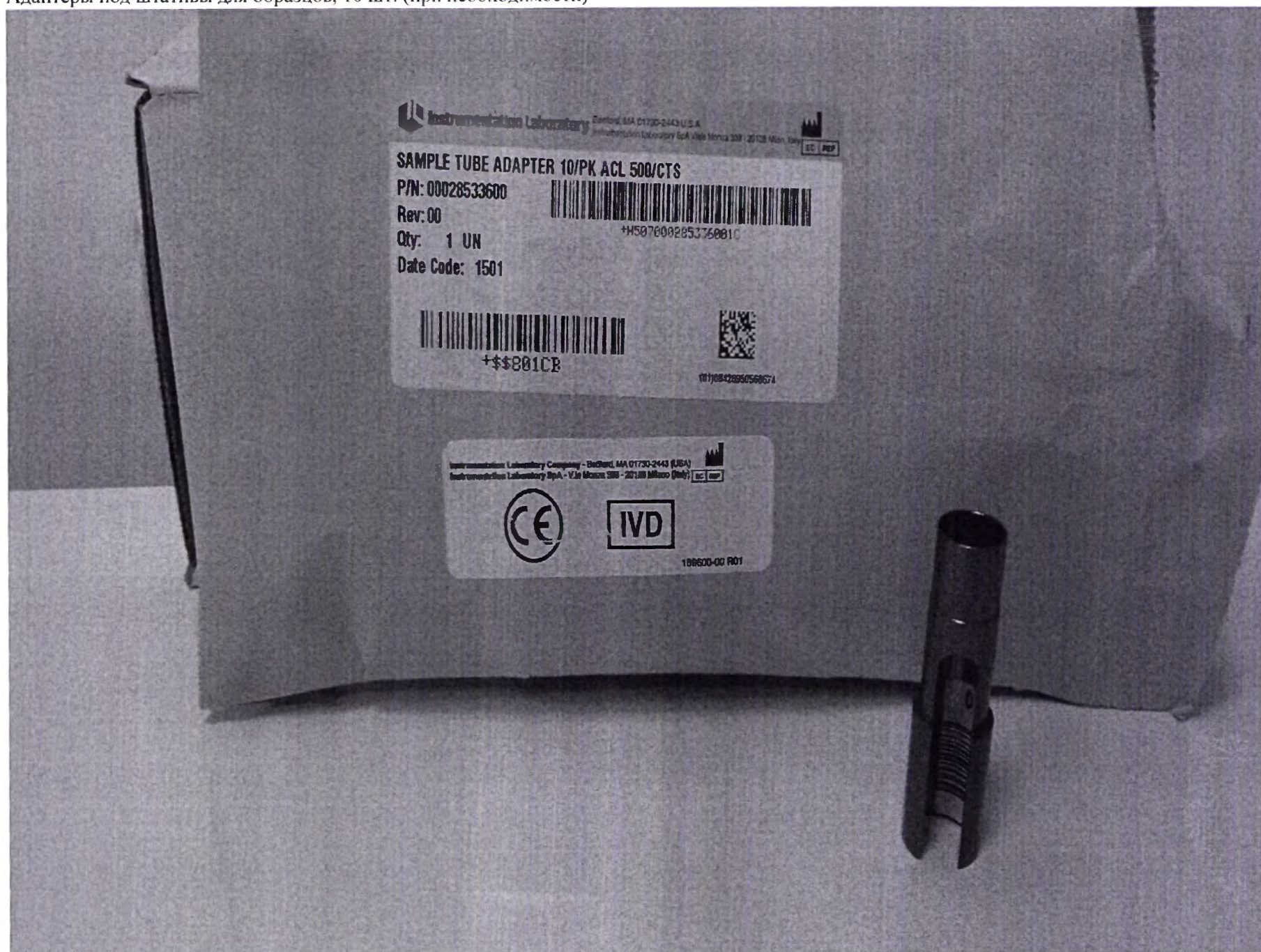
Штативы для образцов под закрытые пробирки 01-04, 4 шт./уп.



Устройство для замены фильтра, 1 шт.



Адаптеры под штативы для образцов, 10 шт. (при необходимости)



Instrumentation Laboratory 150 Markon Pk. Bedford, MA 01730-2443 U.S.A.
Instrumentation Laboratory T.A. Via Roma 22E - 20135 Milano, Italy

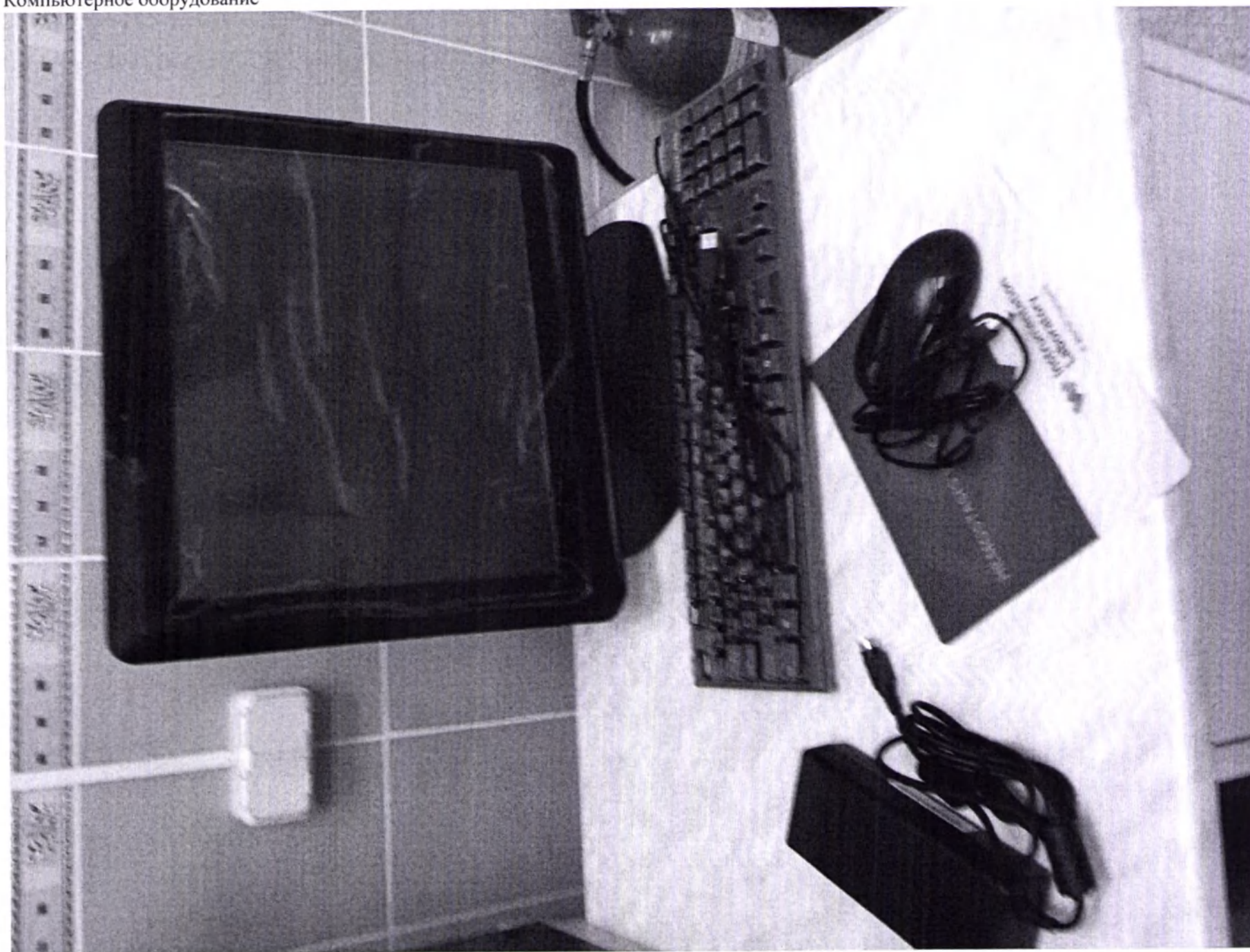
CABLE ASSY, RS232 AMPRO TO CM
P/N: 00027975000
Rev: 00
Qty: 1 UN
Date Code: 1710

+H507000279750001F

+

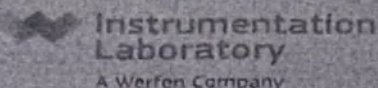
\$\$\$801FE

(P) 000420000007001





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A Werfen Company

February, 2016

ACL TOP Family 50 Series with Software Release V6.1.0, Parameters P-18.1.00 and User Manual (On Line Help) V6.1.0

Dear Valued ACL TOP™ Customer,

Welcome to the ACL TOP Family 50 Series of Analyzers. The ACL TOP Family 50 Series are the newest members of the ACL TOP Family: the best-in-class analyzers for the hemostasis laboratory. These high performance consolidated workstations are for routine and specialty assays: Clotting, Chromogenic and Latex-Immunoassay with pre-analytical sample integrity checks and advanced audit trail and accreditation support tools. They are part of Instrumentation Laboratory's commitment to develop and introduce products that meet the needs of today's demanding hemostasis laboratory. The ACL TOP Family 50 Series is configured with Software V6.1.0, Parameters P-18.1.00, and User Manual (On Line Help) V6.1.0 and available to select regions worldwide.

The ACL TOP Family 50 Series includes the following analyzers:

ACL TOP 350 CTS	Part Number: 00000280065
ACL TOP 550 CTS	Part Number: 00000280045
ACL TOP 750	Part Number: 00000280015
ACL TOP 750 CTS	Part Number: 00000280055
ACL TOP 750 LAS	Part Number: 00000280035

All models of the ACL TOP Family 50 Series offer:

- Same quality results
- Same comprehensive reagent portfolio
- Same powerful and intuitive software
- Same features and usability
- Same assay-specific sample checks
- Same advanced lab accreditation support tools

Software Version 6.1.0 with Parameters P-18.1.00 includes the following parameter files:

- Liquid Anti-Xa [Anti-Xa]
- Antithrombin Liquid [AT LIQ]
- APCR V with APC [APCR V+]
- APCR V without APC [APCR V-]
- APTT Syn Phospholip [APTT-SP]
- APTT SynthASil [APTT-SS]
- D-Dimer HS 500 [DDHS 500]
- D-Dimer HS [DDHS]
- D-Dimer [DD]
- Factor II-RP [FII-RP]
- Factor II- ReadiPlasTin [FIIRead]
- Factor II-RP-8 [FIIIRP-8]
- Factor IX-SS [FIX-SS]
- Factor V ReadiPlasTin [FVRead]
- Factor V-RP-8 [FVRP-8]
- Factor VIII-SS [FVIII-SS]
- Factor VIII-SS with normal vWF [F8v-SS]
- Factor VII-RP [FVII-RP]
- Factor VII-RP-8 [FVIIIRP-8]
- Factor VII ReadiPlasTin [FVIIRead]
- Factor V-RP [FV-RP]
- Factor X HS Plus [FX-HS+]
- Factor X-RP [FX-RP]
- FX ReadiPlasTin [FXRead]
- Factor XI-SS [FXI-SS]
- Factor XII-SS [FXII-SS]
- Factor VIII-SP [FVIII-SP]
- Factor IX-SP [FIX-SP]
- Factor XI-SP [FXI-SP]
- Factor XII-SP [FXII-SP]
- Fib RecombiPlasTin [Fib-RP]



**Instrumentation
Laboratory**

A Werfen Company

November, 2014

Dear Valued ACL TOP 50 customer,

Instrumentation Laboratory is pleased to announce the launch of the new ACL TOP Family 50 Series. The ACL TOP Family 50 Series offer low- to high- volume hemostasis laboratories advanced automation of routine to specialty assays with the added benefit of integrated pre-analytical sample integrity checks, and advanced laboratory accreditation support tools. The ACL TOP Family and new ACL TOP Family 50 Series will be able to use the same comprehensive portfolio of reagents and produce the same quality results.

Since the new ACL TOP Family 50 Series evolved from the ACL TOP Family, you will be able to use the same comprehensive portfolio of HemosIL reagents, calibrators and controls using the same assigned values as listed on the insert sheets for the ACL TOP Family. In addition, the Intended Use, Reagent Storage/Stability, Limitations/Interfering Substances, Expected Values, Performance Characteristics, and any other instrument specific claims on any HemosIL reagent insert sheet will apply to both the ACL TOP Family and the ACL TOP Family 50 Series. Therefore, when using any HemosIL reagent on the ACL TOP Family 50 Series analyzer, please use the assigned values and claims listed on the insert sheet for the ACL TOP Family.

IL is committed to delivering innovative and practical solutions to meet the needs of our customers. The features of the new ACL TOP Family 50 Series will minimize the risk of errors and enhance quality assurance leading to better patient care. Thank you for choosing IL as a partner in Hemostasis testing.

Please contact your local representative if you have any questions.

Sincerely,

Catherine Quirbach Ph.D.
Group Product Manager, Hemostasis Reagents
Instrumentation Laboratory

CON446005

00027503098 R00

180 Hartwell Road, Bedford MA 01730 781-861-0710 www.il.us.com

**IL HEMOSTASIS SYSTEMS
URGENT SAFETY NOTIFICATION**

August 2014

Dear Valued IL Hemostasis Customer:

Our records indicate that your facility has in use one or more IL Hemostasis Systems: ACL TOP® Family, ACL Futura/ACL Advance, ACL ELITE®/ELITE PRO/8/9/10000, ACL Classic (100-7000) and ACL AcuStar. This notification is intended to reinforce that the waste from your IL Hemostasis System contains sodium azide that may potentially form explosives in metal plumbing composed of lead, brass, tin, copper or zinc or containing solder in the plumbing system and to emphasize that good work practices should be followed to mitigate the risk of explosion.

WARNING: When sodium azide preservative in reagents is disposed down the drain, it can react with the metals in the plumbing to form insoluble metallic azides, such as copper and lead azide, which settle in the plumbing and collect in traps, threads, etc. These metallic azides are highly explosive. For example, lead azide is a more sensitive primary explosive than nitroglycerine and copper azide and other metallic azides are even more explosive and are considered too sensitive to be used commercially as explosives. Metallic azides may explode if subjected to friction, heat, shock or by reaction with other chemicals.

To this end, please perform the following steps taken directly from the National Institute of Occupational Safety and Health (NIOSH) guidance on the "Decontamination Procedures for Azide Contaminated Plumbing" (1976):

• **Routine Decontamination:**

Thoroughly flush any drain used for waste disposal with copious amounts of water several times a day to prevent azide build up. The use of copper- and lead-free lines between the point of discharge of azide and the nearest pipe in which there is a good stream of water, or the use of azide-free reagents, may prevent future accumulation of explosive azides in plumbing. **NOTE: These measures will NOT decontaminate plumbing already containing explosive azides.**

• **Decontamination of Plumbing Containing Explosive Azides:**

The procedure below is designed to decontaminate a drain trap. Longer lengths of drain lines can be decontaminated with a similar procedure after plugging the drain below the point at which any azide contamination is likely to have occurred and then filling the entire length of pipe with 10% sodium hydroxide solution.

- Laboratory maintenance workers, especially plumbers, should be alerted to the azide hazard so that proper precautions can be taken. Violent explosions have resulted when plumbers have attempted to penetrate blocked azide-contaminated drainage systems with a flexible metal probe (snake) or to cut or saw azide-contaminated drain lines.
- Prepare 1 to 2 liters of 10% sodium hydroxide solution (100 g NaOH per liter of water). Wear appropriate protective equipment when preparing and handling this corrosive material including gloves, protective clothing, chemical safety goggles and face shield. Contact with eyes or skin will cause severe burns and may cause permanent damage. Carefully read and follow the manufacturer's safety instructions and instructions for diluting concentrated sodium hydroxide or sodium hydroxide solid in water.
- Syphon all liquid from the trap and drain using a soft rubber or plastic hose. Use proper precautions against any hazardous chemicals which may be present.
- Slowly pour the sodium hydroxide solution into the trap.

Instrumentation
Laboratory 180 Hartwell Road
Bedford, MA 01730

Tel 781-861-0710

www.ilus.com

CO# 446484

Page 1 of 2

L0019014800 R03

ACL TOP® & ACL TOP Family 50 Series Analytical Precision Performance Requirements

The table on the following pages reflects the current ACL TOP and ACL TOP Family 50 Series Analytical Precision Performance Requirements. The released parameters for each of the noted assays have been tested by Instrumentation Laboratory, and the imprecision data generated is less than or equal to these requirements.

The results of the internal testing have been submitted to the respective governing bodies for instrument clearance where the reagent is sold, and is also published in the insert sheets of the respective reagent products. Those published values reflect the testing performed on specific ACL TOP and ACL TOP Family 50 Series instruments using specific lots of reagent, calibrator, and control materials.

The information supplied here can serve as a guide to ACL TOP and ACL TOP Family 50 Series users.

Assay	Reagent	Result Unit	Control	Within Run Imprecision (%CV)	Total Imprecision (%CV)
PT	PT-Fib HS + PT-Fibrinogen	Seconds	HemosIL® Normal Control	≤ 2.0	≤ 3.0
			HemosIL Normal Control 1	≤ 2.0	≤ 3.0
			HemosIL Low Abnormal Control	≤ 3.0	≤ 4.0
			HemosIL Abnormal Control 2	≤ 3.0	≤ 4.0
			HemosIL High Abnormal Control	≤ 5.0	≤ 8.0
			HemosIL Abnormal Control 3	≤ 5.0	≤ 8.0
PT	RecombiPlasTin 2G ReadiPlasTin	Seconds	HemosIL® Normal Control	≤ 3.0	≤ 3.0
			HemosIL Normal Control 1	≤ 3.0	≤ 3.0
			HemosIL Low Abnormal Control	≤ 4.0	≤ 4.0
			HemosIL Abnormal Control 2	≤ 4.0	≤ 4.0
			HemosIL High Abnormal Control	≤ 5.0	≤ 8.0
			HemosIL Abnormal Control 3	≤ 5.0	≤ 8.0
PT-based Fibrinogen	PT-Fib HS + PT-Fibrinogen	mg/dL	HemosIL Normal Control	≤ 10.0	≤ 12.0
			HemosIL Normal Control 1	≤ 10.0	≤ 12.0



**Instrumentation
Laboratory**

A Werfen Company

For North America Customers Only

September 19, 2016

Dear Valued ACL TOP Family 50 Series customer,

When using any HemosIL reagent on the ACL TOP Family 50 Series analyzer, please use the assigned values and the claims listed on the insert sheet for the ACL TOP Family. Since the ACL TOP Family 50 Series evolved from the ACL TOP Family, you will be able to use the same comprehensive portfolio of HemosIL reagents, calibrators and controls. The claims for Intended Use, Reagent Storage/Stability, Limitations/Interfering Substances, Expected Values on a HemosIL reagent insert sheet will apply for both the ACL TOP Family and the ACL TOP Family 50 Series.

In addition, Instrumentation Laboratory performed additional precision and method comparison studies to achieve 510k clearance. While the HemosIL labeling is being updated, the corresponding Precision and Method Comparison data for ACL TOP 50 Series from the current 510k cleared assays are listed in this letter for your reference.

Please share this information with your laboratory staff and retain a copy of this letter for your records. Thank you for choosing IL as a partner in Hemostasis testing.

Please contact your local representative if you have any questions.

Sincerely,

Catherine Quirbach Ph.D.

Group Product Manager, Hemostasis Reagents
Instrumentation Laboratory

Instrumentation Laboratory
ACCEPTANCE CERTIFICATE

Tested By:
Inspected By:
Part No.:
Date:

Serial No. 17110698

Part No. 00000280045

STATE of COMPLIANCE

Instrumentation Laboratory
180 Hartwell Road
Bedford, MA US 01730

ACL TOP 550 CTS SYSTEM
00000280045
2800-45 ACL TOP 550 CTS
17110698

V = 1.7 %	0.7	PASS
V = 3.2 %	1.2	PASS
V = 1.7 %	1.2	PASS
V = 3.0 %	2.6	PASS
V = 3.0 %	1.2	PASS
V = 6.0 %	1.4	PASS
V = 2.3 %	1.1	PASS
V = 10.0 %	6.8	PASS
V = 0.200 Ohm	0.070	PASS
V = 2 MOhm	734	PASS
0.1 .. 1000.0 μ A	524.1	PASS
0.1 .. 500.0 μ A	265.3	PASS
0.1 .. 1000.0 μ A	530.4	PASS
0.1 .. 500.0 μ A	268.7	PASS
2.00 .. 10.00 mA	4.21	PASS

TESTING STATEMENT:

This instrument has been certified to meet all applicable electrical and analytical specifications as outlined in Instrumentation Laboratory's final test and QC procedures.

Instrument Test Voltage Signature: JNUON

Date: 11/03/2017

QC Signature: SYI

Date: 11/07/2017

CO # 464252

Sheet 1 of 1

Part No. 00028766200 Rev 18

CE DECLARATION OF CONFORMITY **IL ACL TOP 50 Series Instruments**

Manufacturer: Hersteller Fabricante Fabricant Produttore	Fabricante Producent Tilværgere Κατασκευαστής	Instrumentation Laboratory Co 180 Hartwell Road Bedford, MA 01730-2443 U.S.A
EU Authorized Representative: EU-Bevollmächtigter Representante Autorizado por la UE Mandataire Representante Autorizzato in EU	Representante Autorizado na UE EU-autoriseret repræsentant EU Autoriserad representant Εξουσιοδοτημένος αντιπρόσωπος στην ΕΕ	Instrumentation Laboratory SpA Viale Monza, 338 20128 - Milano, Italy

Instrumentation Laboratory hereby declares that the product(s) listed below conform to the European Union directive and standards identified in this declaration.

Instrumentation Laboratory erklärt, dass die aufgeführten Produkt(e) mit den Bestimmungen der angegebenen EU-Richtlinien und mit den aufgeführten normativen Dokumenten in Übereinstimmung sind.

Instrumentation Laboratory déclare par la présente que les produit(s) abajo mencionados, están conformes con las directivas y normas Europeas identificadas en esta declaración.

Instrumentation Laboratory déclare par la présente, que le(s) produit(s) sous-mentionné(s), est (sont) conforme(s) aux directives et normes Européennes identifiées dans cette déclaration.

Instrumentation Laboratory dichiara con la presente che il(i) prodotto(i) sotto menzionato(i) è(sono) conformi alle direttive e agli standard specificati in questa dichiarazione.

Instrumentation Laboratory declara pelo presente que o(s) produto(s) abaixo mencionado(s) está(estão) conforme a Directiva e normas da Comissão Europeia especificadas nesta declaração.

Instrumentation Laboratory erklærer herved, at det (de) nedenfor anførte produkt(er) er i overensstemmelse med de EU-direktiver og standarder, der er anført i denne erklæring.

Instrumentation Laboratory bekräftar härmed att produkt(er) listade nedan, vara förenliga med Europeiska Union-ens direktiv och standarder identifierade i denna deklaration.

Η Instrumentation Laboratory με το παρόν δηλώνει ότι τα προϊόντα που αναφέρονται κατωτέρω συμμορφούνται με την οδηγία της Ευρωπαϊκής Ένωσης και τα πρότυπα που προσδιορίζονται στην παρούσα δήλωση.

EU Directive:

EU-Richtlinie Directive UE Directive Européenne Directive Europea Directiva UE EU-direktiv EU Direktiv Οδηγία ΕΕ

IVD - 98/79/EC (27/10/1998) - Annex I and III

RoHS2 Directive 2011/65/EU (Starting with an# 1606XXXX)

Standard(s):

Normen und Richtlinien Estándar(es) Norme(s) Norma(e) Padrão/Padrões Standard(er) Standard(er) Πρότυπα

- ISO 13485, "Medical Devices - Quality Management Systems"
- ISO 14971 "Medical Devices-Application of risk management to medical devices"
- IEC 61010-1 (2nd & 3rd Editions): "Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements"
- IEC 61010-2-101 "Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment"
- IEC 61010-2-081 "Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes"
- IEC 61326-1 "Electrical equipment for measurement, control and laboratory use - EMC requirements"
- IEC 61326-2-6 "Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment"
- FCC Part 15 Subpart B
- ISO 15223-1 Medical Devices - "Symbols to be used with medical device labels, labelling and information to be supplied"
- EN 980 Terminology, symbols and information provided with medical devices - Graphical symbols for use in the labelling of medical devices
- ISO 18113-3 "In Vitro Diagnostic medical devices-Information supplied by the manufacturer (labelling) Part 3- In Vitro diagnostic instruments for professional use"
- ISTA 2a/2b Shipping Shock and Vibration, Domestic & International Tests.

Carol Marble
Carol Marble

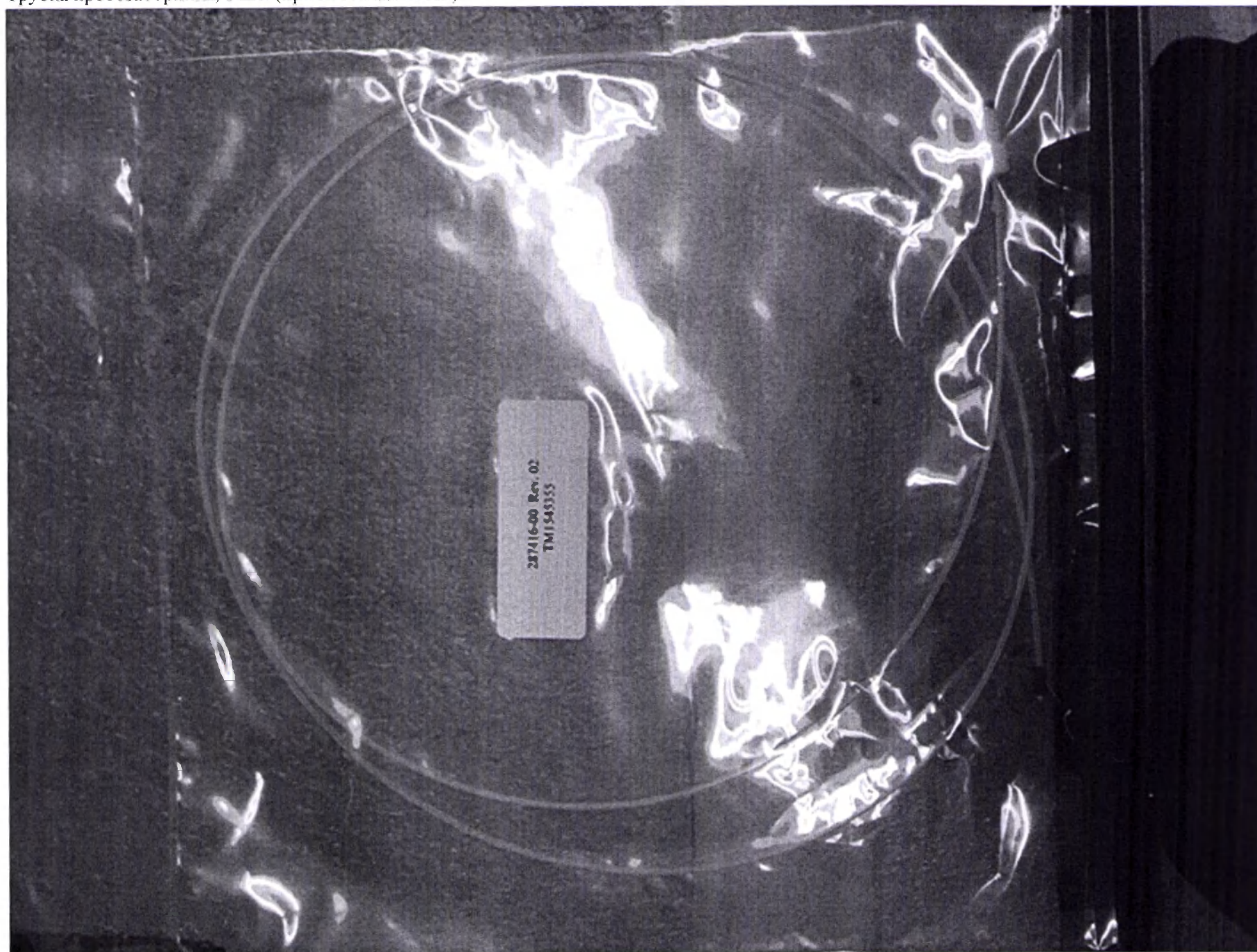
Director of Regulatory Affairs

3-August-2017
Date

Наконечники для шприца, 250 мкл, 1 уп. (при необходимости)



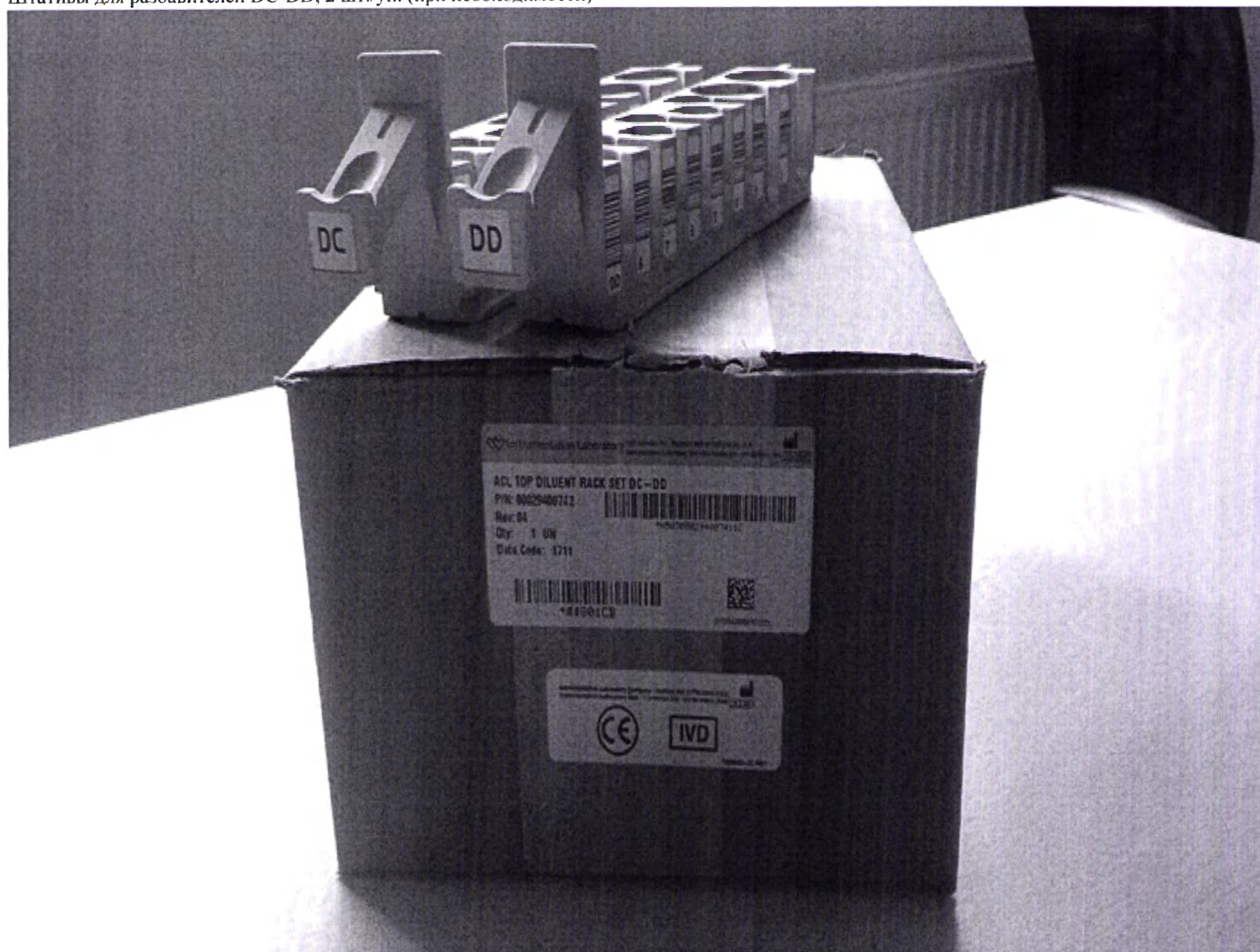
Трубка пробозаборника, 1 шт. (при необходимости)



Штативы для реагентов RE-RH, 4 шт./уп. (при необходимости)



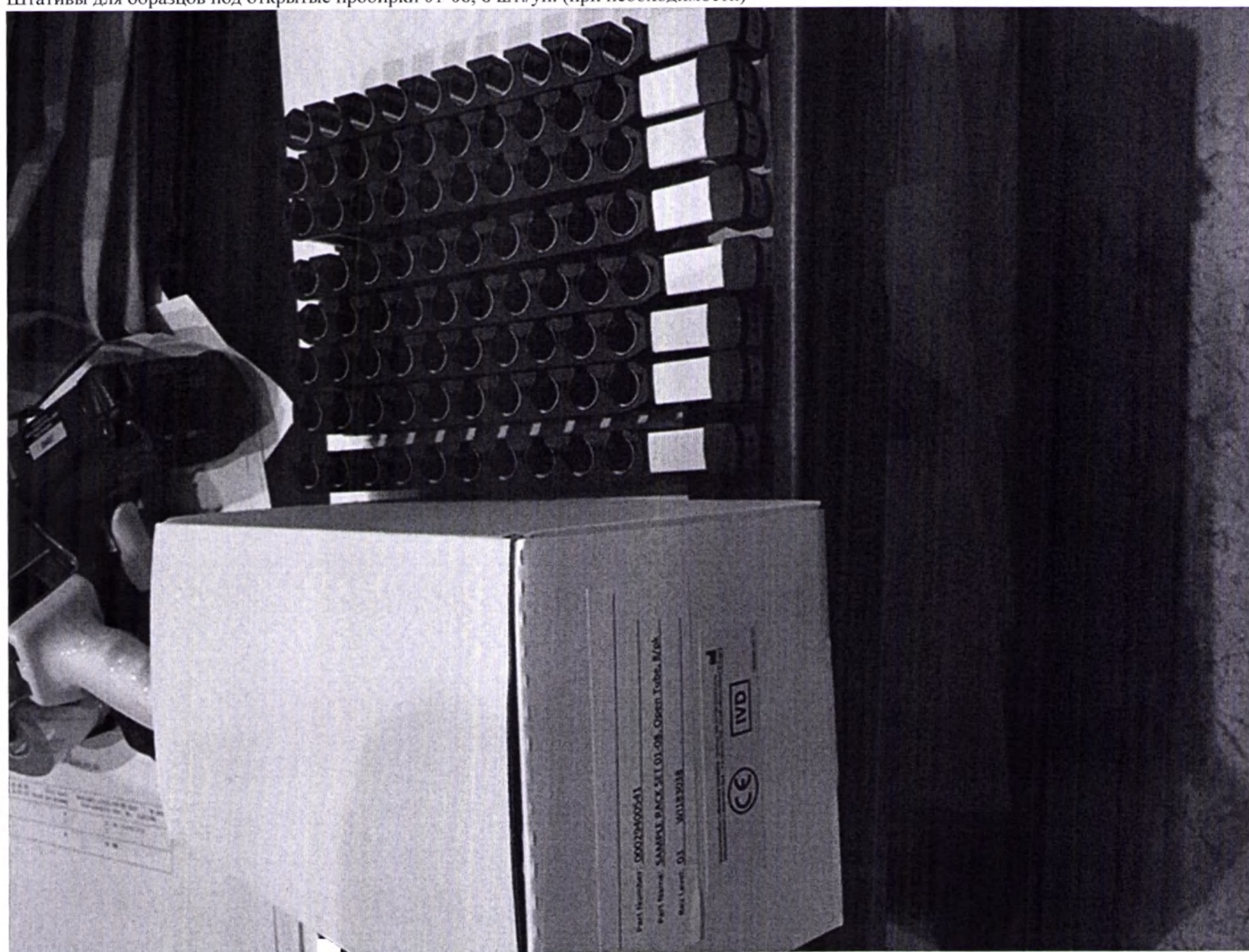
Штативы для разбавителей DC-DD, 2 шт./уп. (при необходимости)



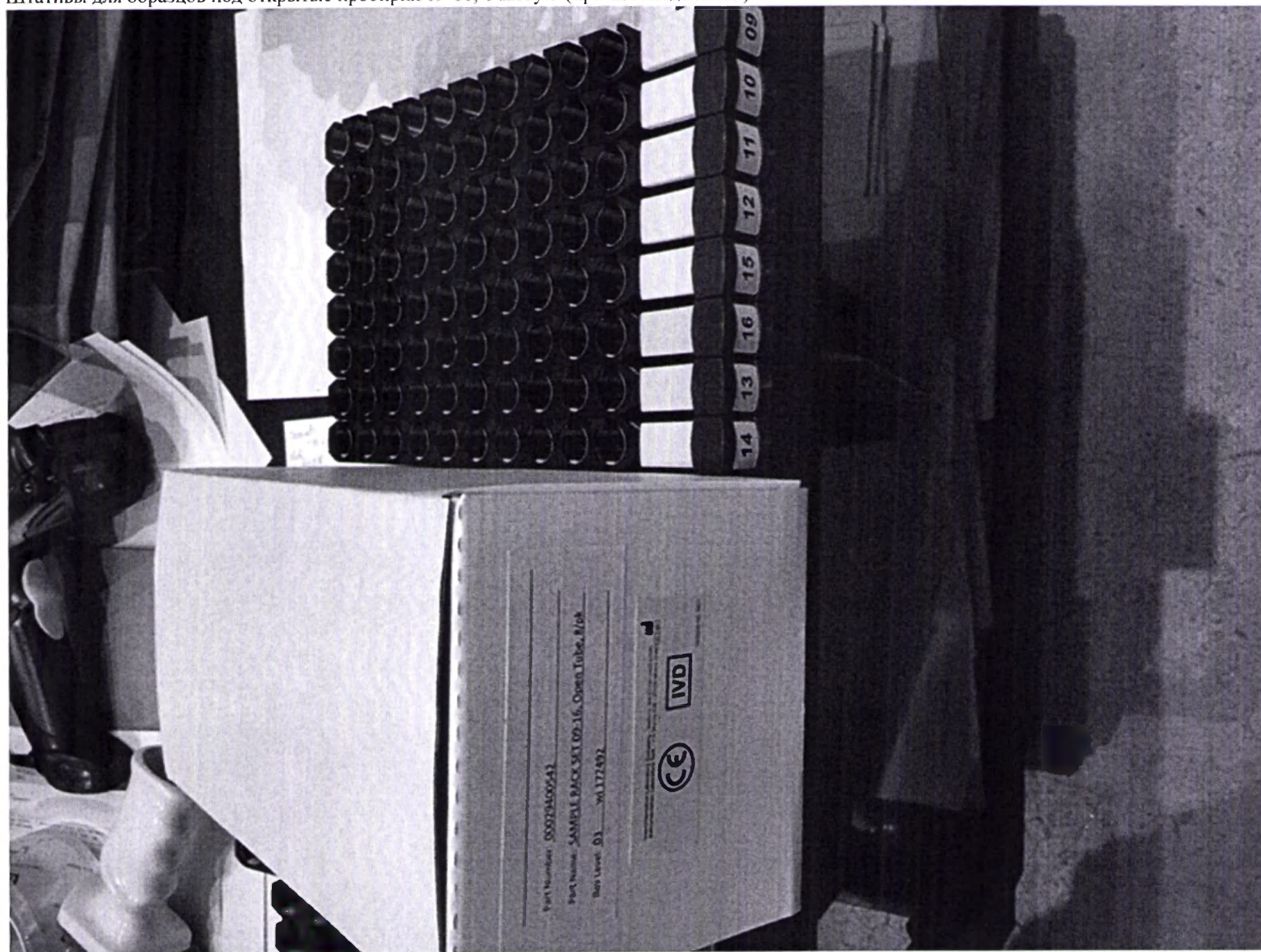
Подставка под 6 штативов для образцов, 1 шт. (при необходимости)



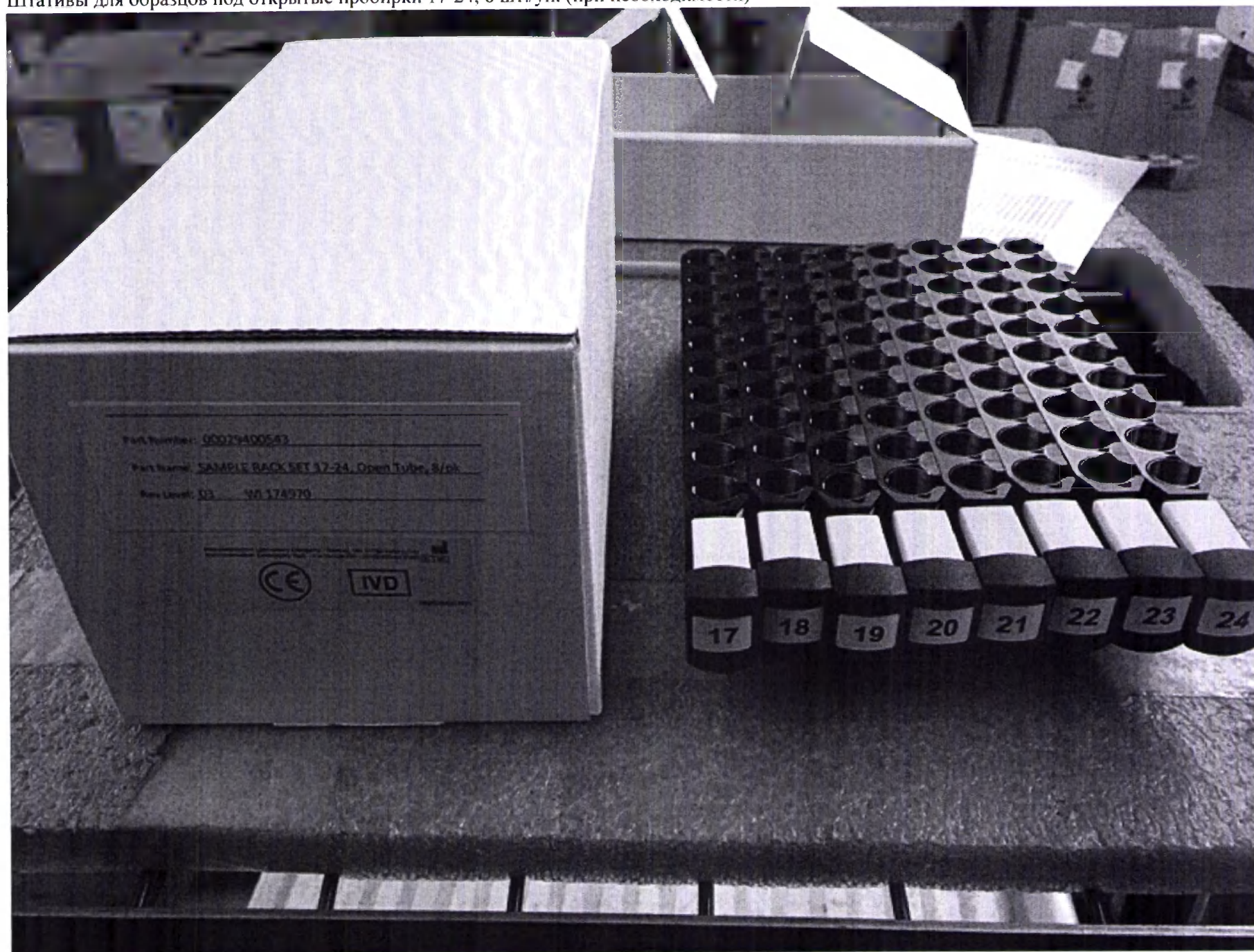
Штативы для образцов под открытые пробирки 01-08, 8 шт./уп. (при необходимости)



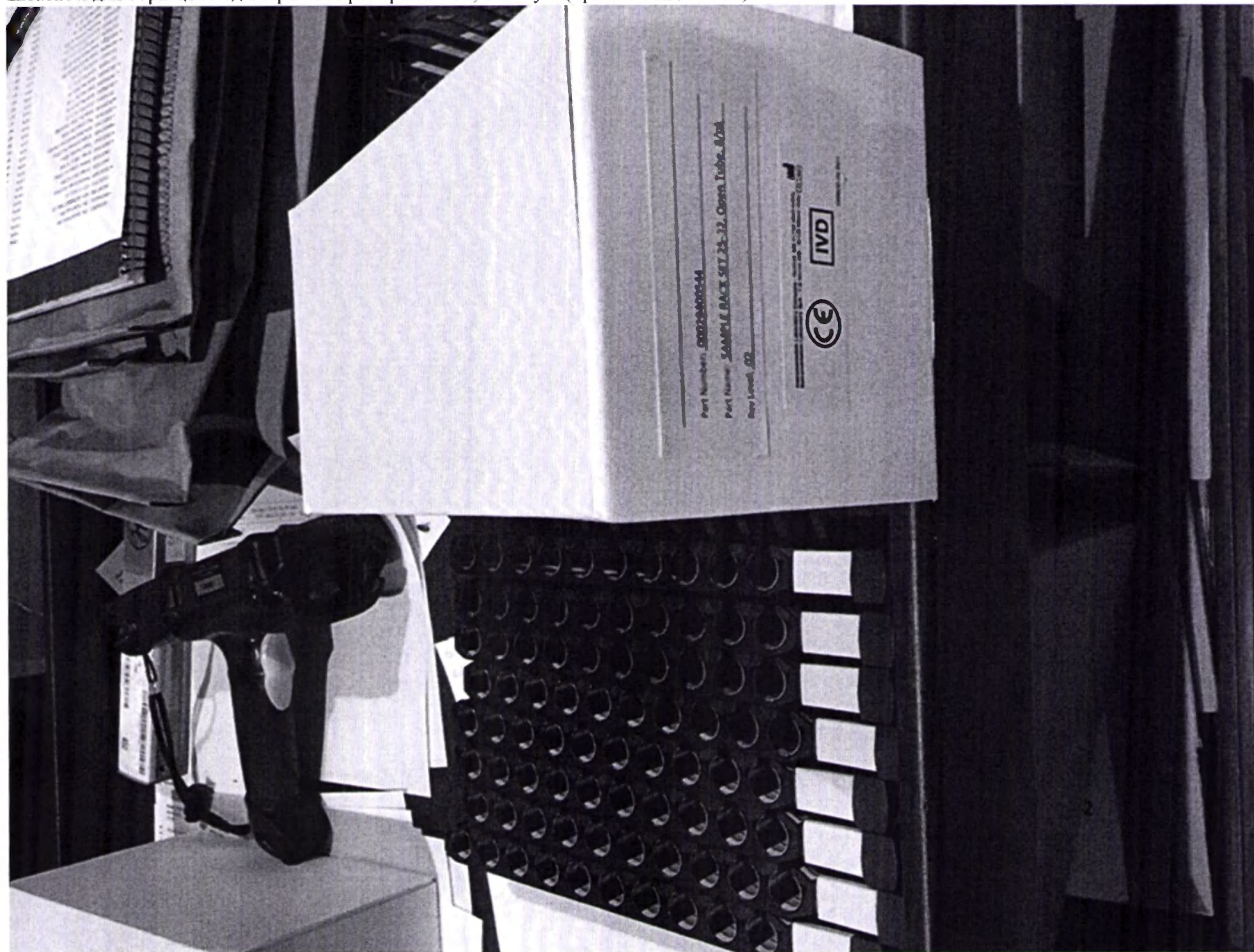
Штативы для образцов под открытые пробирки 09-16, 8 шт./уп. (при необходимости)



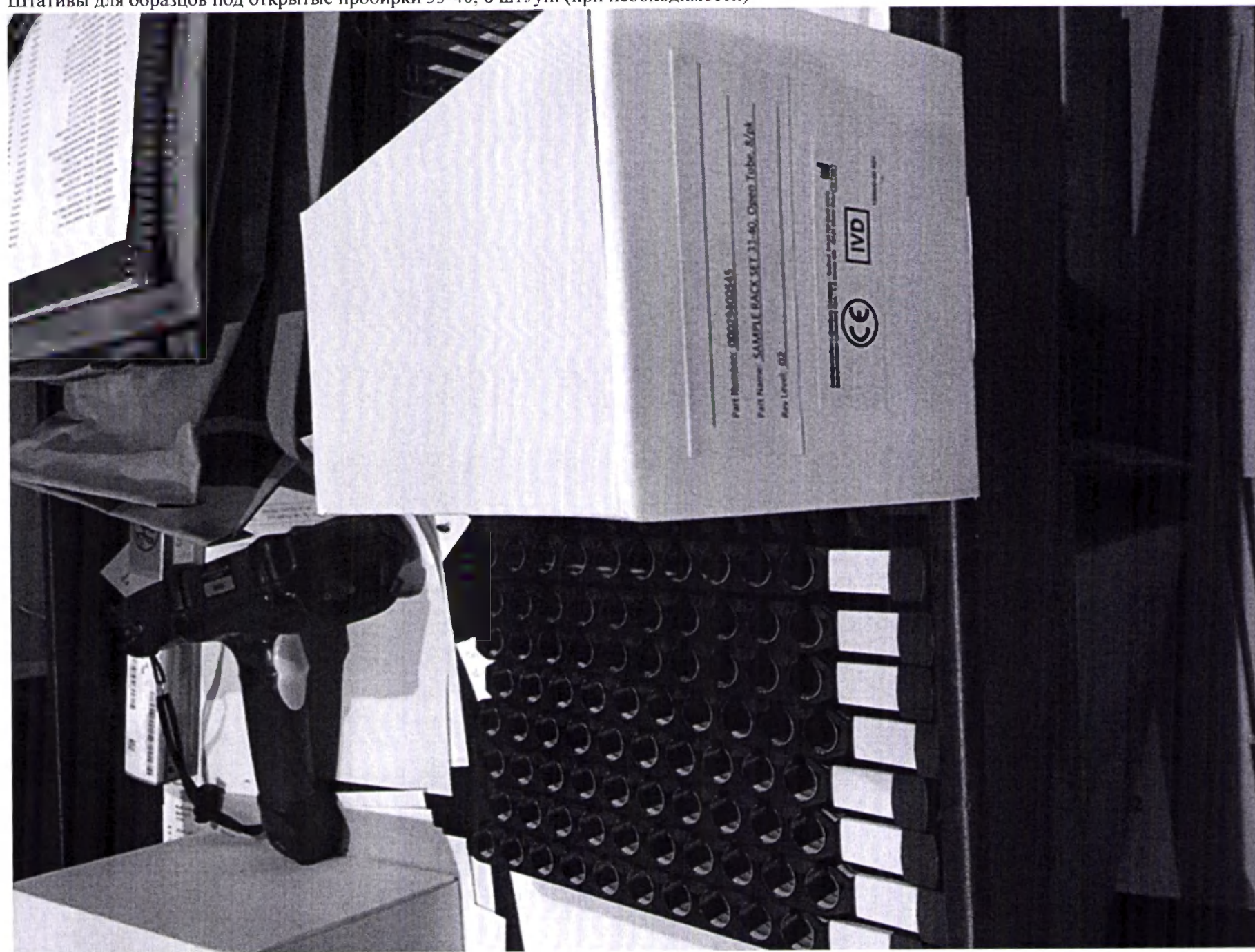
Штативы для образцов под открытые пробирки 17-24, 8 шт./уп. (при необходимости)



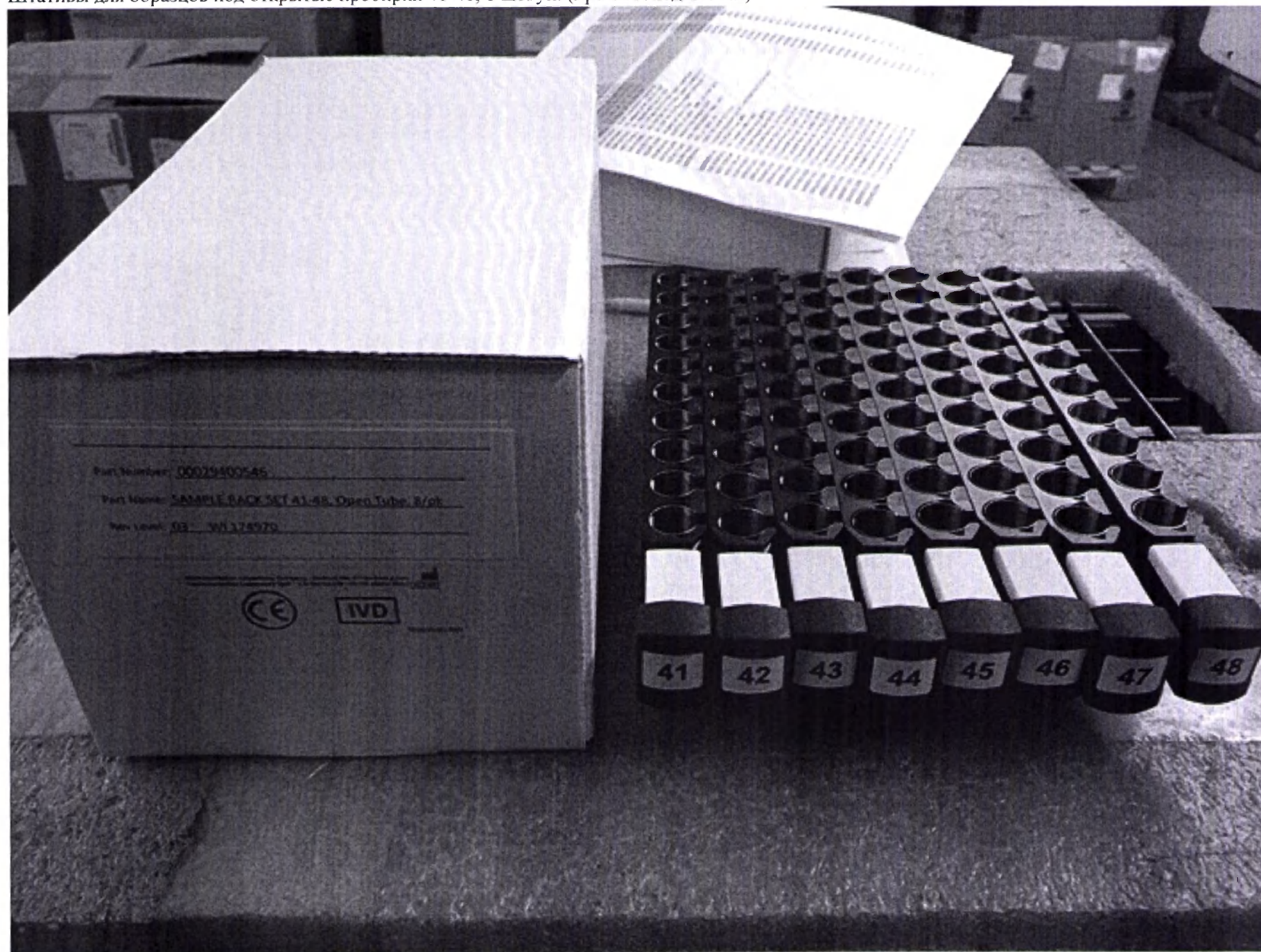
Штативы для образцов под открытые пробирки 25-32, 8 шт./уп. (при необходимости)



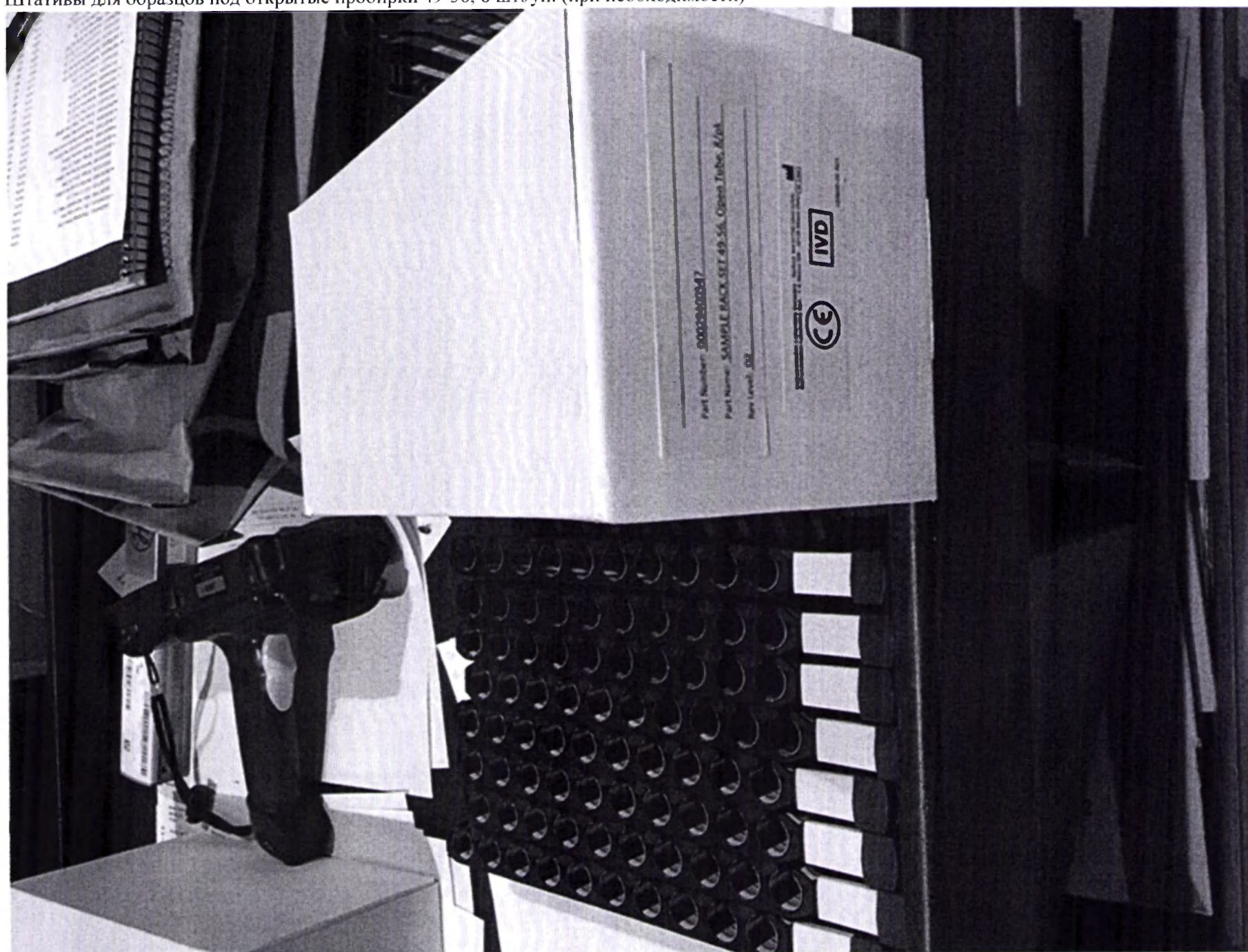
Штативы для образцов под открытые пробирки 33-40, 8 шт./уп. (при необходимости)



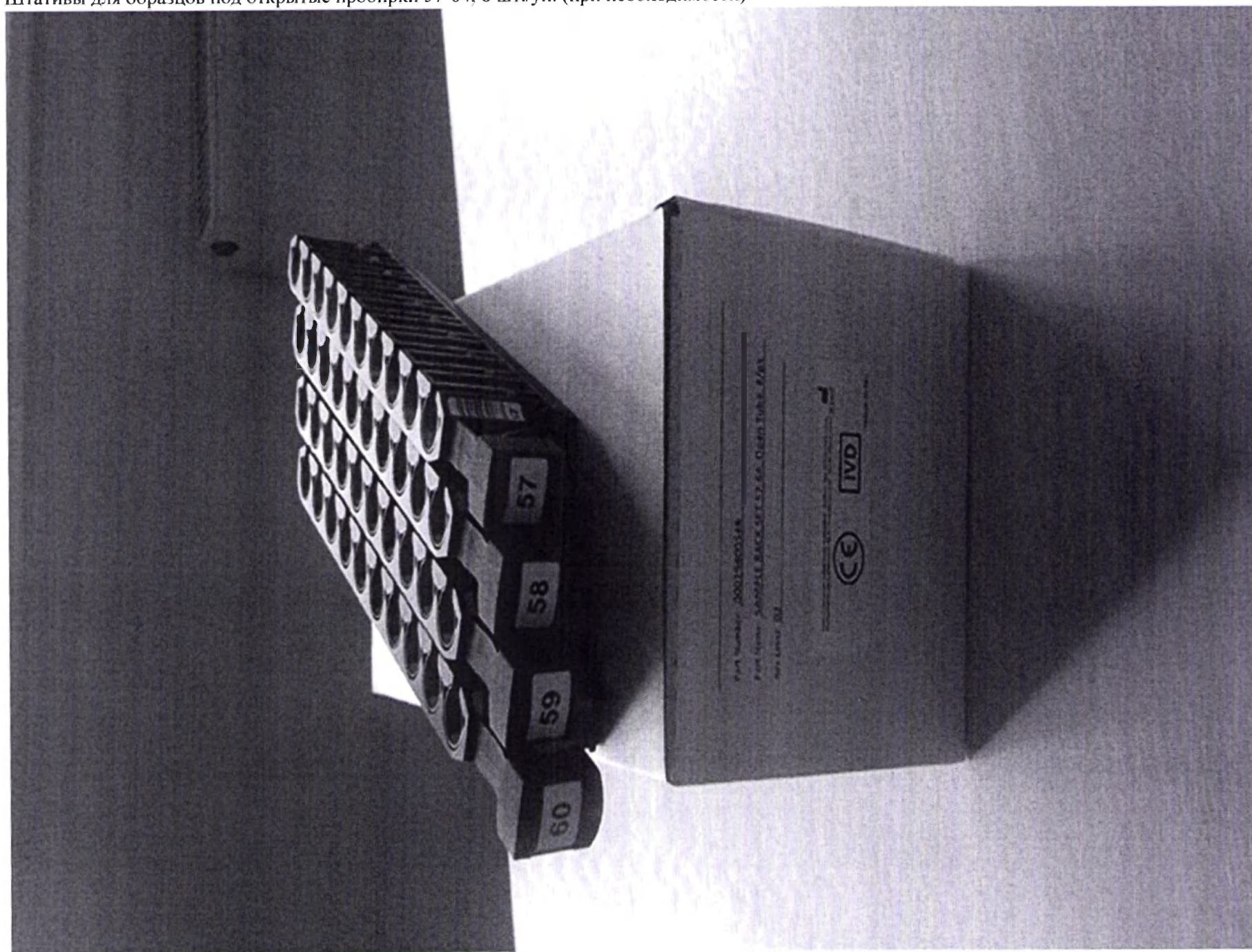
Штативы для образцов под открытые пробирки 41-48, 8 шт./уп. (при необходимости)



Штативы для образцов под открытые пробирки 49-56, 8 шт./уп. (при необходимости)



Штативы для образцов под открытые пробирки 57-64, 8 шт./уп. (при необходимости)



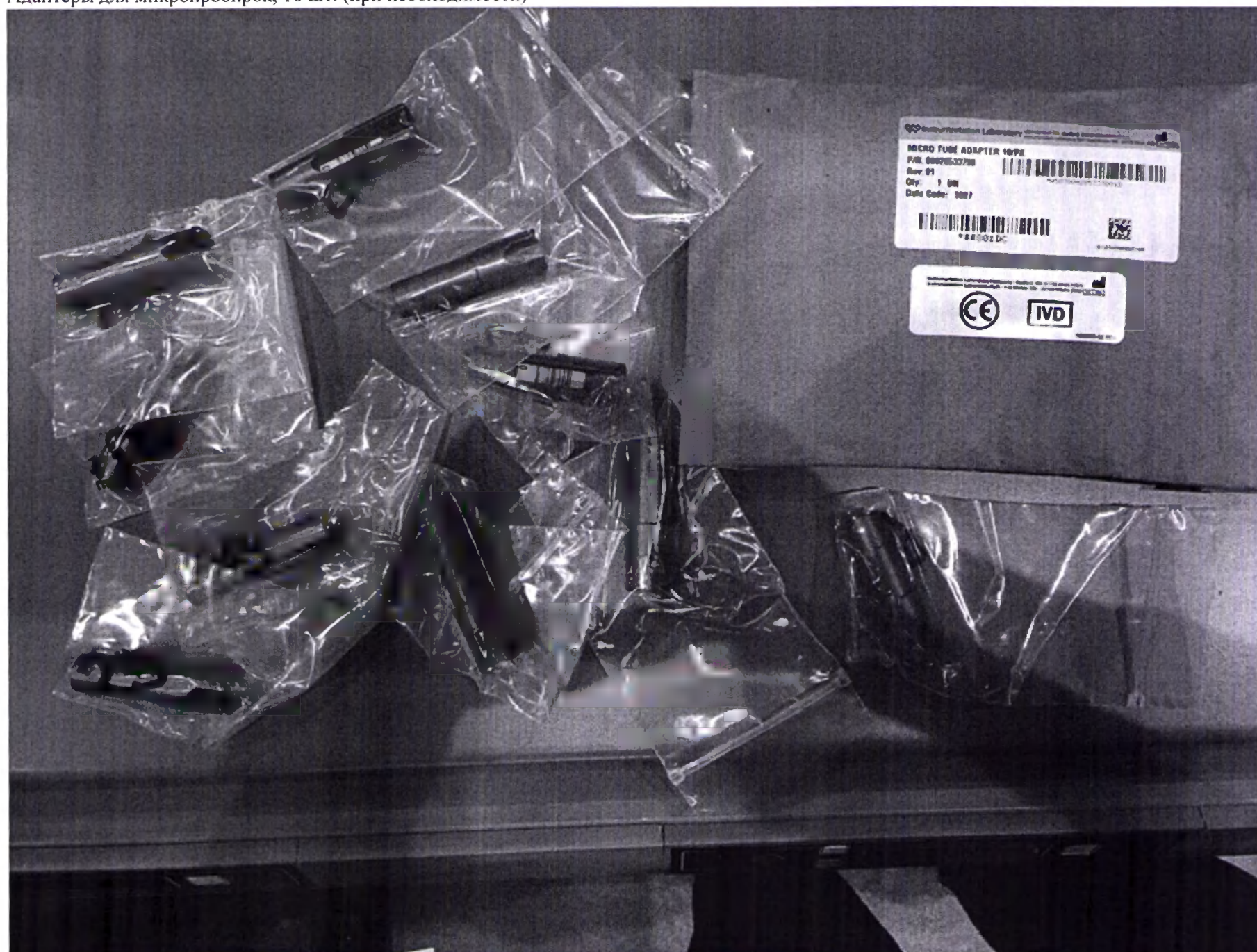
Адаптеры для алиquotных пробирок, 10 шт. (при необходимости)



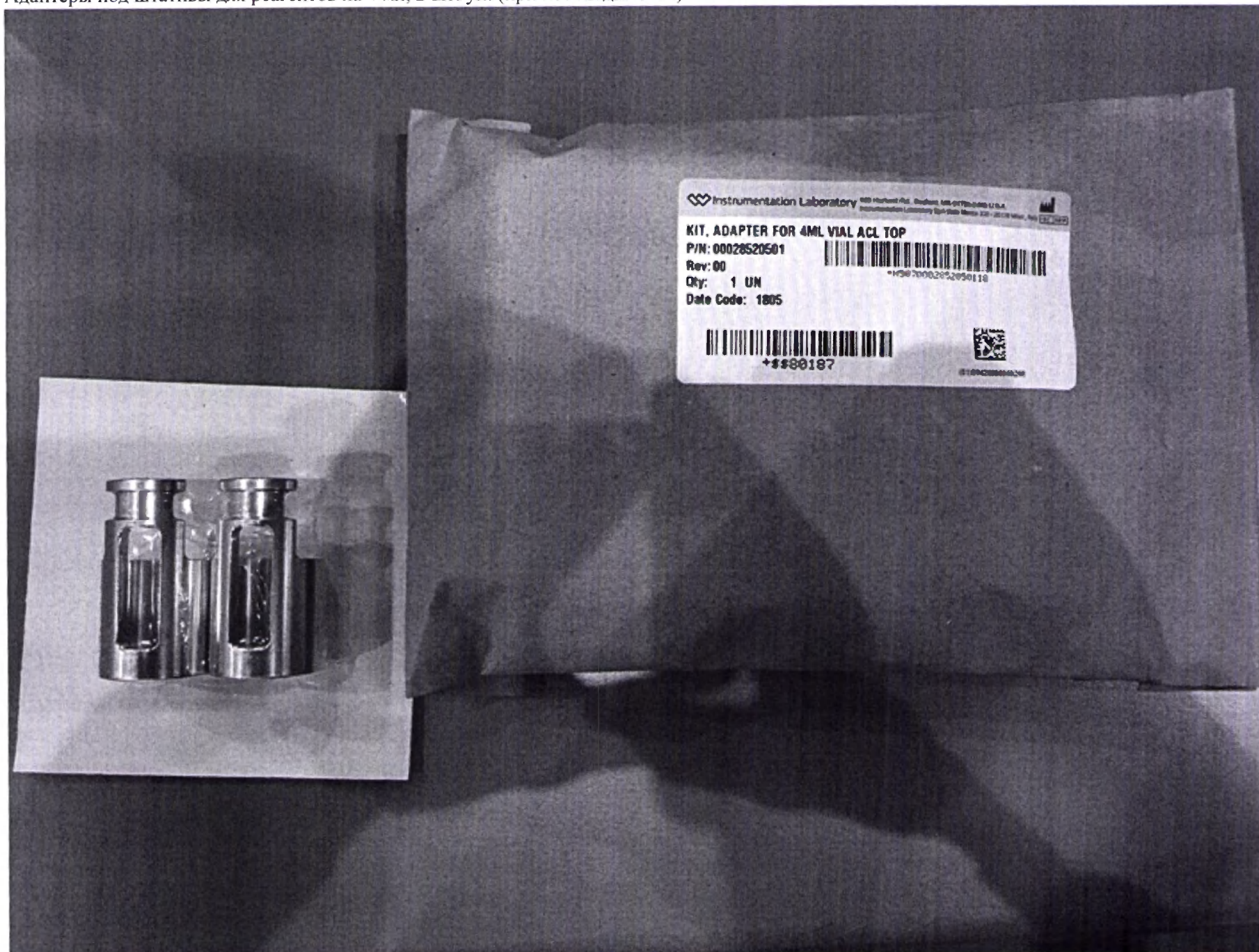
Адаптеры для педиатрических пробирок, 10 шт. (при необходимости)



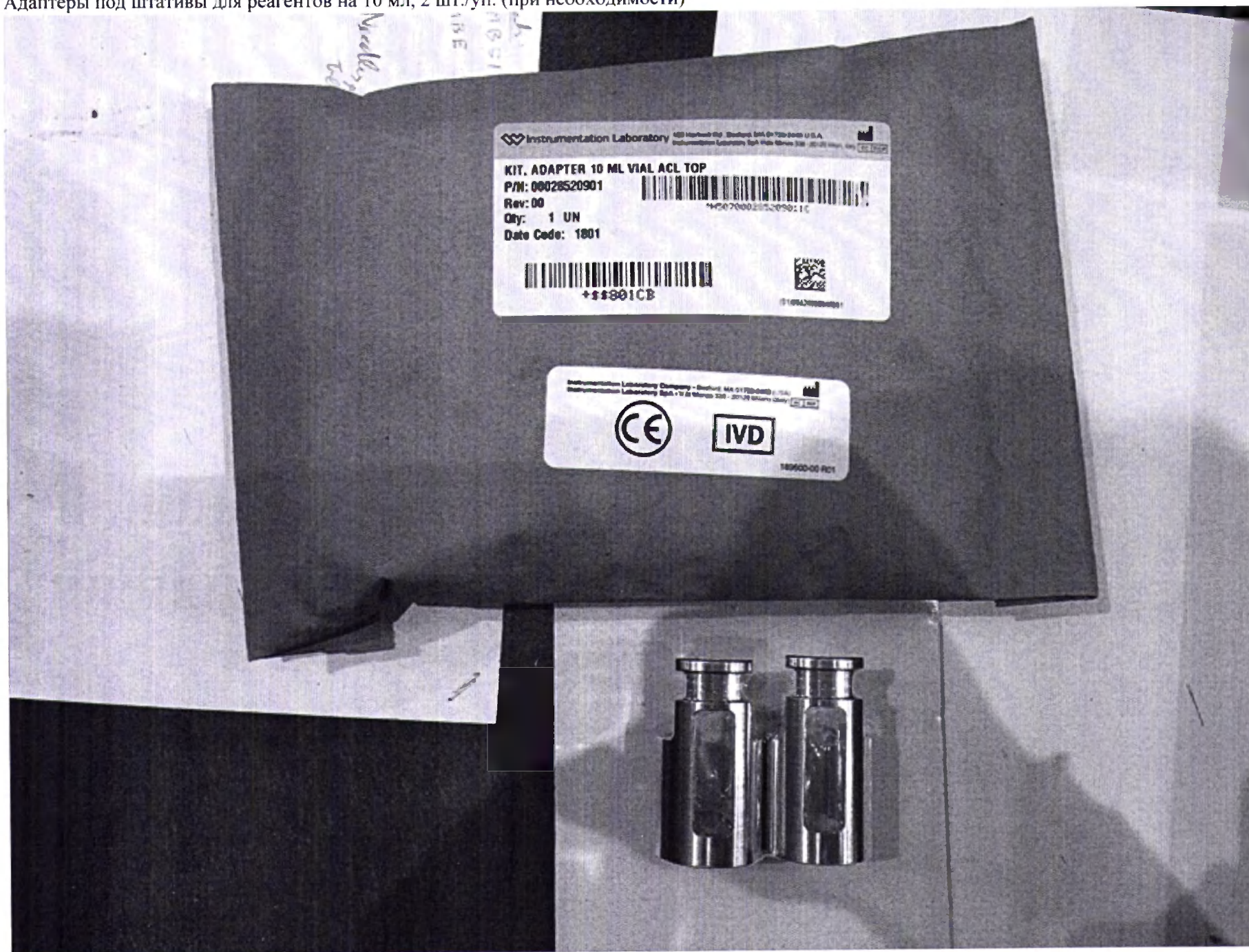
Адаптеры для микропробирок, 10 шт. (при необходимости)



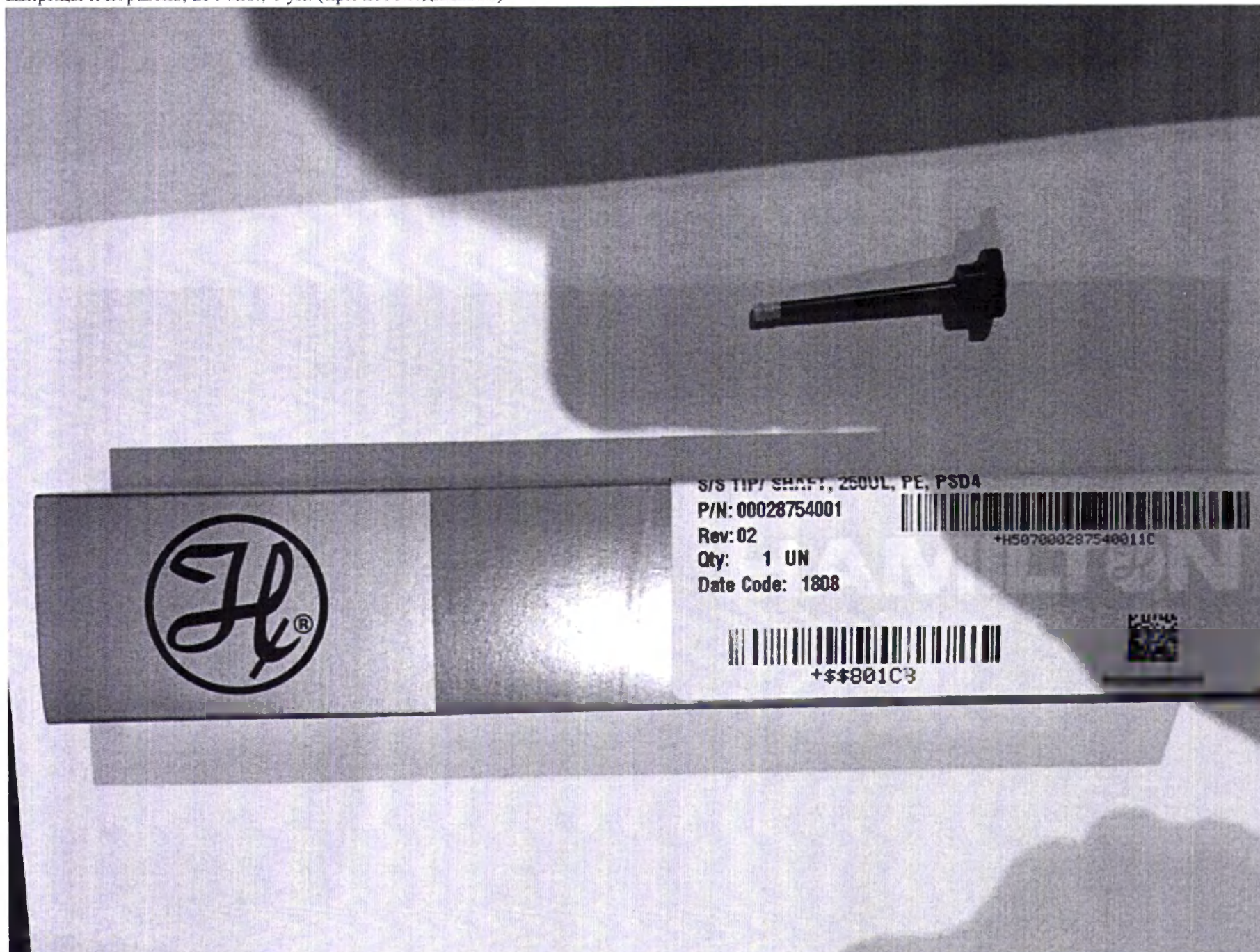
Адаптеры под штативы для реагентов на 4 мл, 2 шт./уп. (при необходимости)



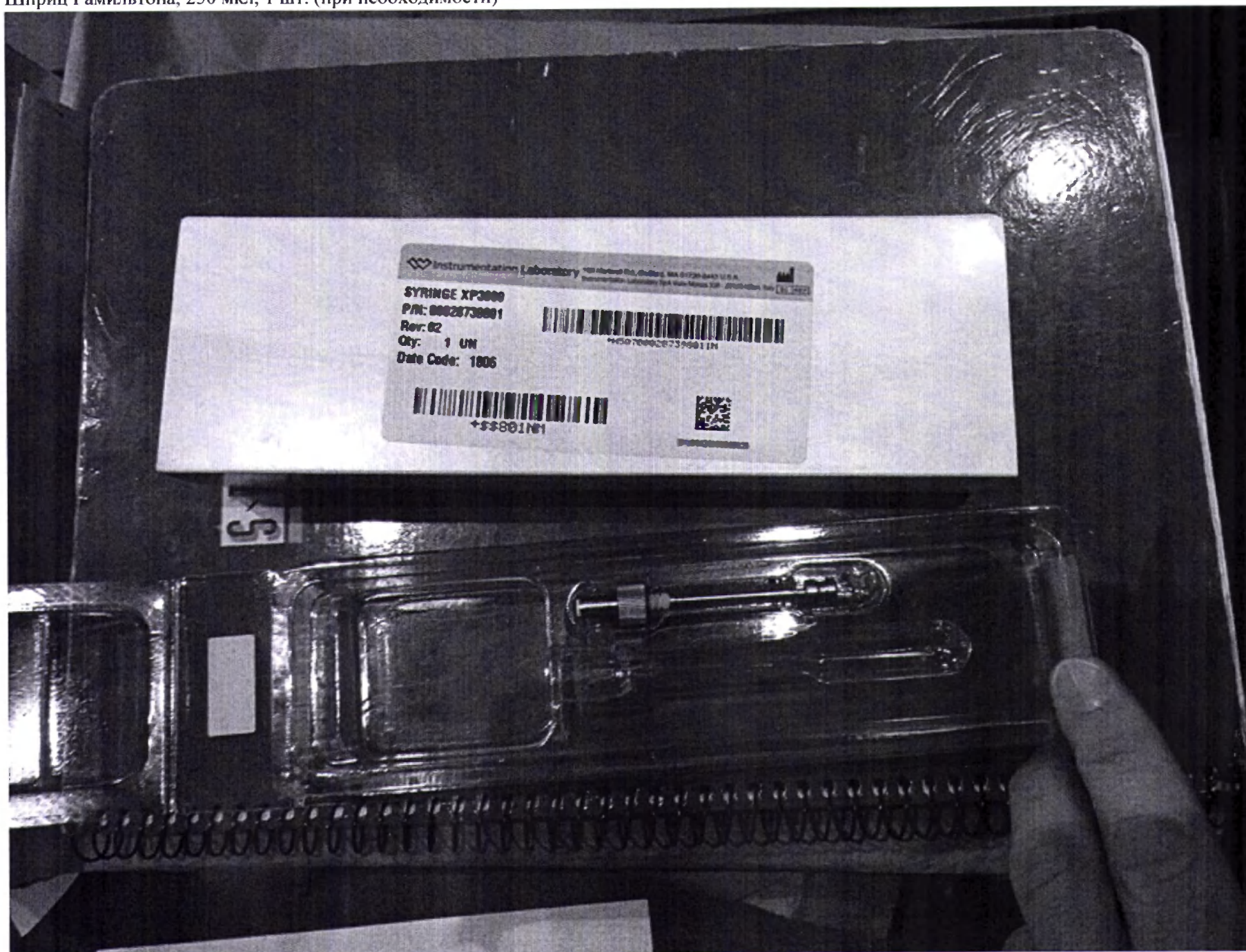
Адаптеры под штативы для реагентов на 10 мл, 2 шт./уп. (при необходимости)



Шприцы и поршень, 250 мкл, 1 уп. (при необходимости)



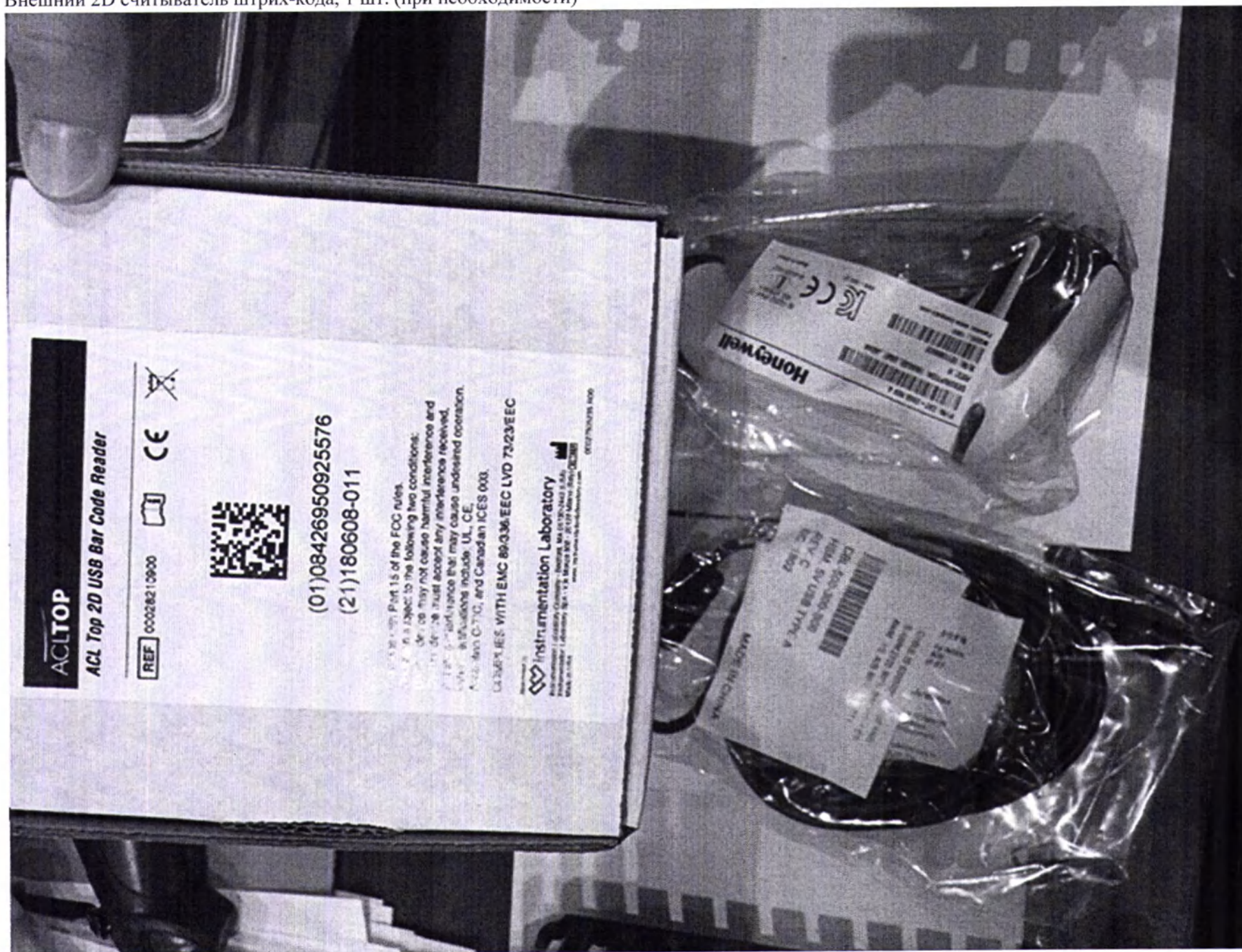
Шприц Гамильтона, 250 мкл, 1 шт. (при необходимости)

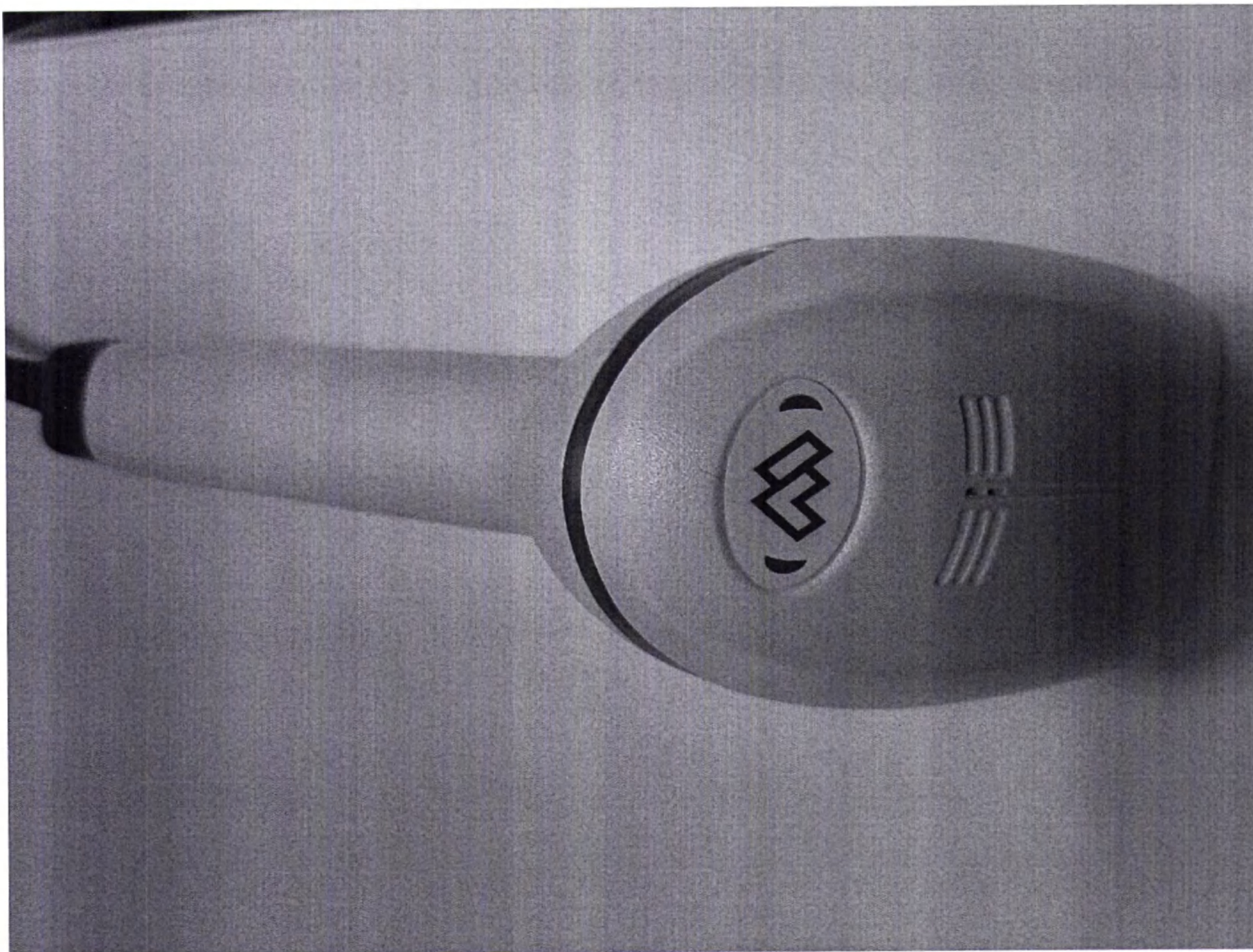


Сенсор отходов, 1 шт. (при необходимости)



Внешний 2D считыватель штрих-кода, 1 шт. (при необходимости)







Syringe Drive Motor

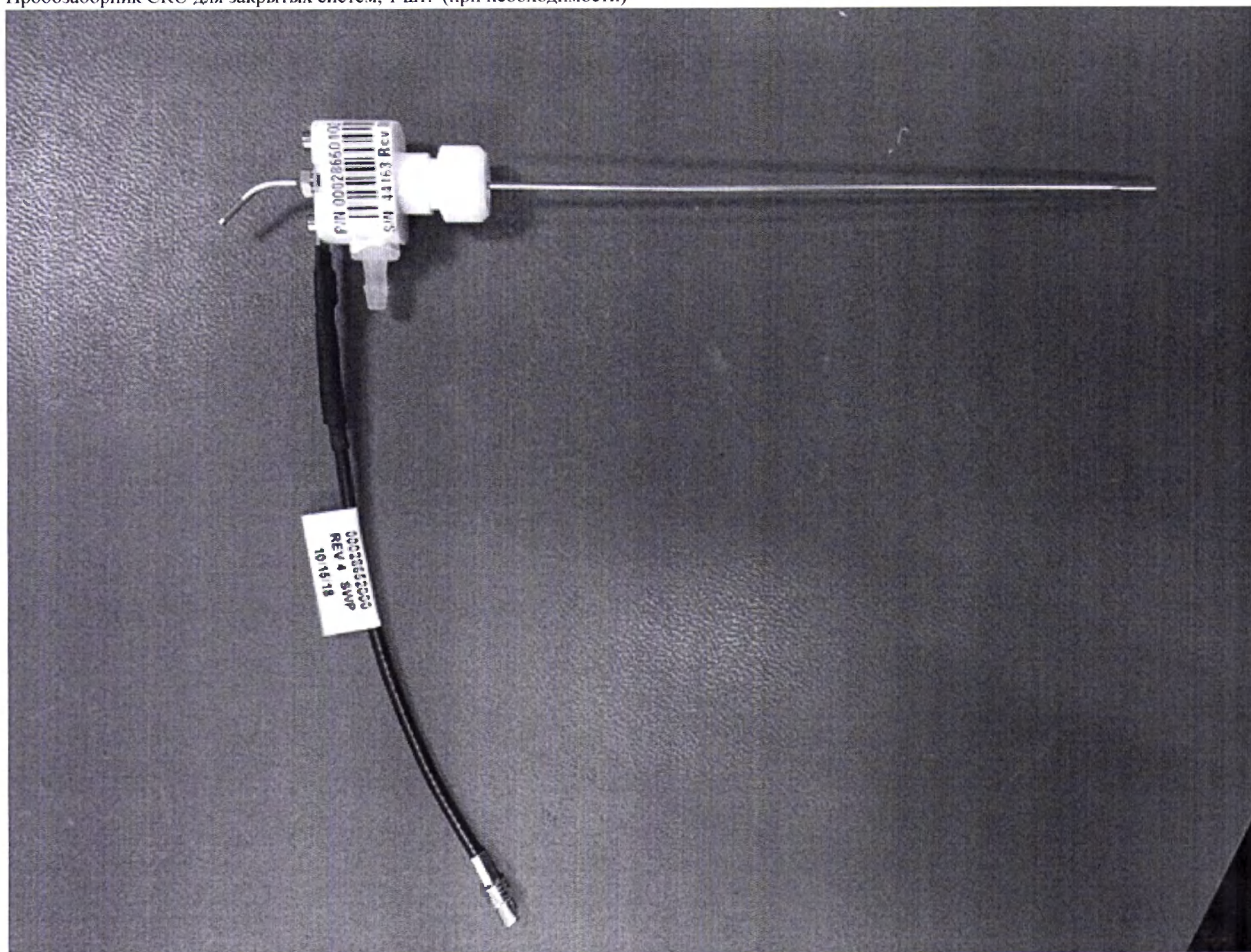
Шприц PE PSD4, 250 мкл, 1 шт. (при необходимости)

Syringe

Контейнер для твердых отходов, 10 шт



Пробозаборник CRU для закрытых систем, 1 шт. (при необходимости)



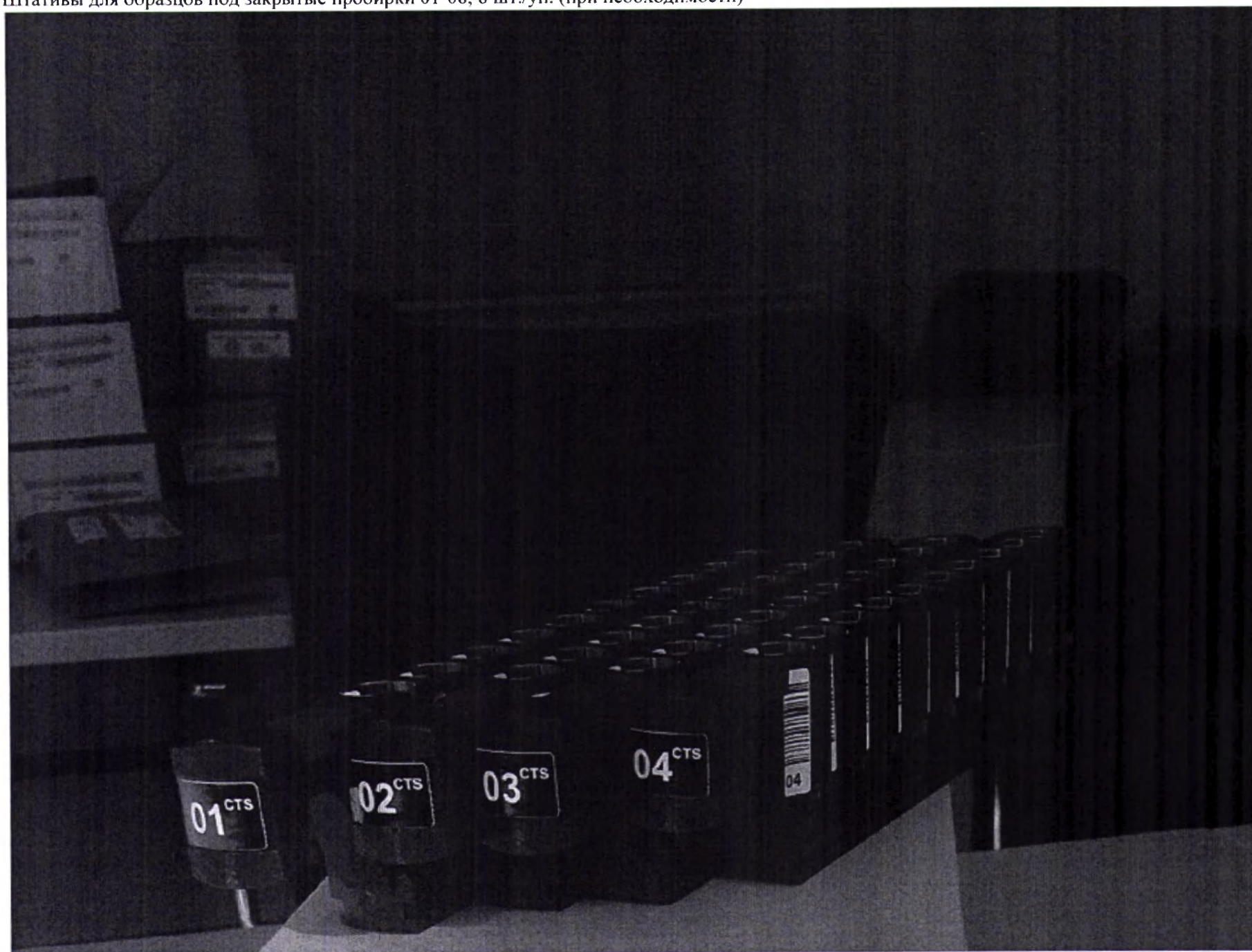
Адаптеры для CTS штативов, голубые, 48 шт. (при необходимости)



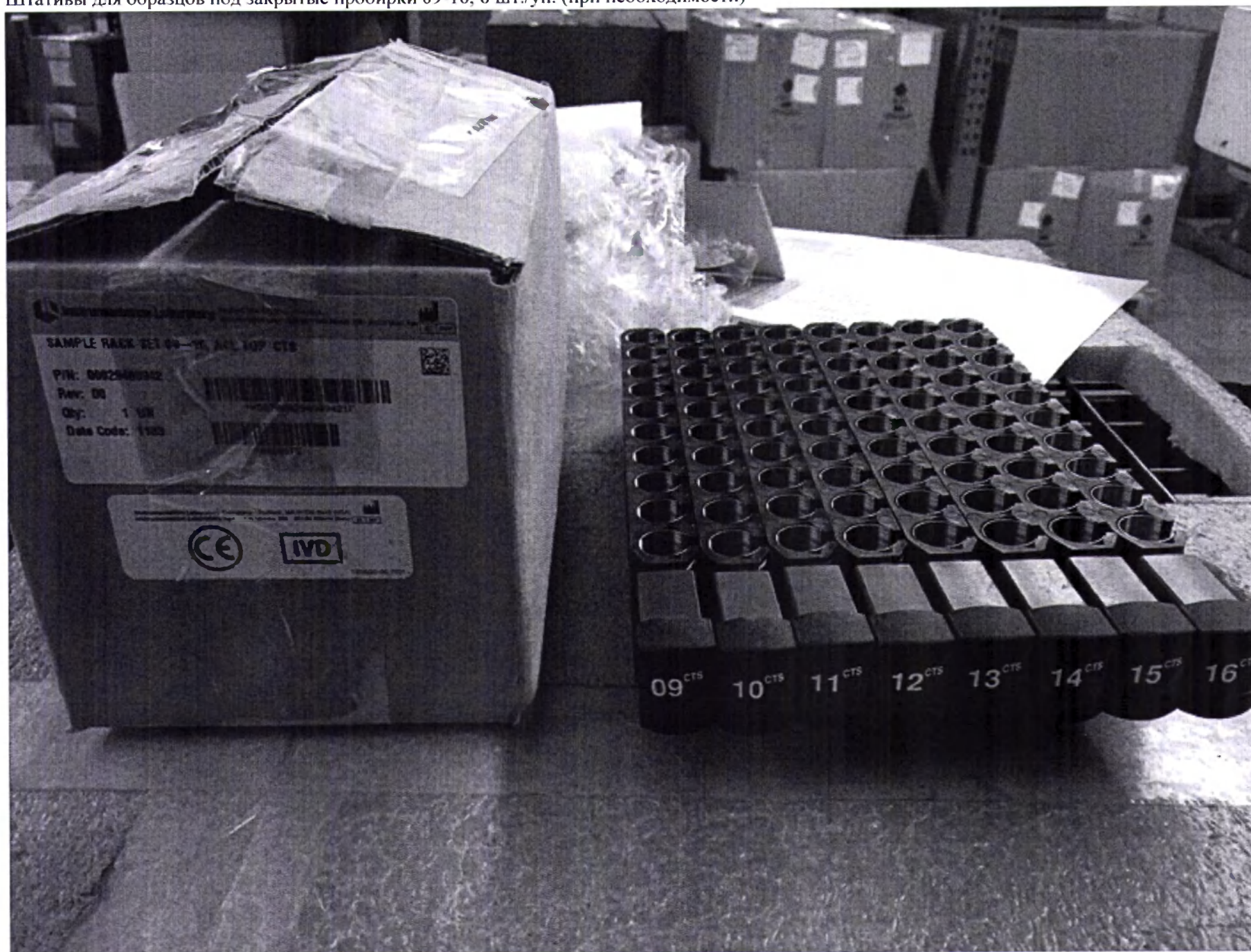
Адаптеры для CTS штативов, голубые, 96 шт. (при необходимости)



Штативы для образцов под закрытые пробирки 01-08, 8 шт./уп. (при необходимости)



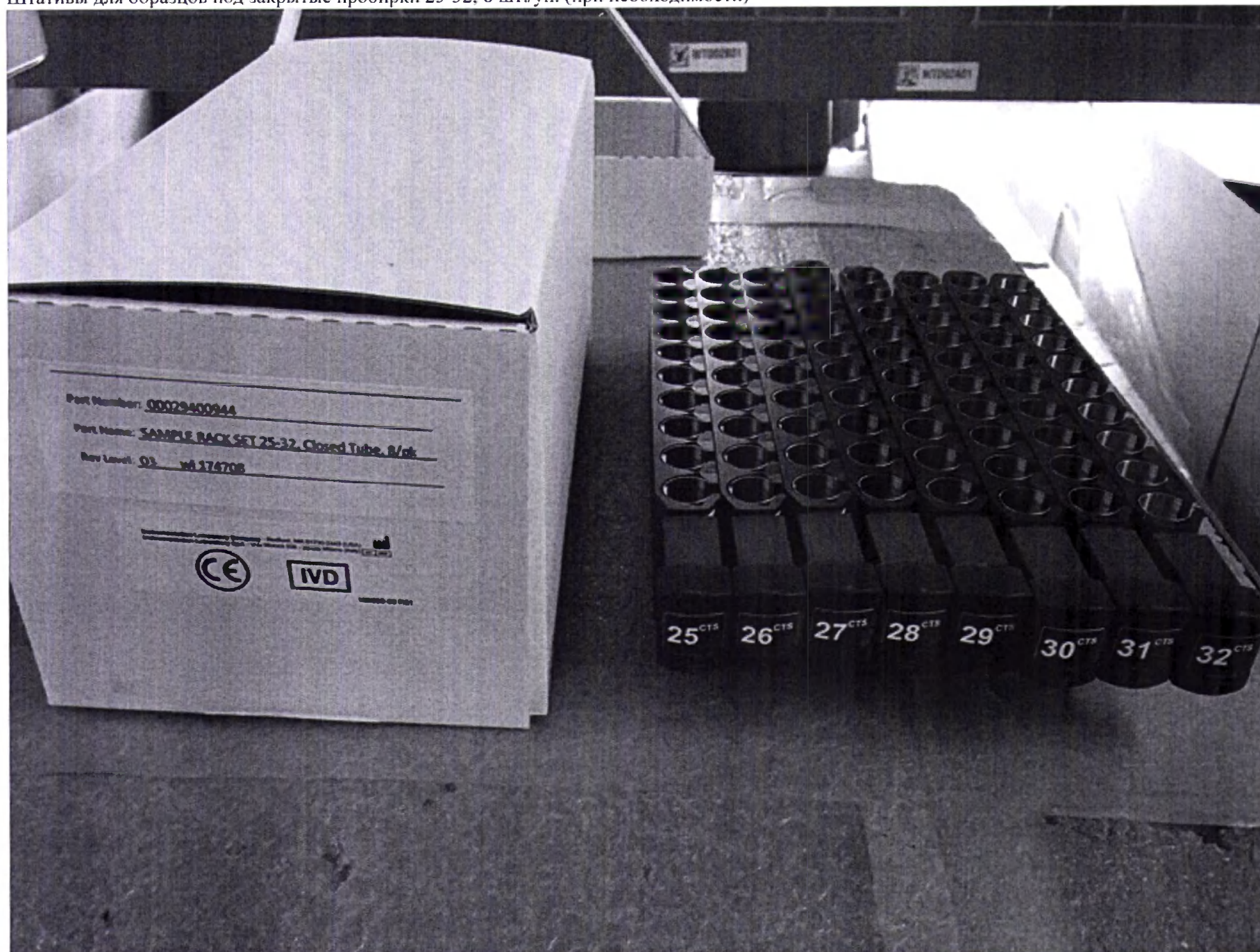
Штативы для образцов под закрытые пробирки 09-16, 8 шт./уп. (при необходимости)



Штативы для образцов под закрытые пробирки 17-24, 8 шт./уп. (при необходимости)



Штативы для образцов под закрытые пробирки 25-32, 8 шт./уп. (при необходимости)



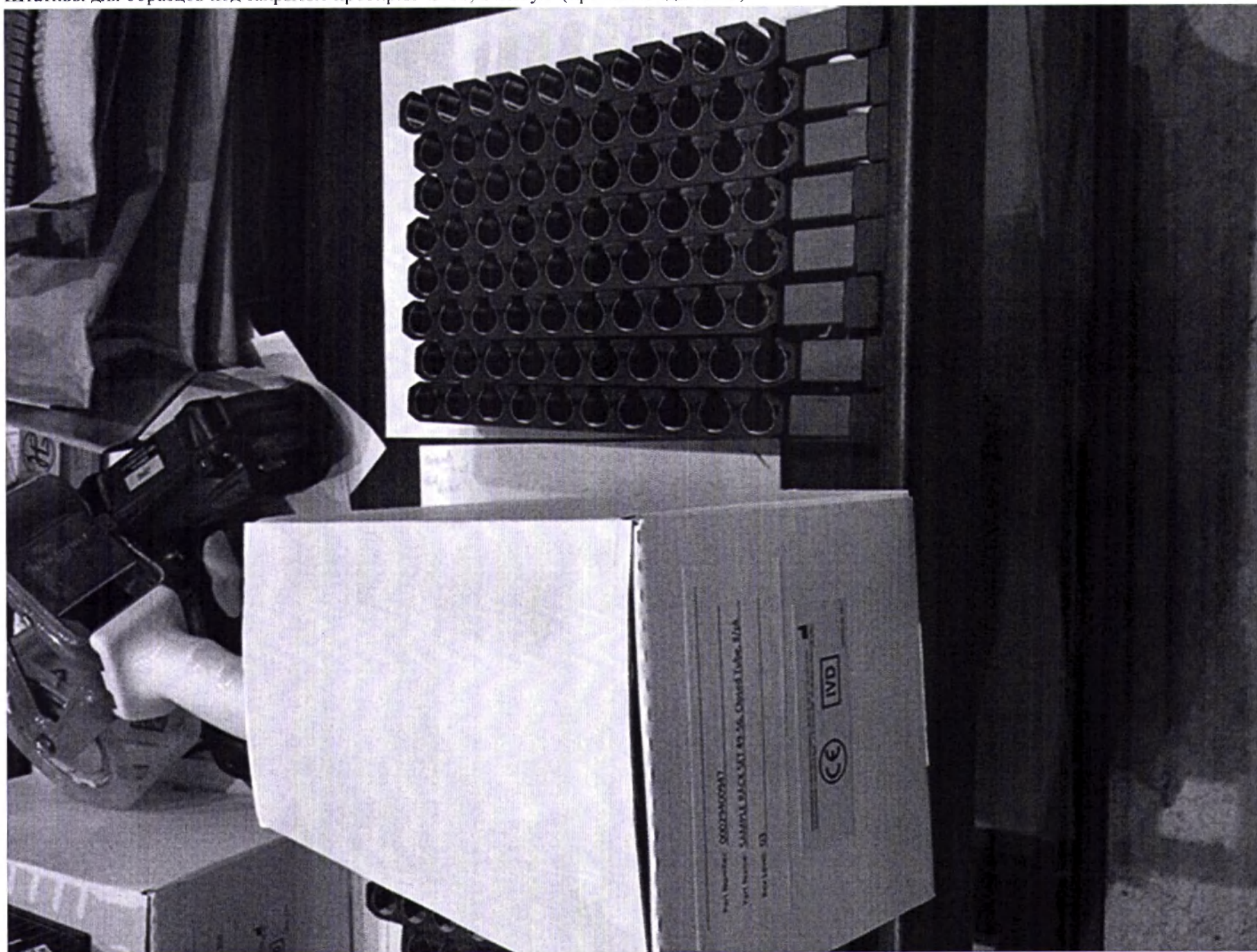
Штативы для образцов под закрытые пробирки 33-40, 8 шт./уп. (при необходимости)



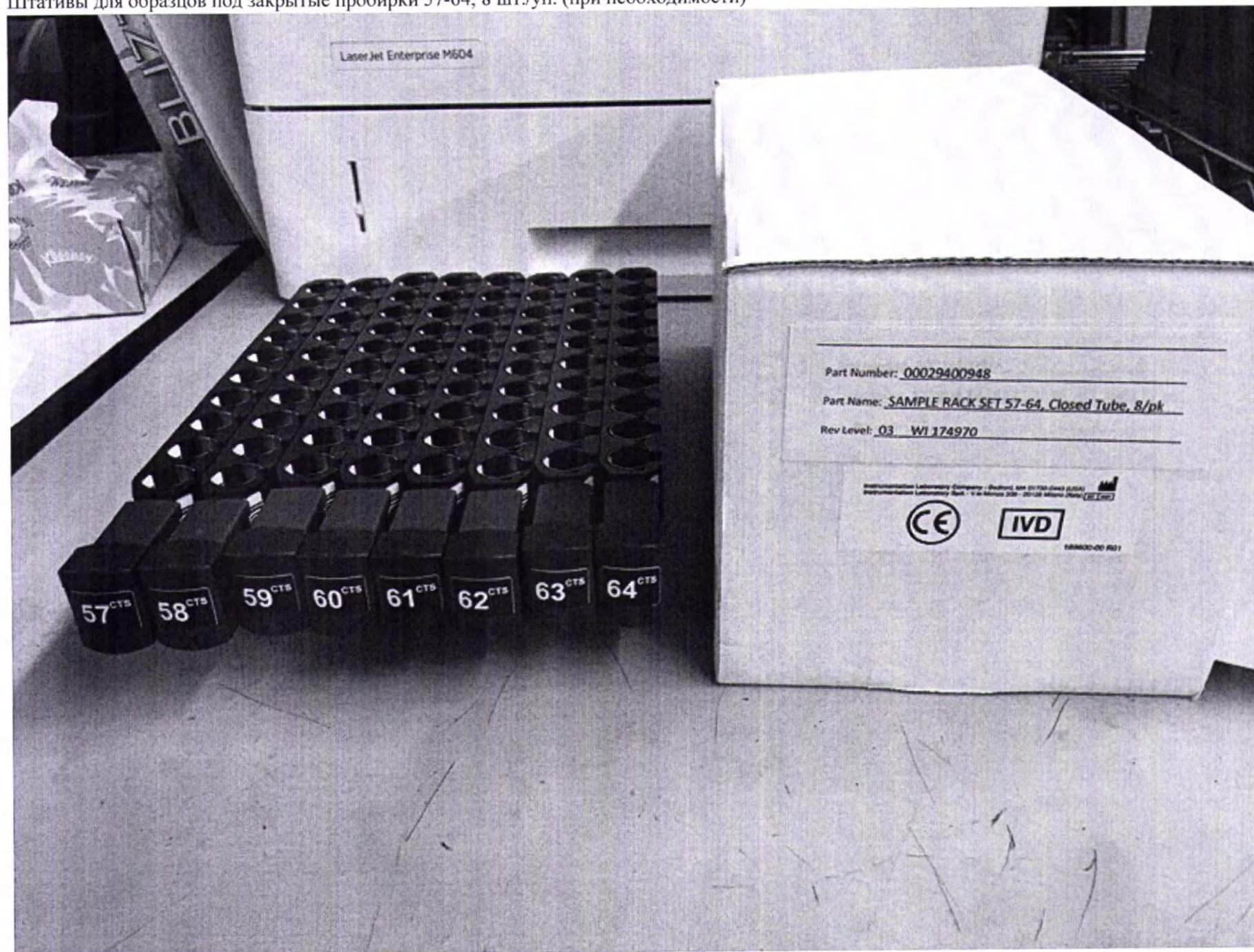
Штативы для образцов под закрытые пробирки 41-48, 8 шт./уп. (при необходимости)



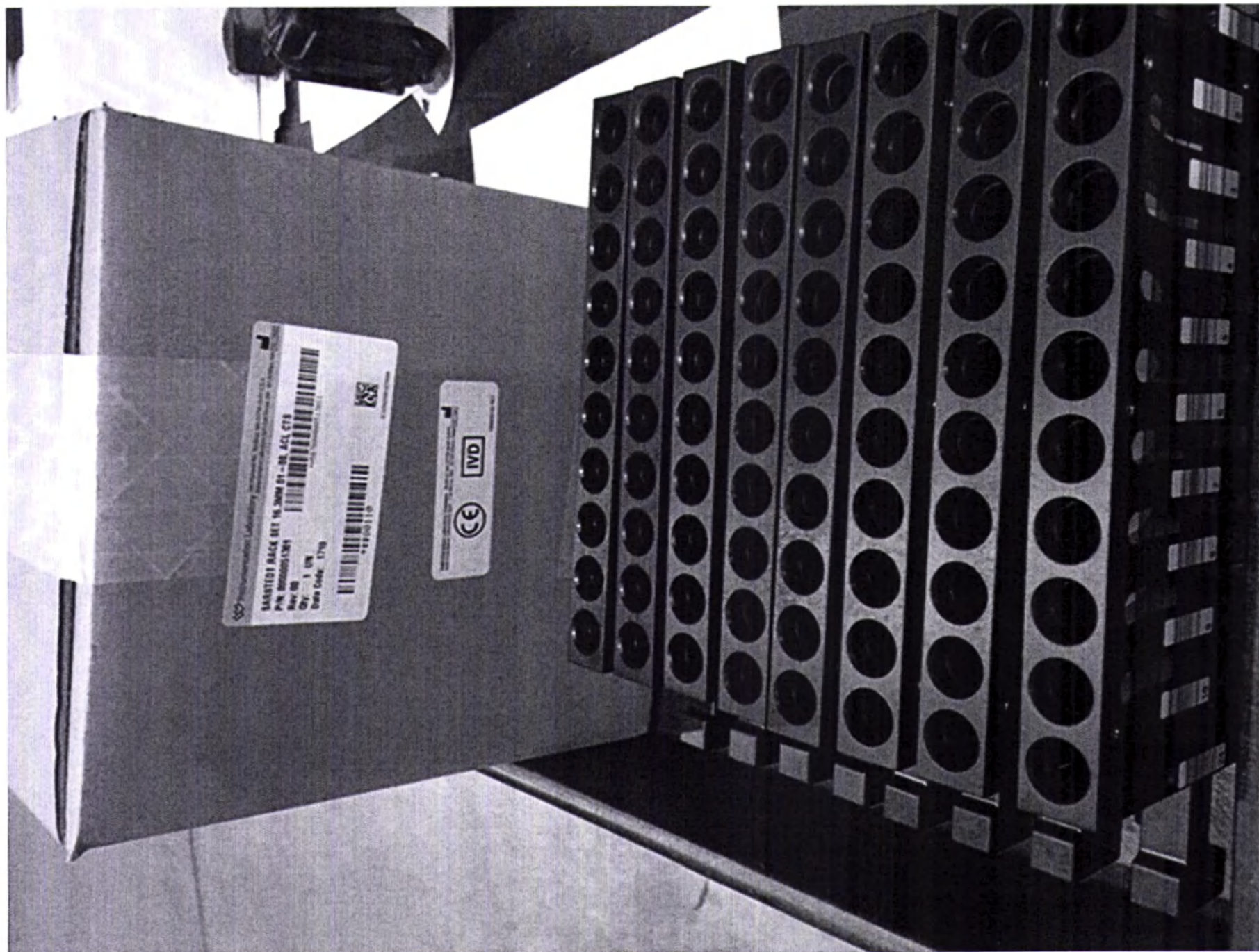
Штативы для образцов под закрытые пробирки 49-56, 8 шт./уп. (при необходимости)



Штативы для образцов под закрытые пробирки 57-64, 8 шт./уп. (при необходимости)



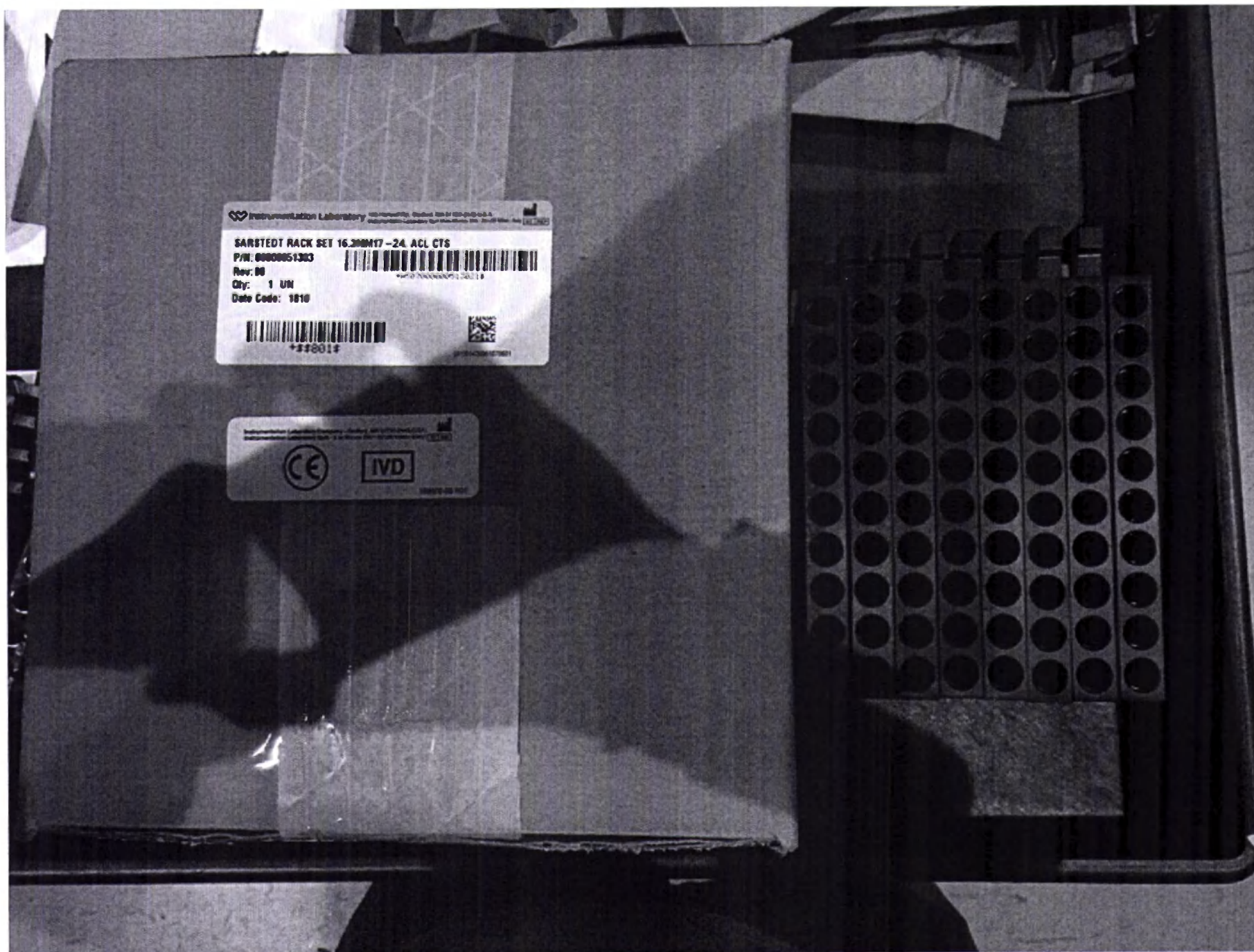
Штативы ACL CTS для пробирок Саршедт 16.3 мм (01-08), 8 шт./уп. (при необходимости)



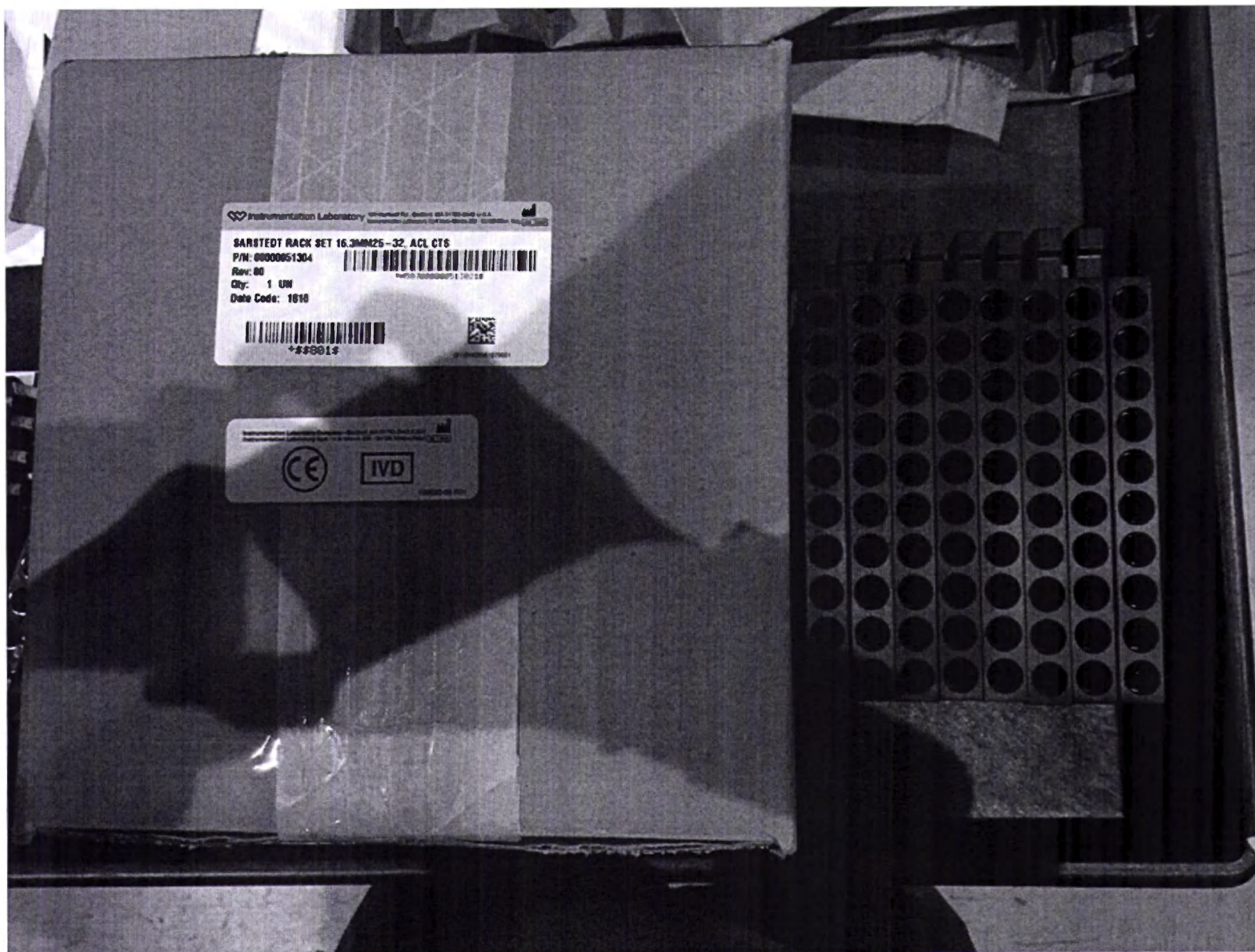
Штативы ACL CTS для пробирок Сарштедт 16.3 мм (09-16), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Саршедт 16.3 мм (17-24), 8 шт./уп. (при необходимости)



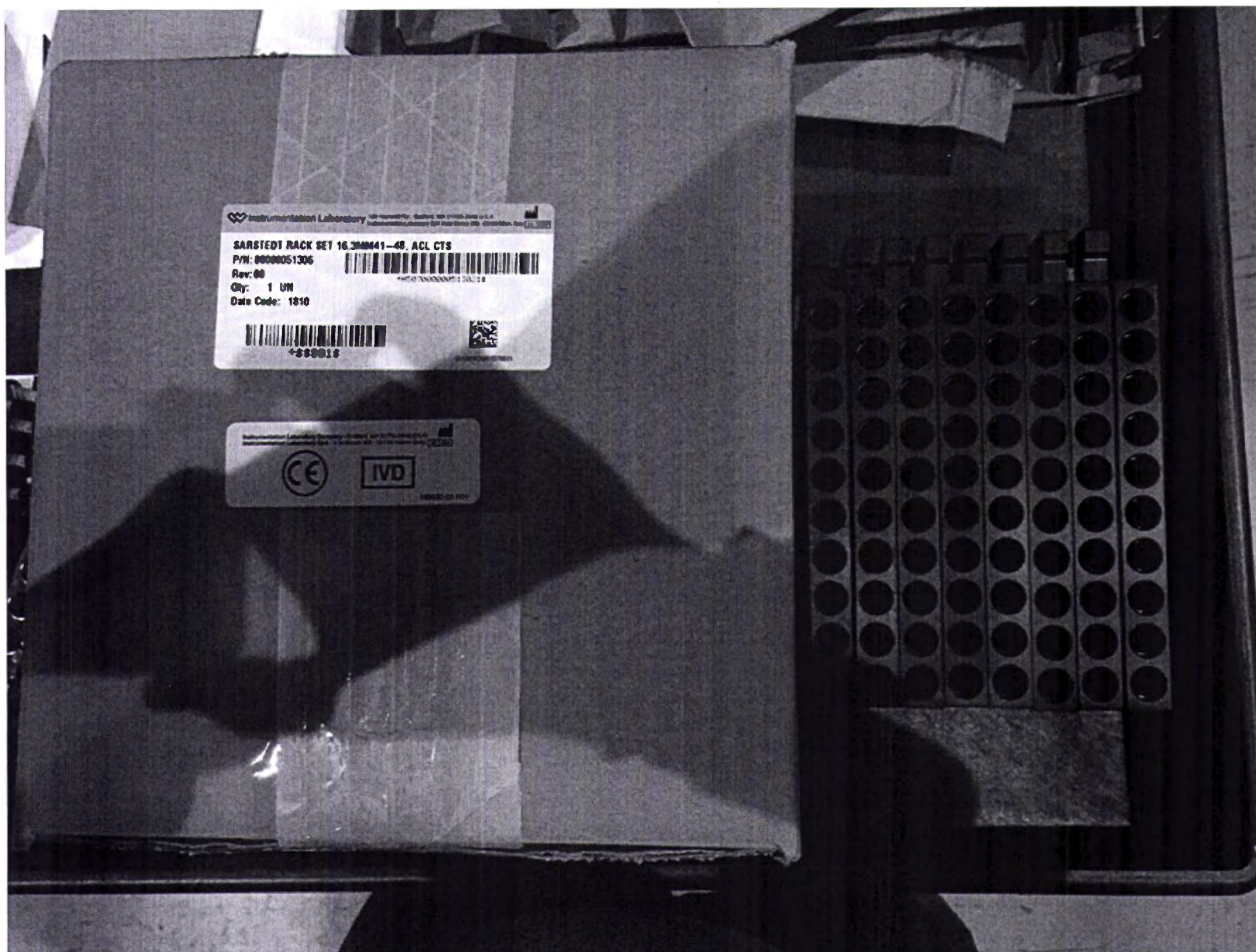
Штативы ACL CTS для пробирок Сарштедт 16.3 мм (25-32), 8 шт./уп. (при необходимости)



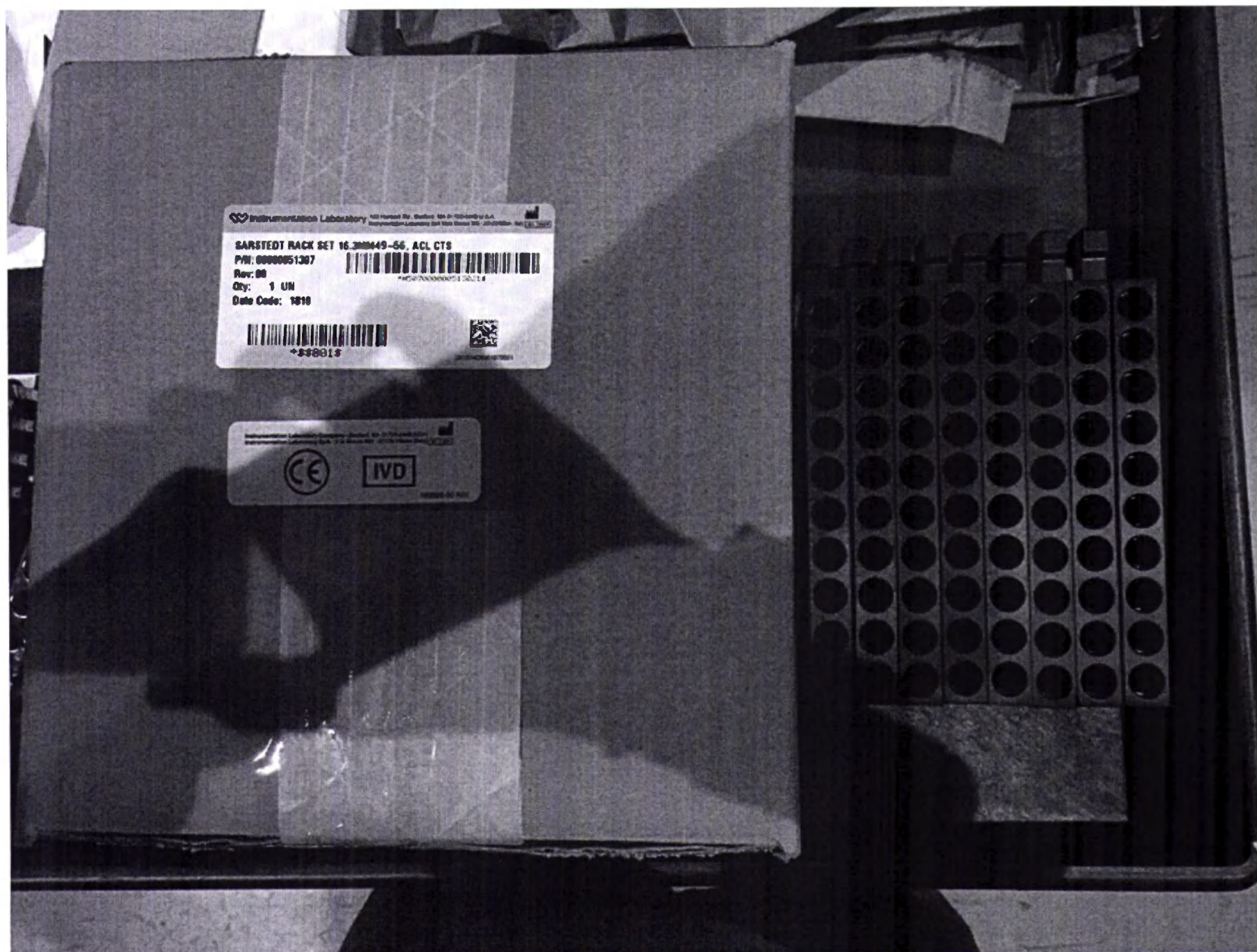
Штативы ACL CTS для пробирок Саршедт 16.3 мм (33-40), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 16.3 мм (41-48), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 16.3 мм (49-56), 8 шт./уп. (при необходимости)



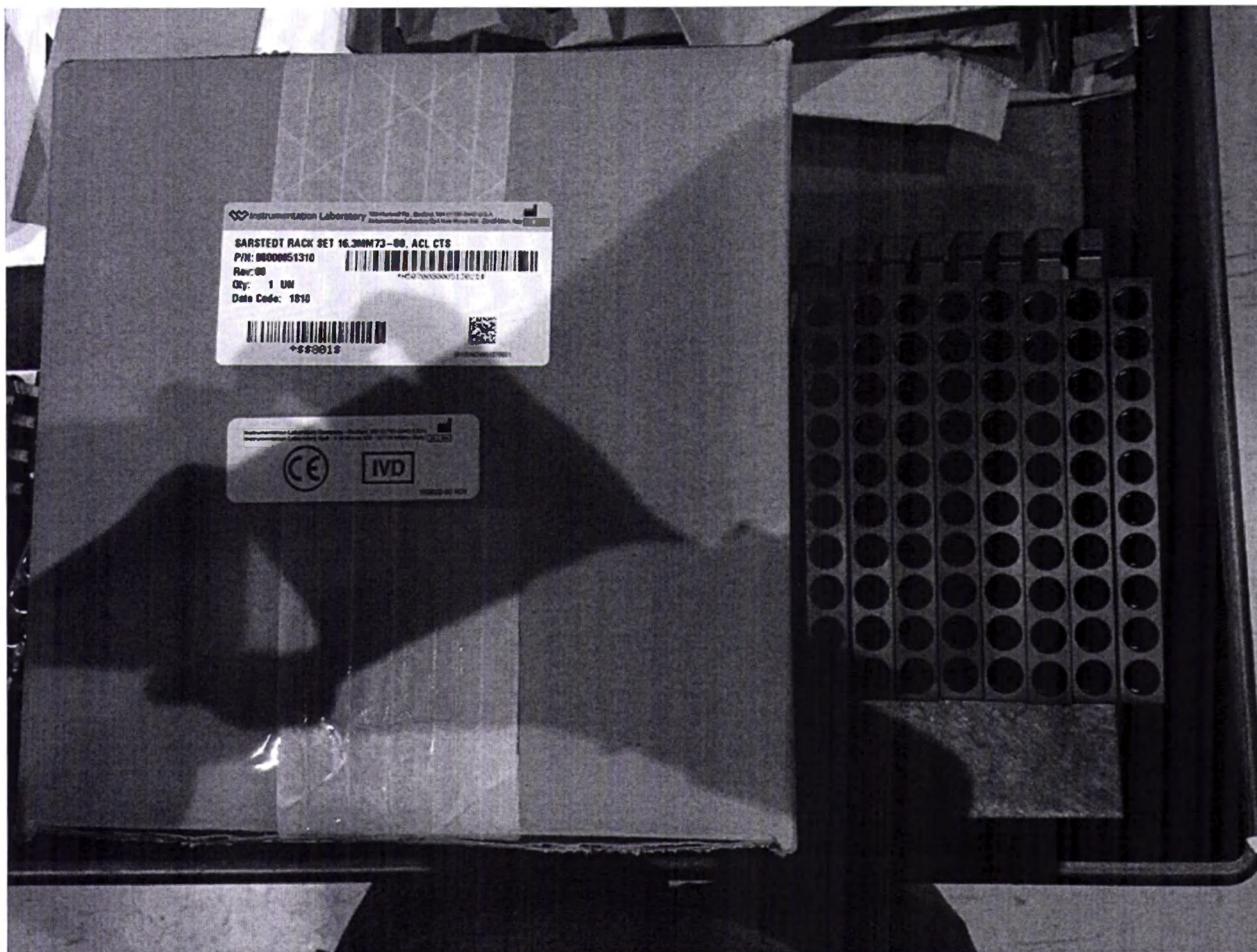
Штативы ACL CTS для пробирок Сарштедт 16.3 мм (57-64), 8 шт./уп. (при необходимости)



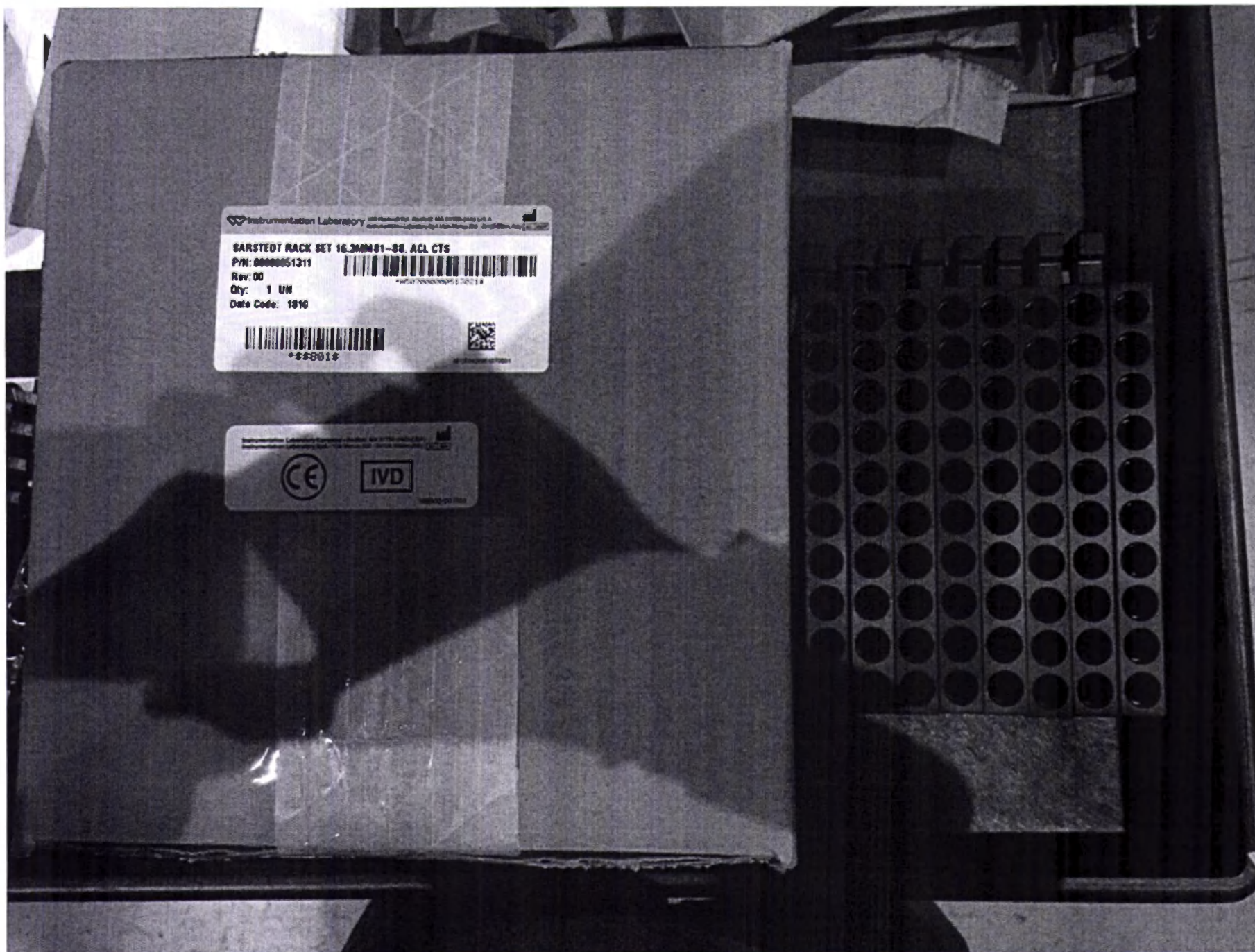
Штативы ACL CTS для пробирок Сарштедт 16.3 мм (65-72), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 16.3 мм (73-80), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 16.3 мм (81-88), 8 шт./уп. (при необходимости)



Instrumentation Laboratory 100 Portland Pk., Boston, MA 02128-0440 U.S.A.
 Instrumentation Laboratory SpA Via Roma 238 - 40139 Bologna, Italy

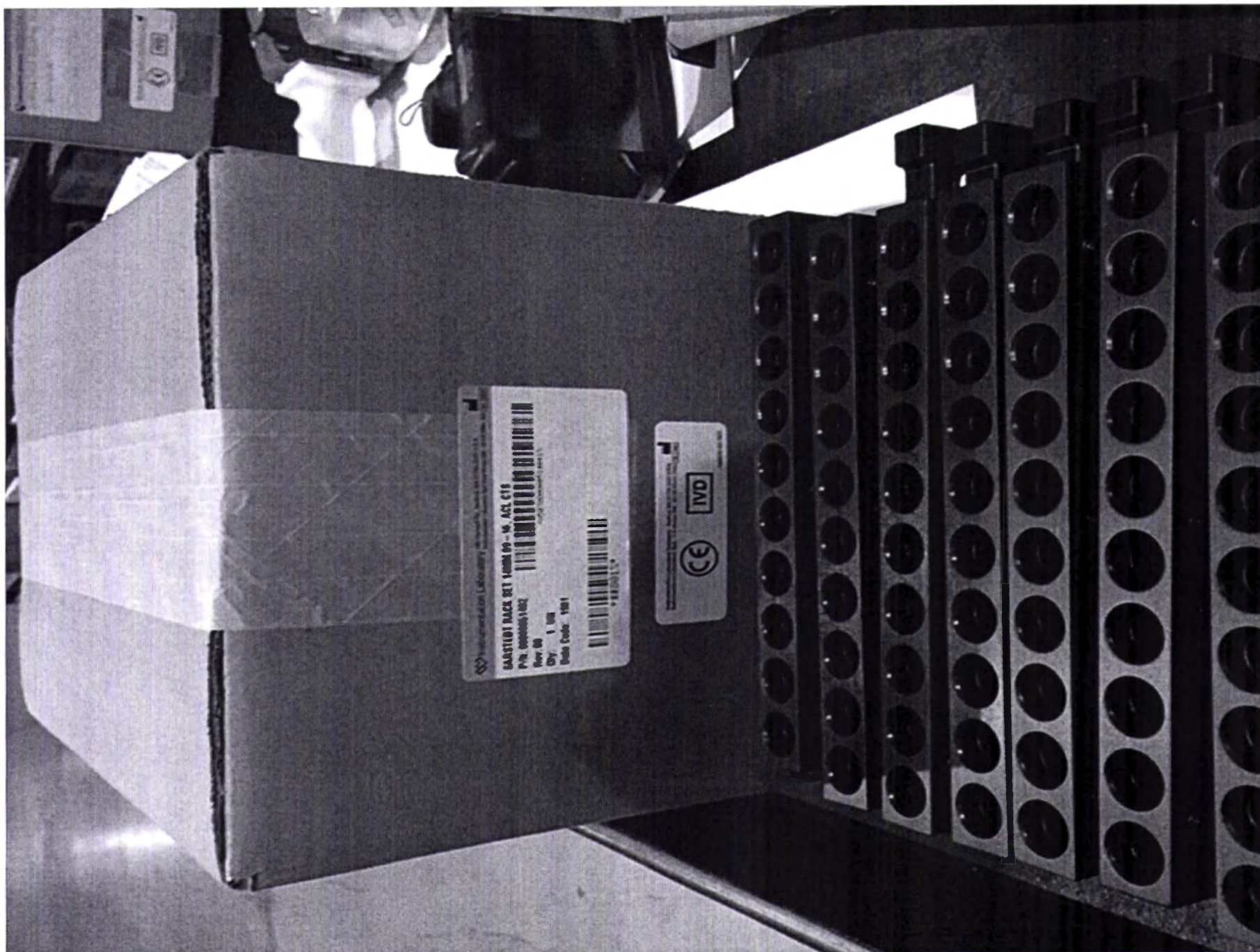
SARSTEDT RACK SET 16.3MMØ9-96, ACL C75
 P/N: 0000051312
 Rev: 00
 Qty: 1 UN
 Date Code: 1870

163000-00 P/N

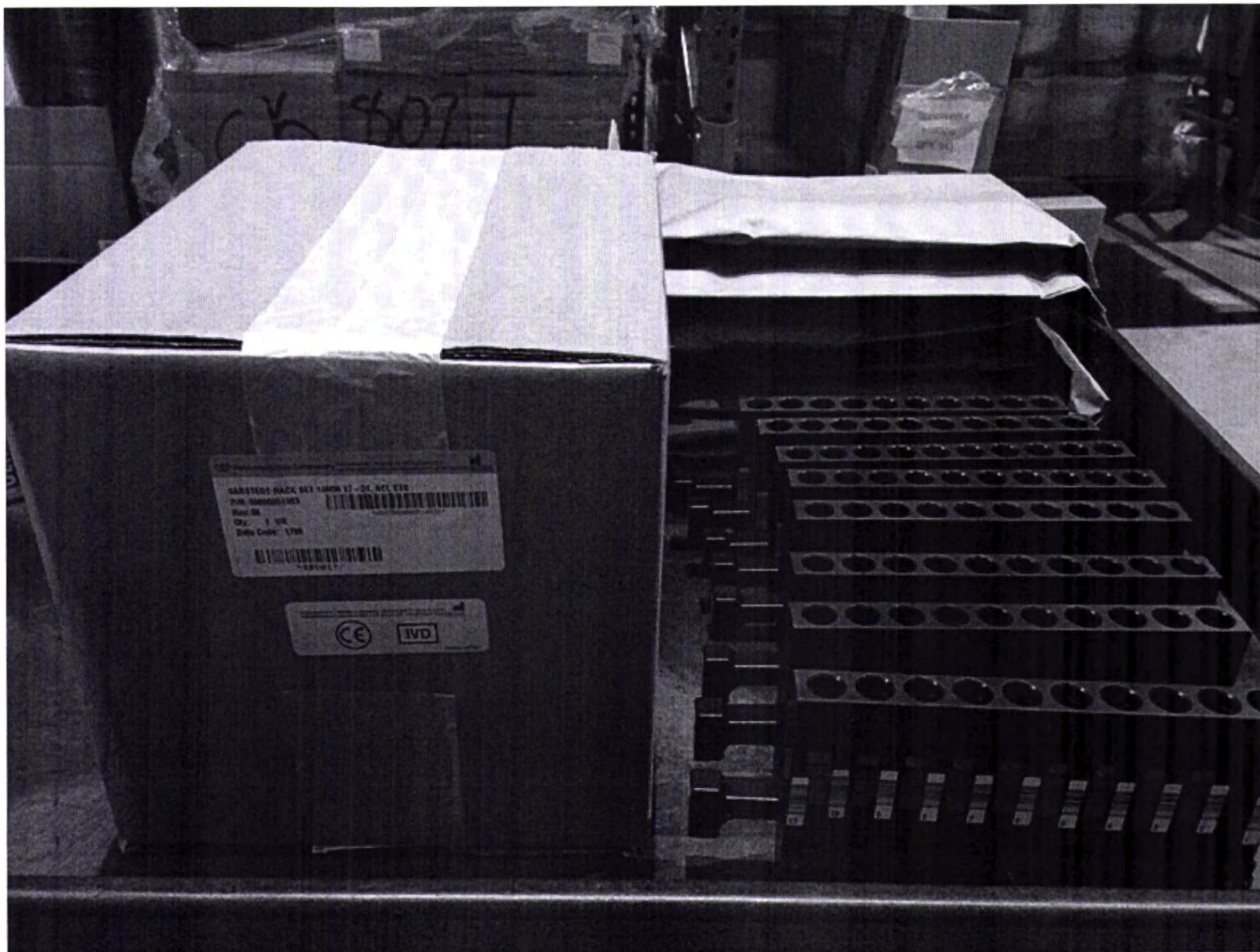
Штативы ACL CTS для пробирок Сарштедт 14 мм (01-08), 8 шт./уп. (при необходимости) - Sarstedt rack set 14mm 01-08, ACL CTS



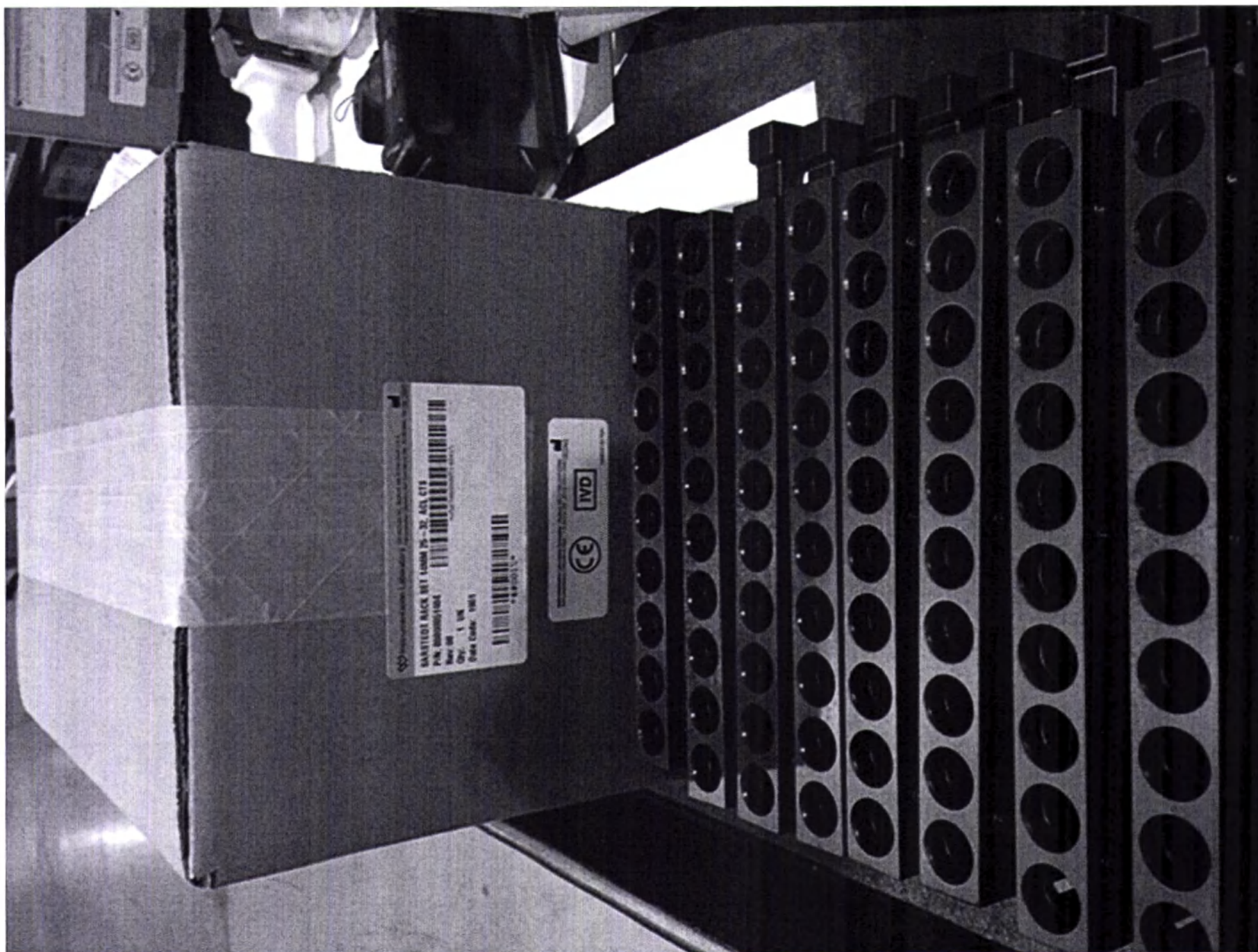
Штативы ACL CTS для пробирок Сарштедт 14 мм (09-16), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 14 мм (17-24), 8 шт./уп. (при необходимости)



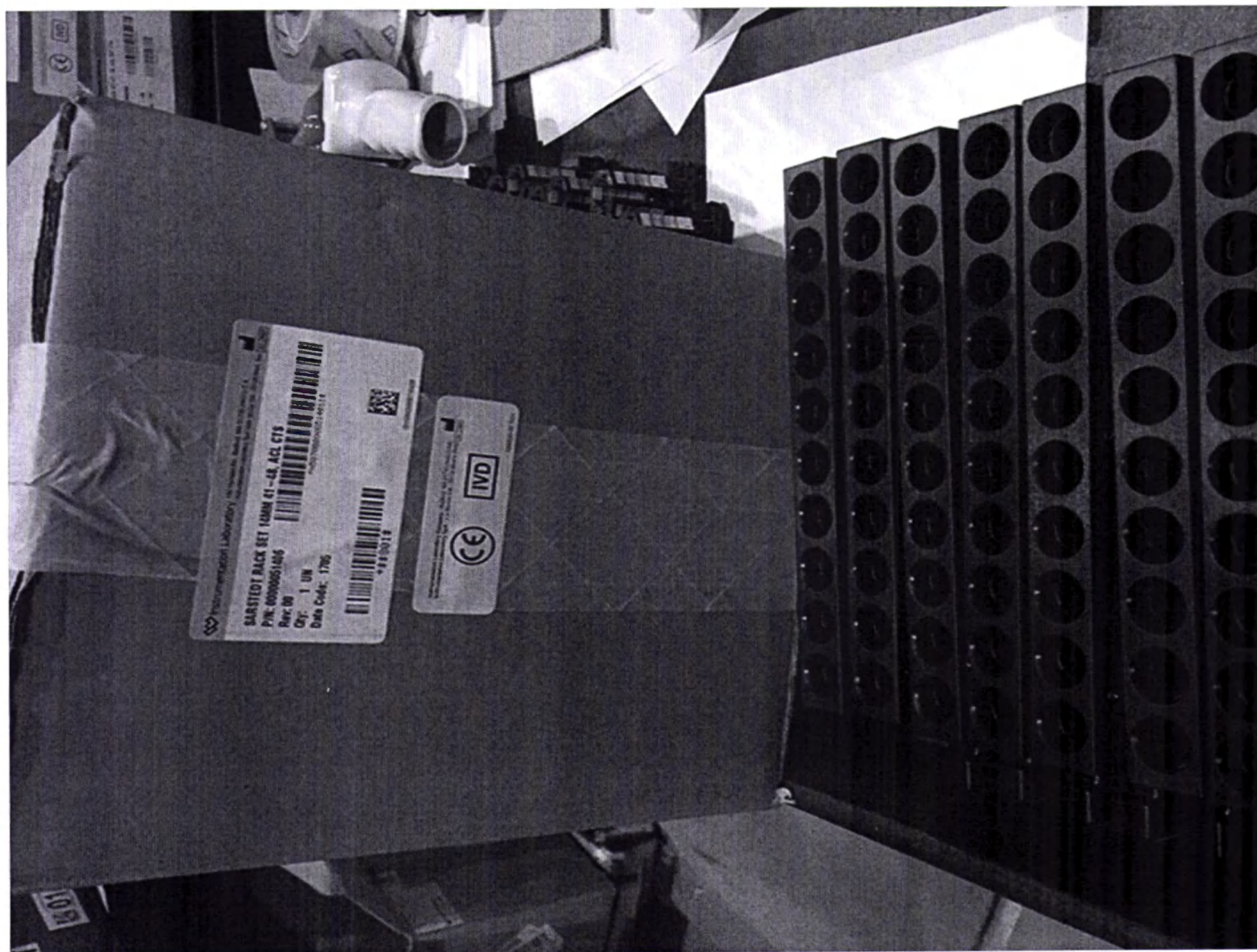
Штативы ACL CTS для пробирок Саршедт 14 мм (25-32), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Саршедт 14 мм (33-40), 8 шт./уп. (при необходимости)



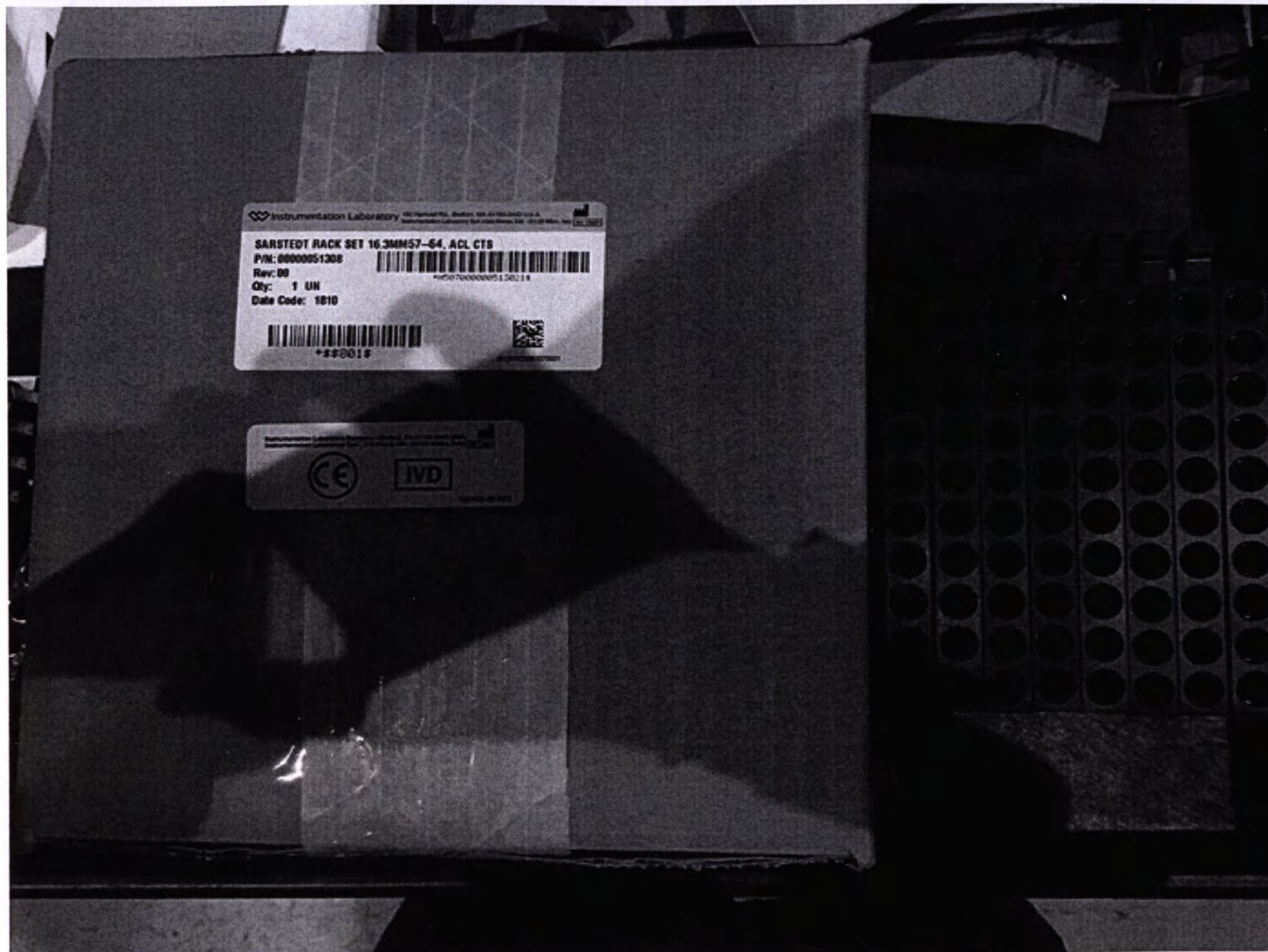
Штативы ACL CTS для пробирок Саршедт 14 мм (41-48), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 14 мм (49-56), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 14 мм (57-64), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 14 мм (65-72), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 14 мм (73-80), 8 шт./уп. (при необходимости)



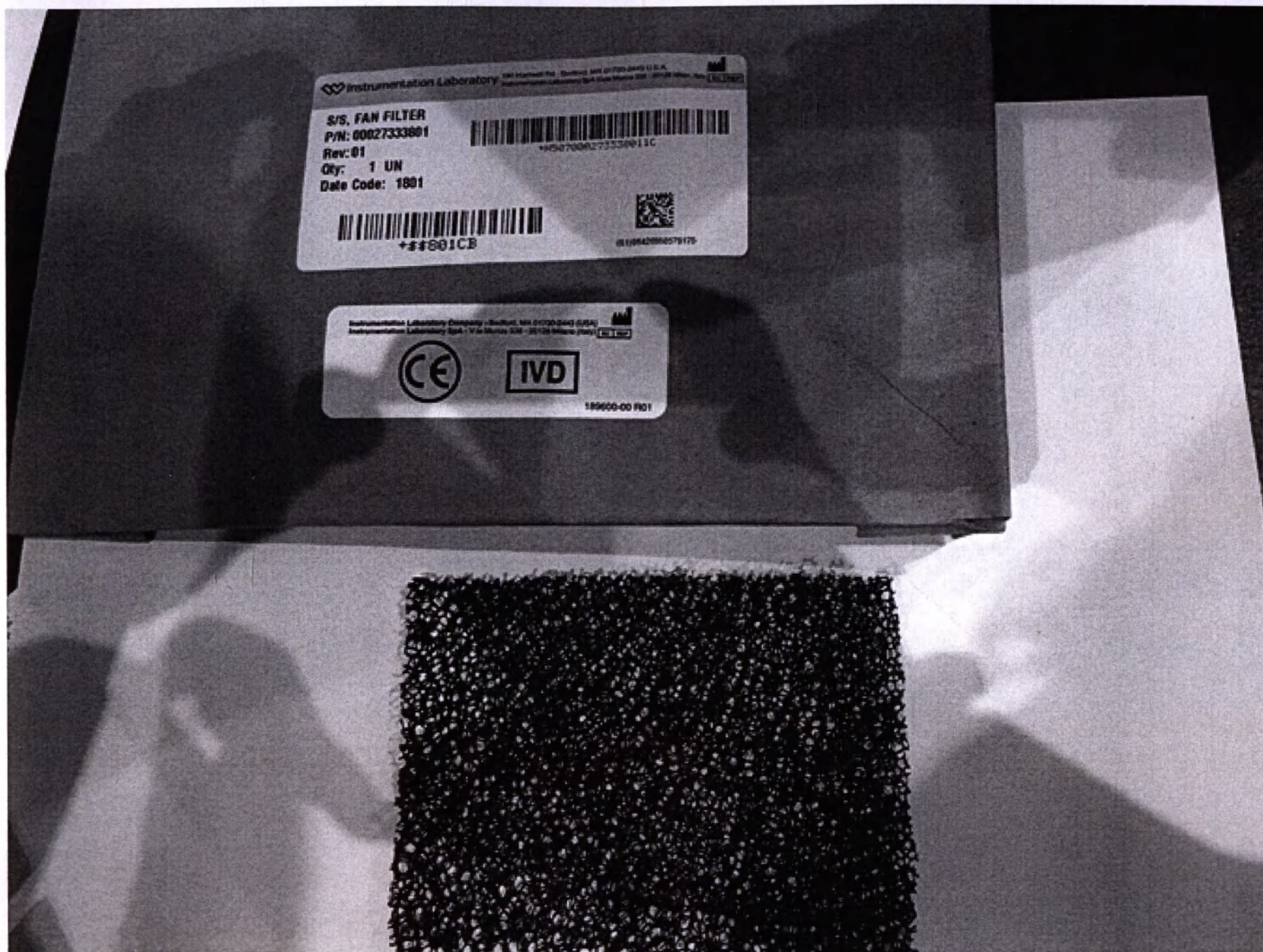
Штативы ACL CTS для пробирок Сарштедт 14 мм (81-88), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 14 мм (89-96), 8 шт./уп. (при необходимости)



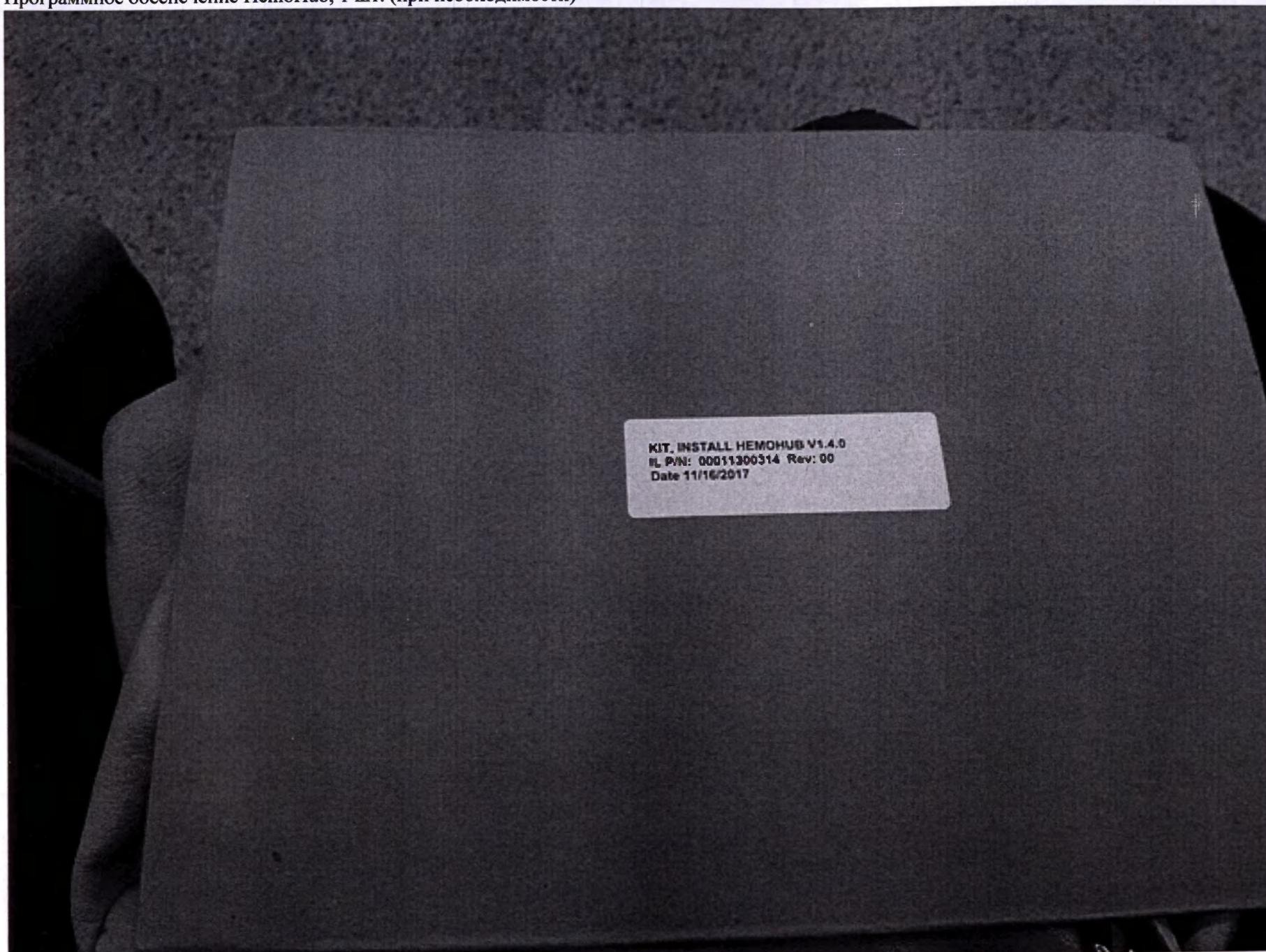
Вентилятор для охлаждения реагентов, ACL TOP 300/350 CTS, 1 шт. (при необходимости)

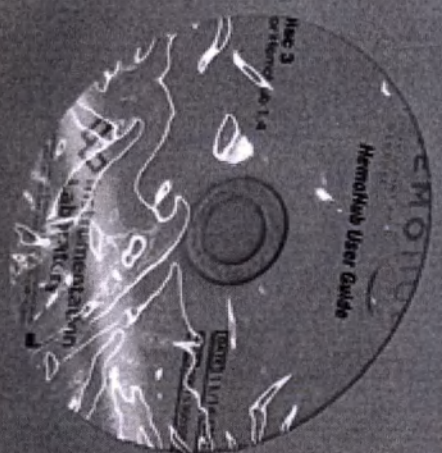
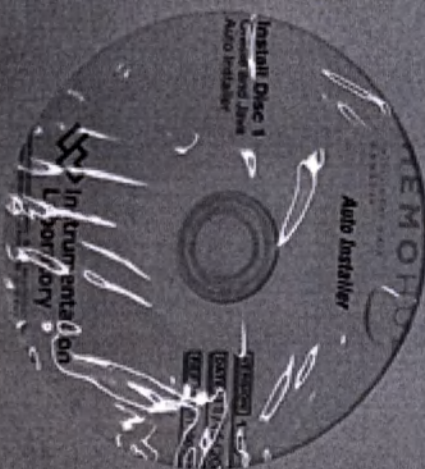
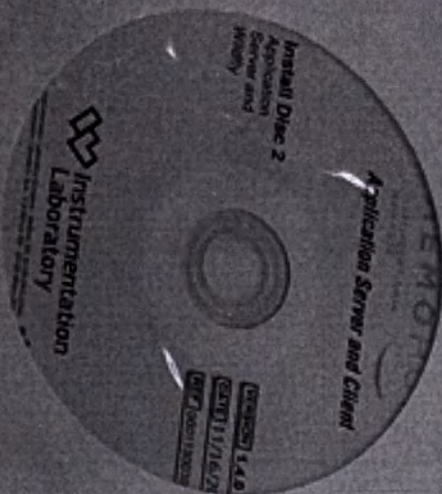


Набор для замены прокалывателя CTS: прокалыватель, 1 шт.; винт, 1 шт.; кольца, 6 шт. (при необходимости)



Программное обеспечение НетоHub, 1 шт. (при необходимости)





Вопрос и ответ

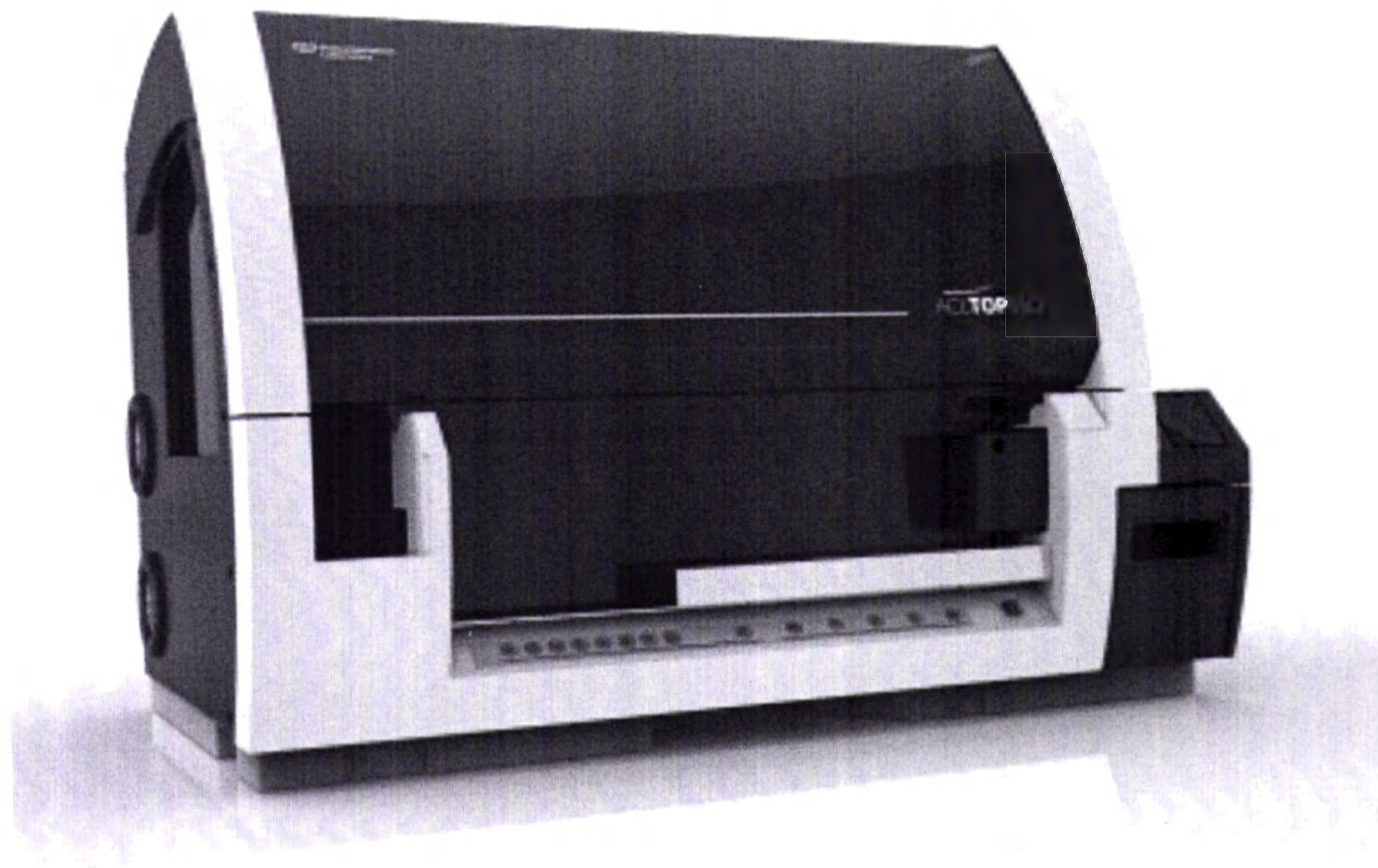


Директор ФГБУ «ЦПМ»
Иванов И.И.

ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ МЕДИЦИНСКОГО ИЗДЕЛИЯ

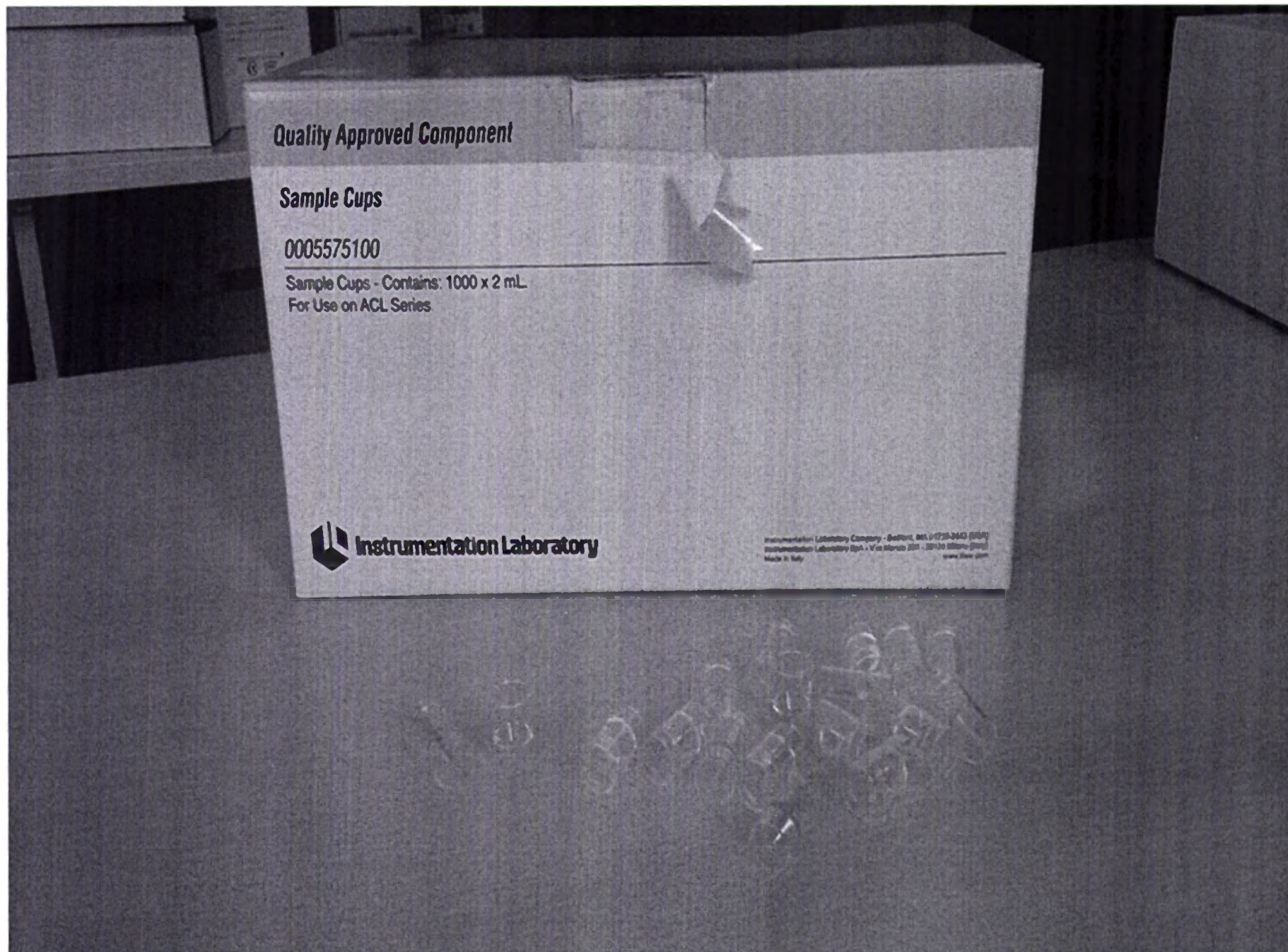
Анализатор автоматический коагулометрический для диагностики in vitro ACL TOP,
вариант исполнения ACL TOP 550 CTS

Анализатор





Чашечки для образцов 2.0 мл, 1000 шт.



Магнитные мешалки, 6 шт.

MAGNETIC STIR BARS, 6/PK

Q.ty : 1

Item N° : 0009746606

Instrumentation Laboratory Company - Bedford, MA 01730-2443 (USA)
Instrumentation Laboratory SpA - V.le Monza 338 - 20128 Milano (Italy)



EC REP

ily)

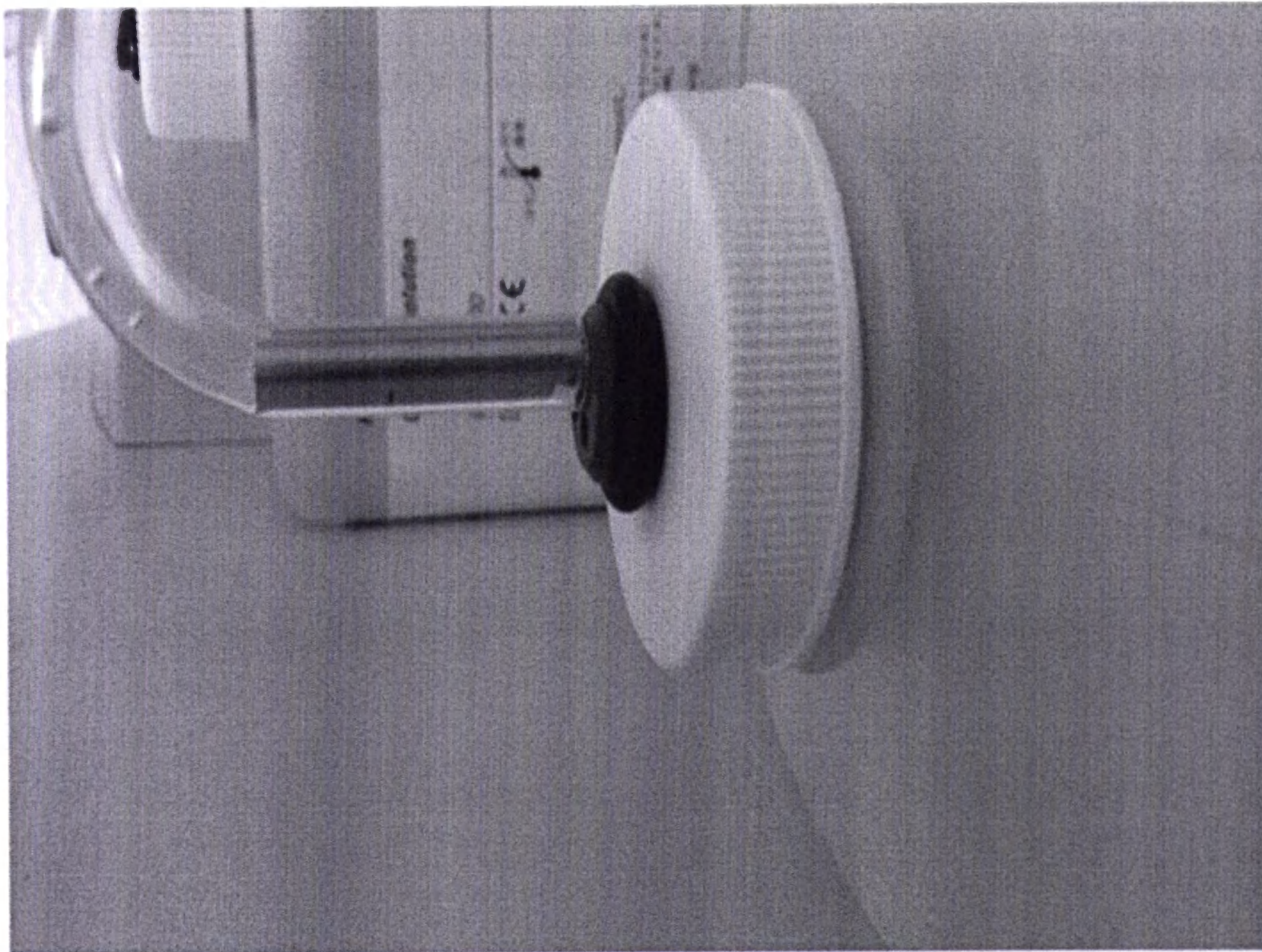


189600-00 R01

Instrumentation Laboratory INSTRUMENTATION LABORATORY
P/N: 00028713400
Rev: 07
Qty: 1 UN
Date Code: 1501

ASSY, 4L RINSE, ASPIRATOR, ACL TOP

18900-00 R01



Аспиратор моющего раствора для ACL TOP, 1 шт.



Instrumentation Laboratory

Bedford, MA 01730-3443 (USA)
Instrumentation Laboratory SpA - Via Monza 308 - 20128 Milano (Italy)

ASSY, CLEAN ASPIRATOR, ACL TOP

P/N: 00028713200

Rev: 06

Qty: 1 UN

Date Code: 1501



+HS020002871320018



+150180187

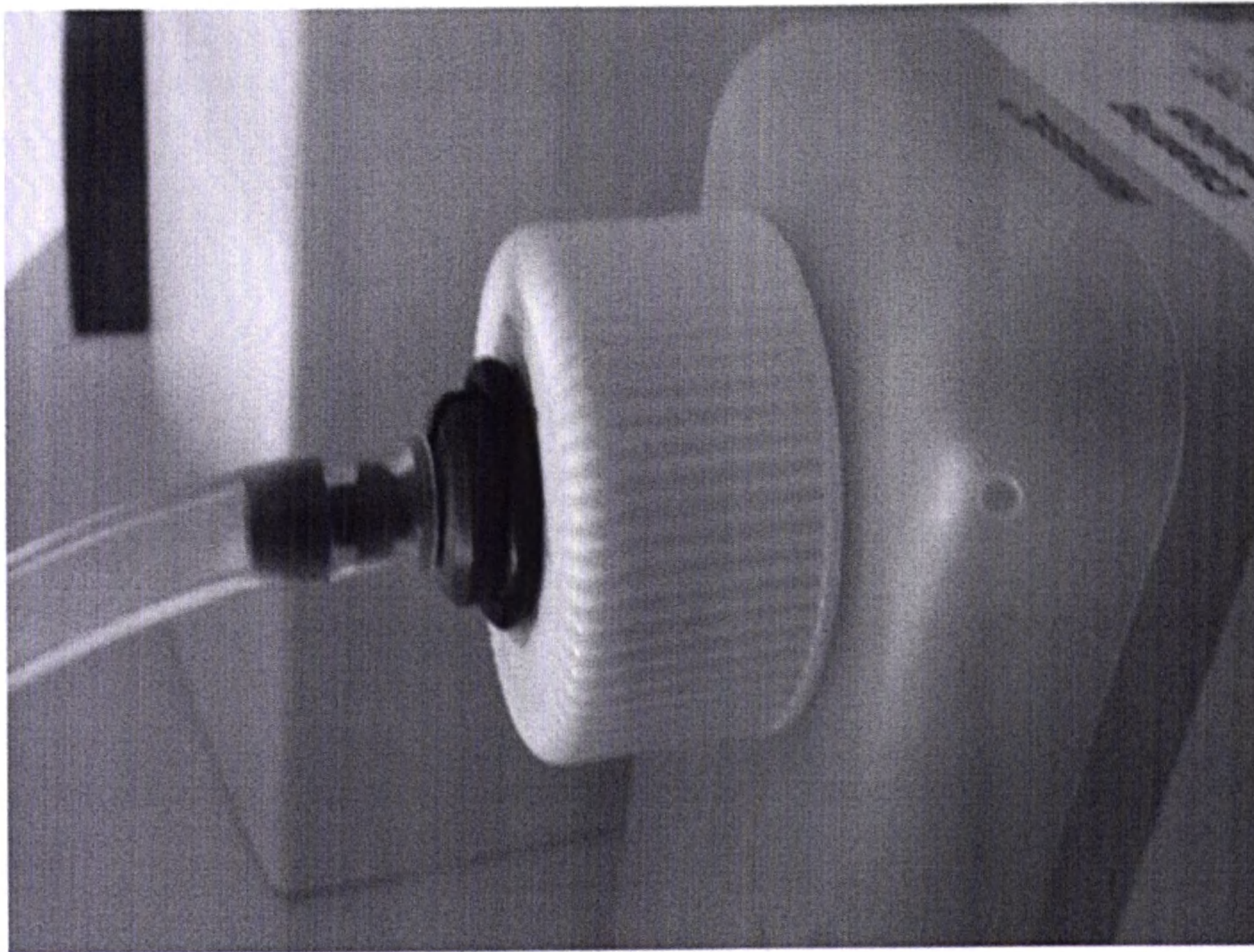


(815842695567853

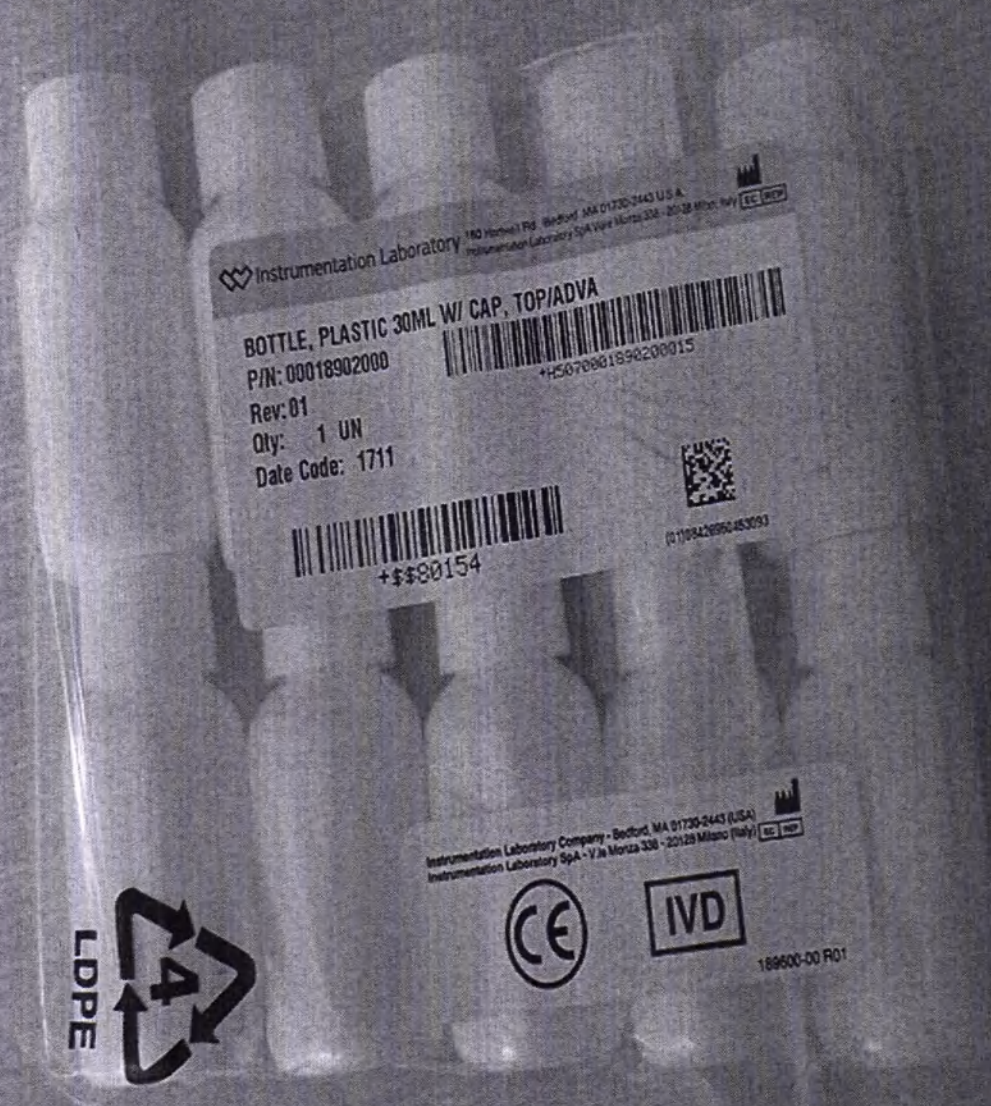
Instrumentation Laboratory Company - Bedford, MA 01730-3443 (USA)
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189600-00 R01



Пластиковые емкости 30 мл (с крышками), 10 шт.



Предохранители на 2А, 10 шт.

 Instrumentation Laboratory 180 Hartwell Rd., Bedford, MA 01730-2443 U.S.A.
Instrumentation Laboratory SpA Viale Monza 338 - 20128 Milan, Italy 

FUSE, 2.0AMP 250 VOLT, 682

P/N: 00014871705

Rev: 03

Qty: 10 PK

Date Code: 1710



+H5070001487170590

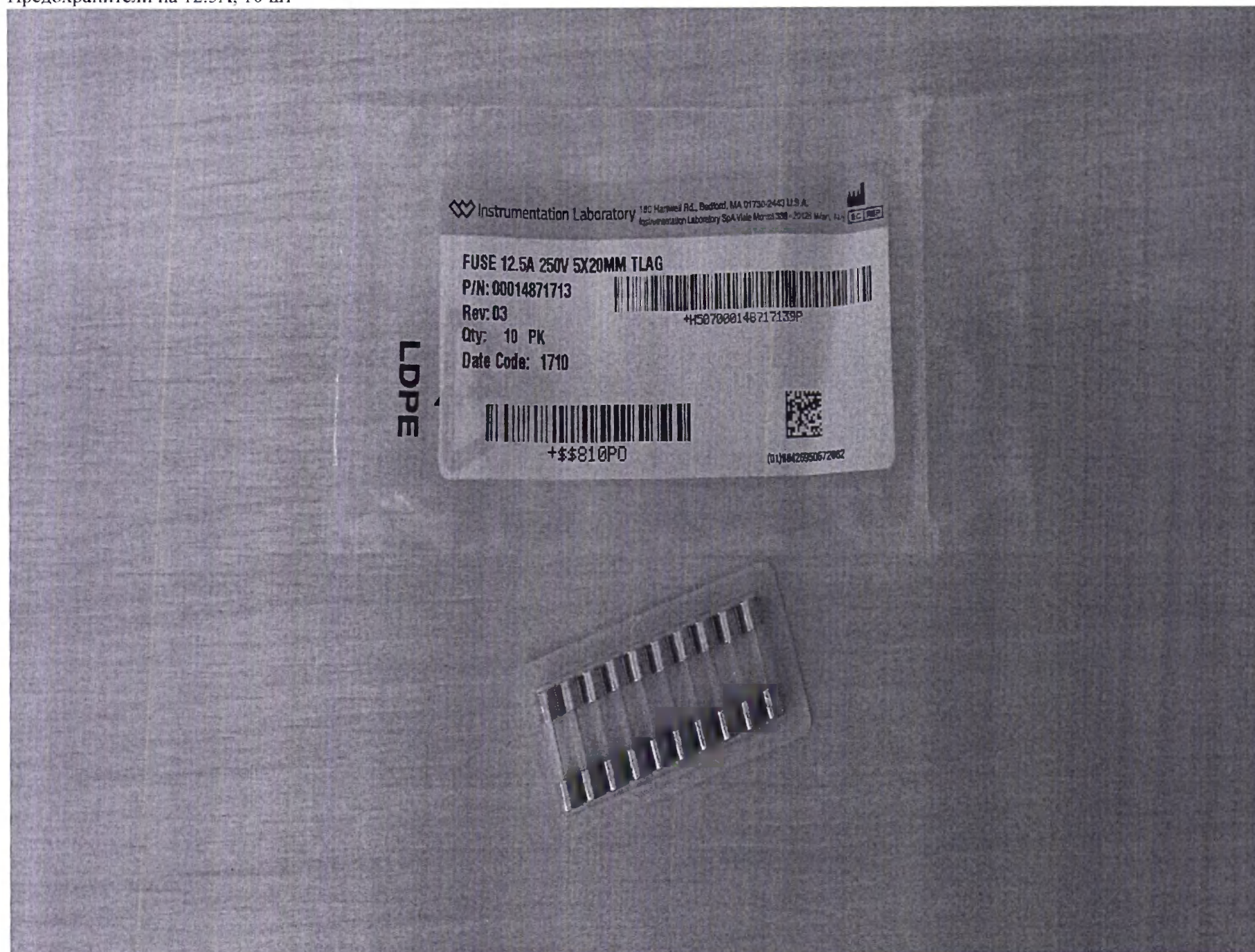


+\$810QP



(01)08426960572442

Предохранители на 12.5А, 10 шт



Предохранители на 4А, 10 шт



 Instrumentation Laboratory

180 Hawthell Rd., Bedford, MA 01730-2643 U.S.A.

Instrumentation Laboratory SpA Viale Monza 338 - 20128 Milan, Italy



FUSE 4A 250V 5X20MM TLAG

P/N: 00014871708

Rev: 03

Qty: 10 PK

Date Code: 1710



+H507000148717089T



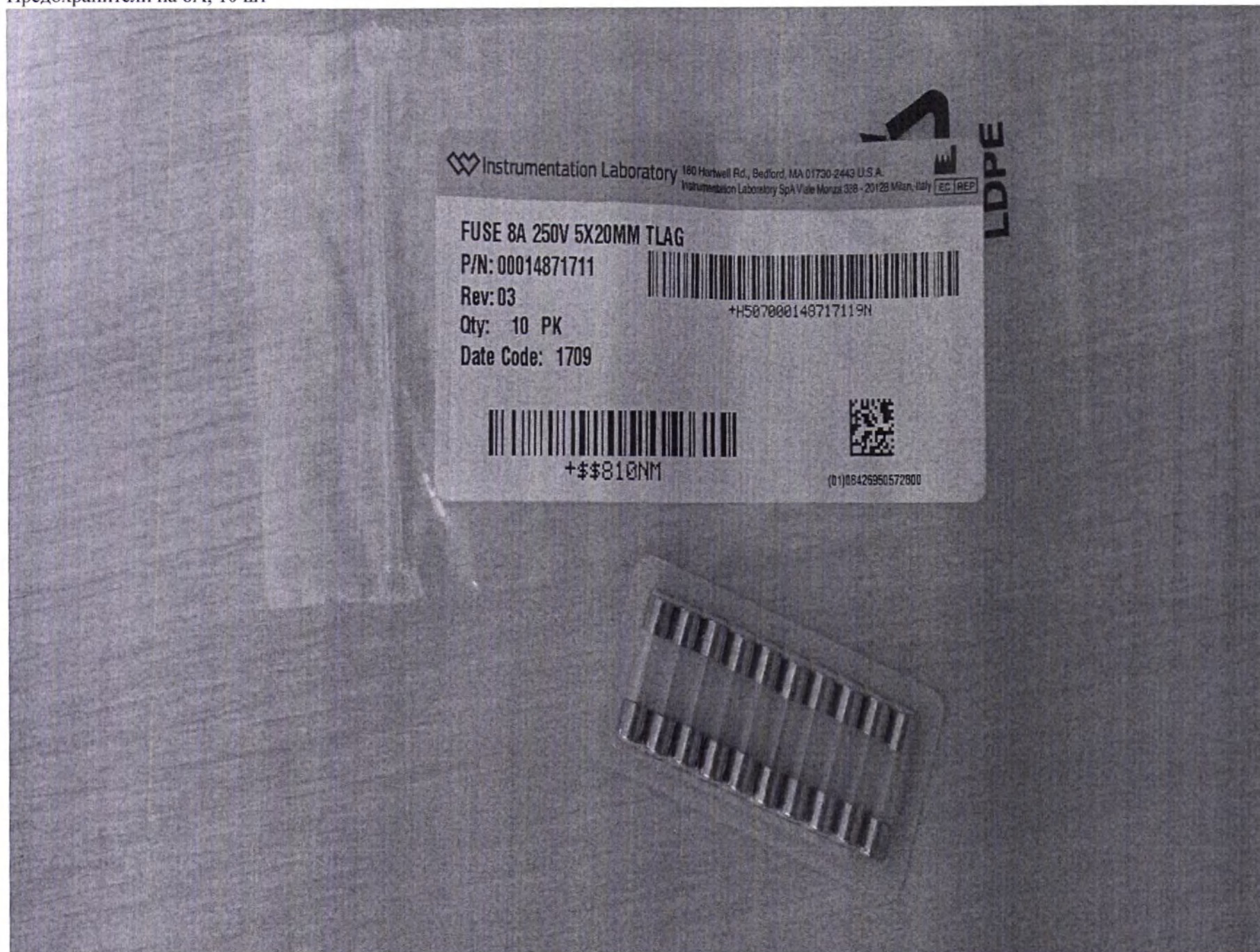
+\$810TS



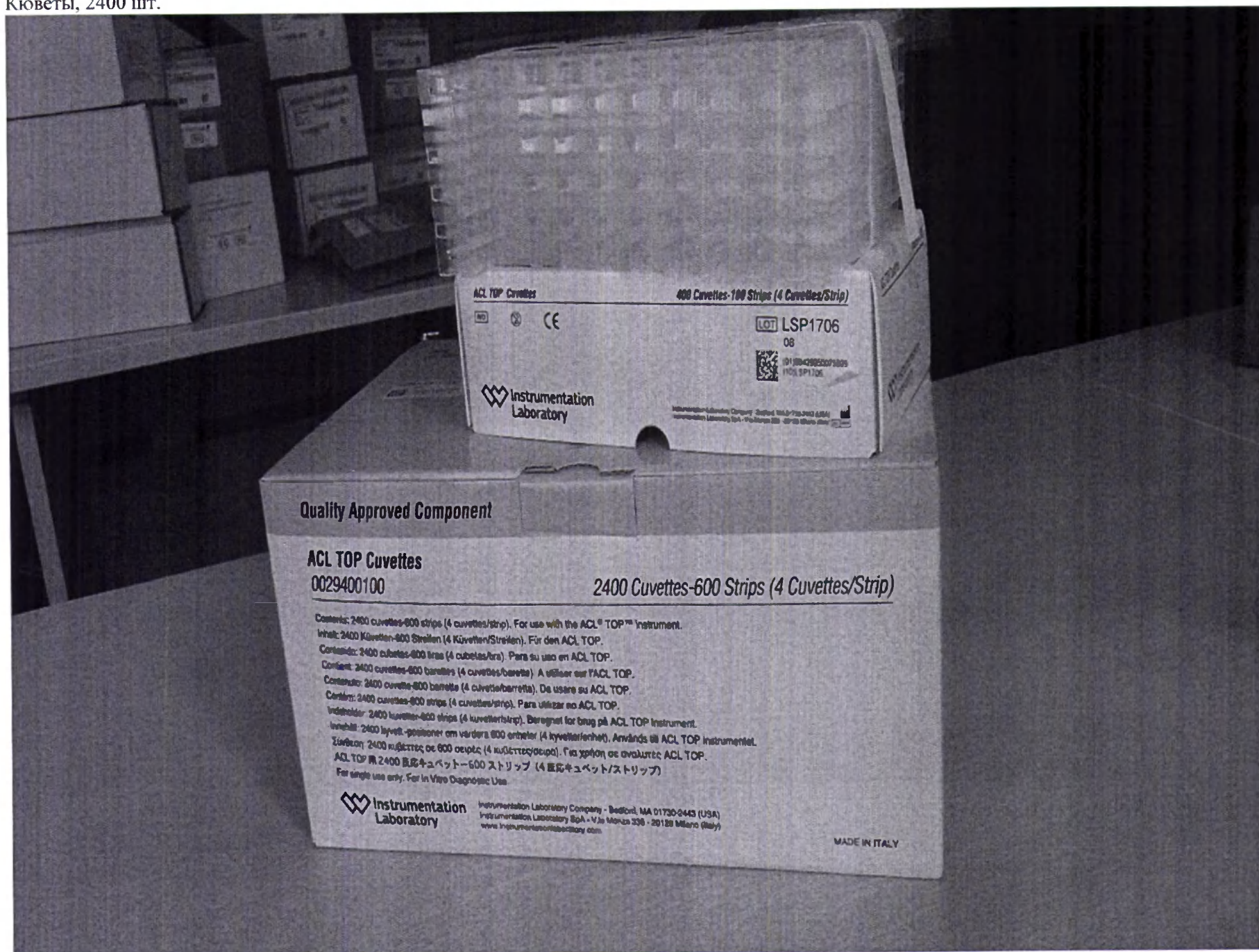
(01)08426950572367

FDPE

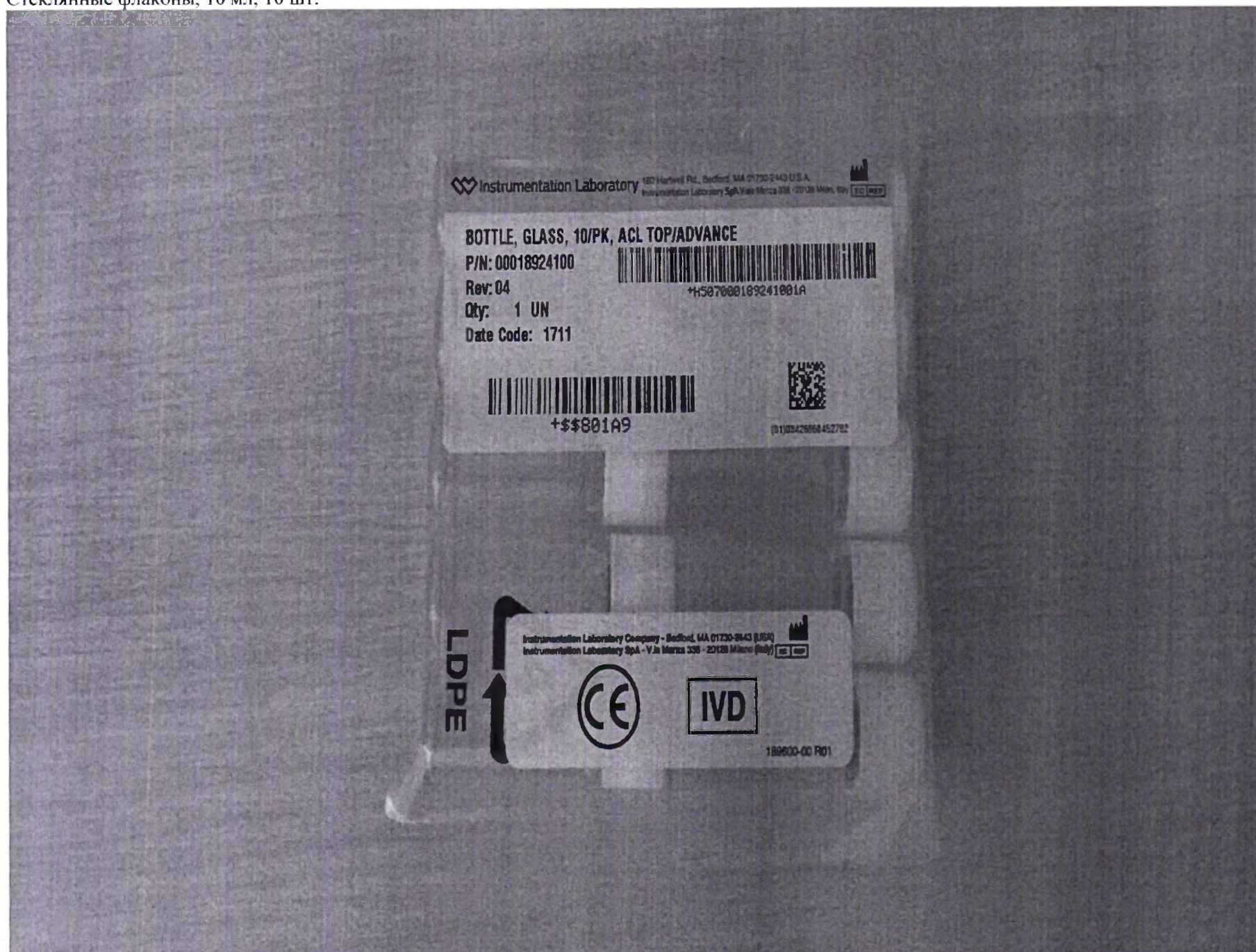
Предохранители на 8А, 10 шт



Кюветы, 2400 шт.



Стеклянные флаконы, 10 мл, 10 шт.

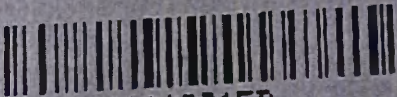


Стеклянные флаконы, 4 мл, 10 шт.

Instrumentation Laboratory 180 Harwell Rd., Bedford, MA 01730-2443 U.S.A.
Instrumentation Laboratory SpA Viale Monza 338 - 20128 Milano

BOTTLE KIT, 10X4 ML
P/N: 00018924104
Rev: 05
Qty: 1 UN
Date Code: 1710


+H507000189241041E


+\$\$\$801ED


(01)084269504521

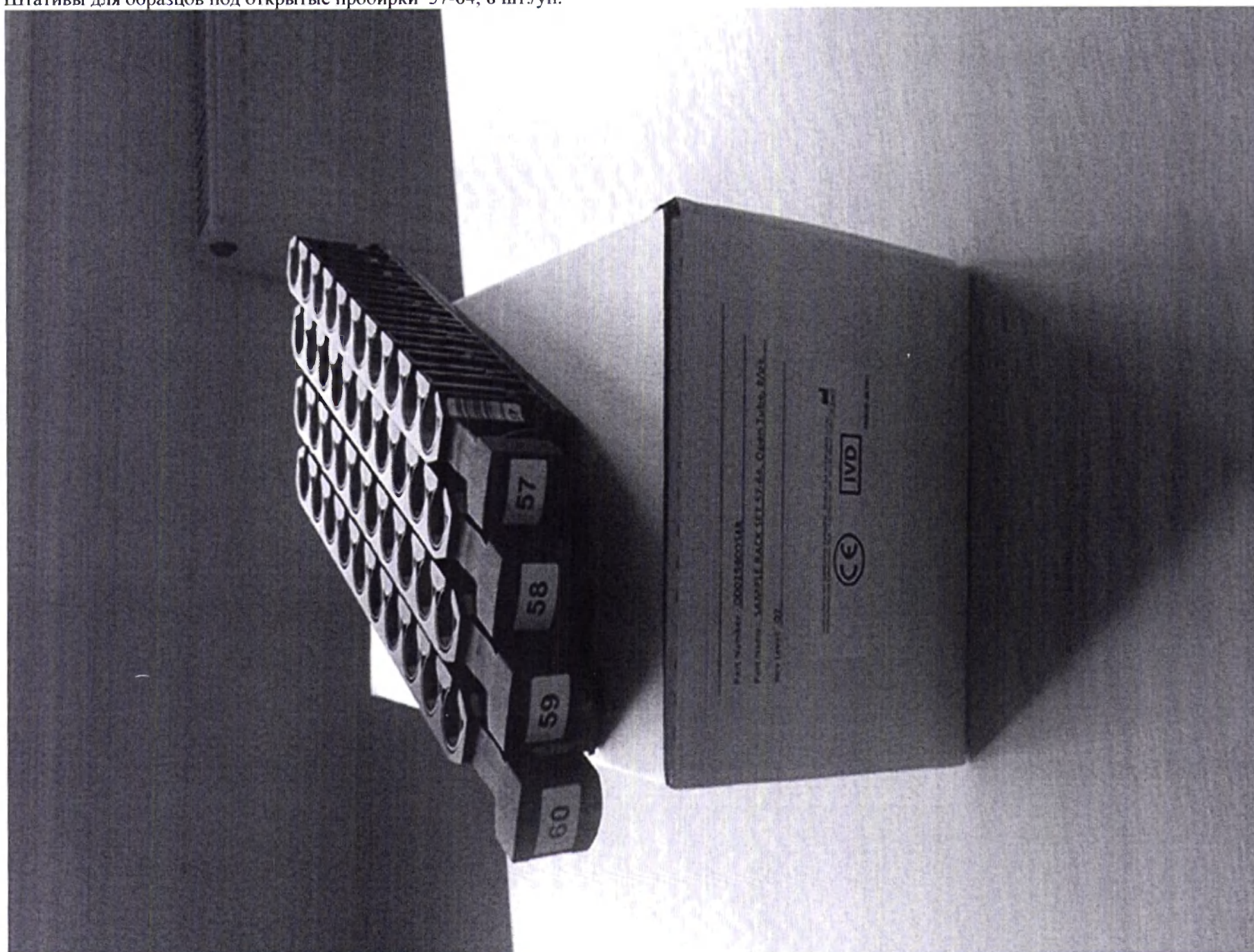
LDPE

Instrumentation Laboratory Company - Bedford, MA 01730-2443 (USA)
Instrumentation Laboratory SpA - V.le Monza 338 - 20128 Milano (Italy) 

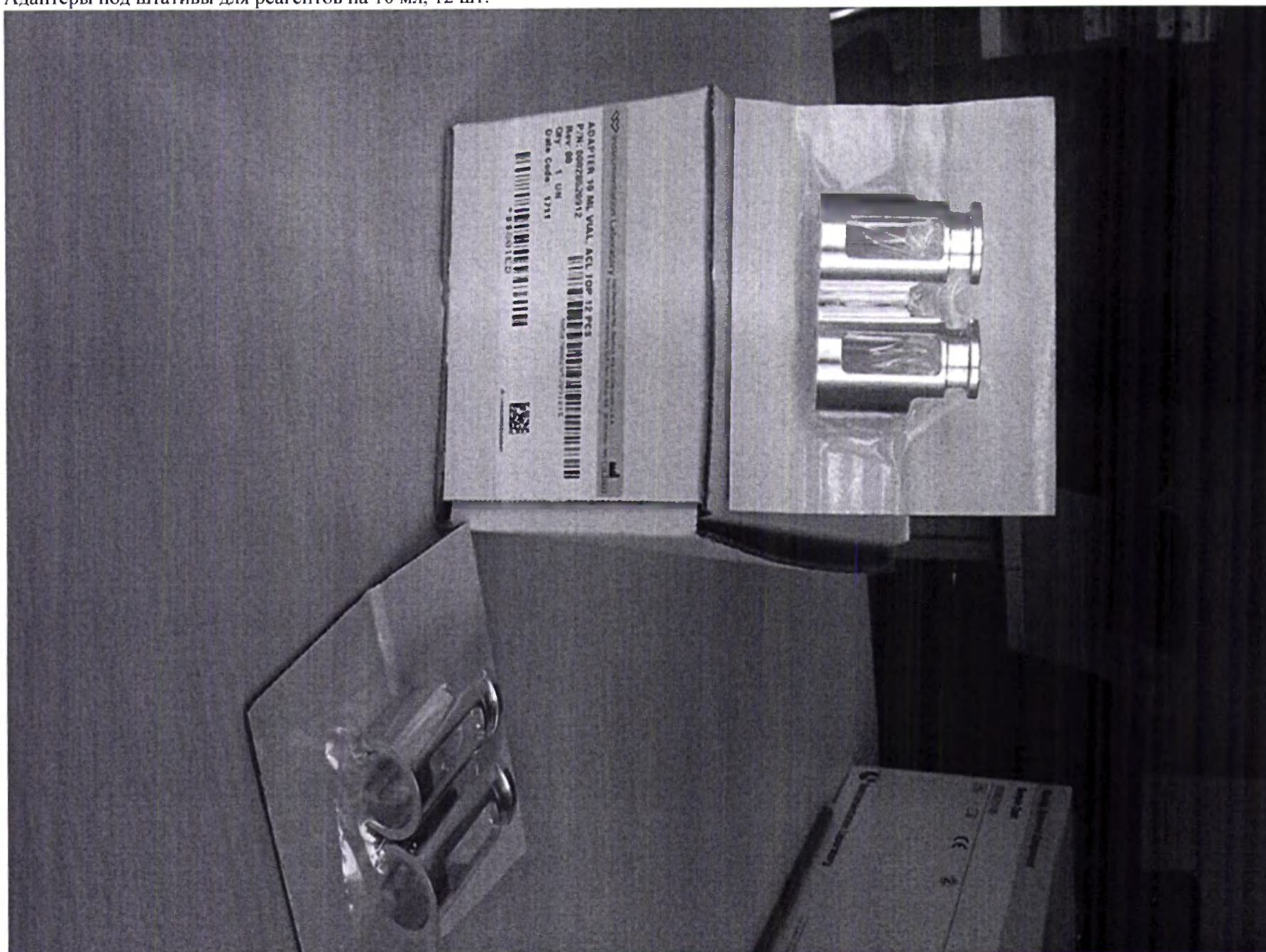
 

189600-00 R01

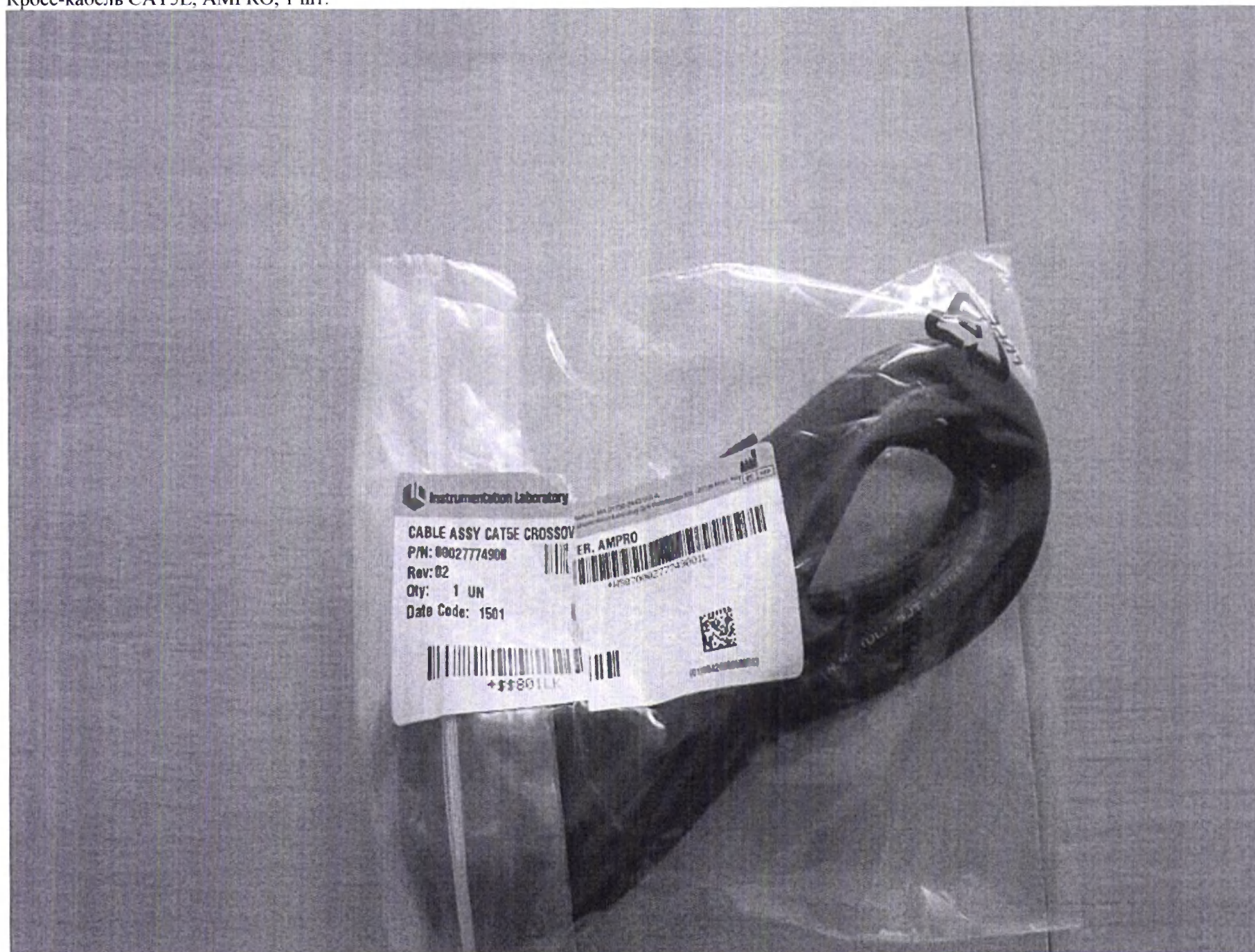
Штативы для образцов под открытые пробирки 57-64, 8 шт./уп.



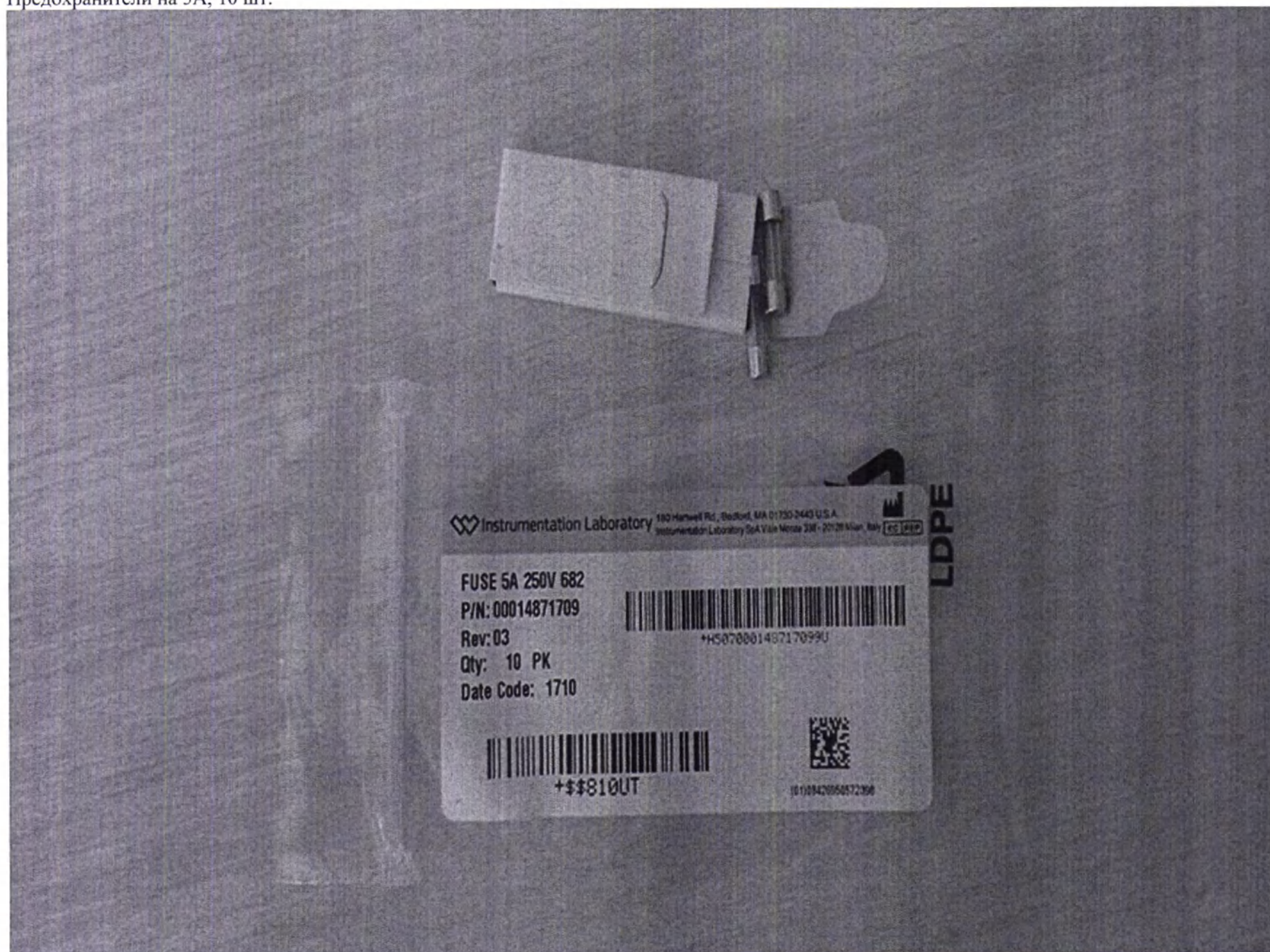
Адаптеры под штативы для реагентов на 10 мл, 12 шт.



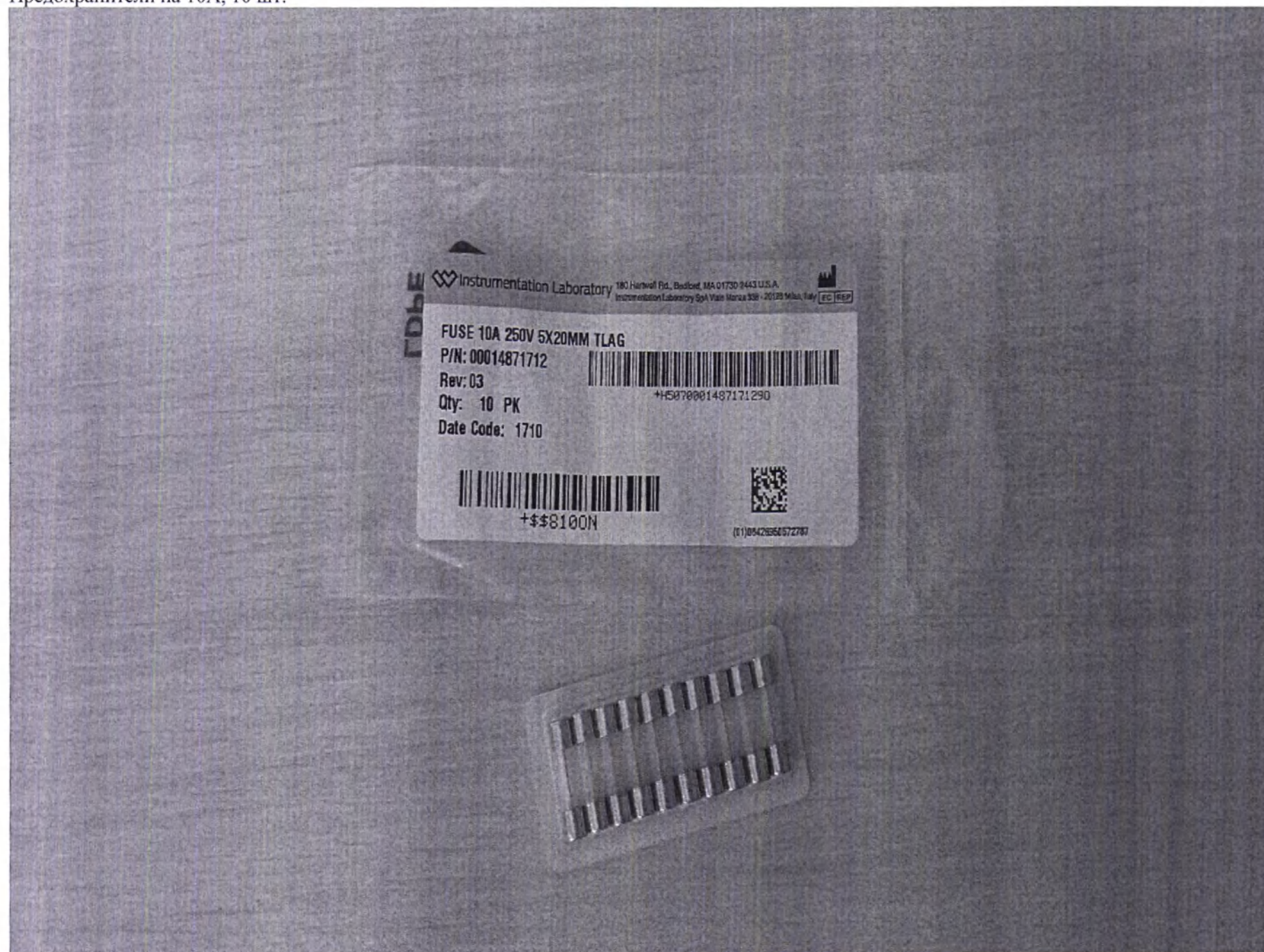
Кросс-кабель CAT5E, AMPRO, 1 шт.



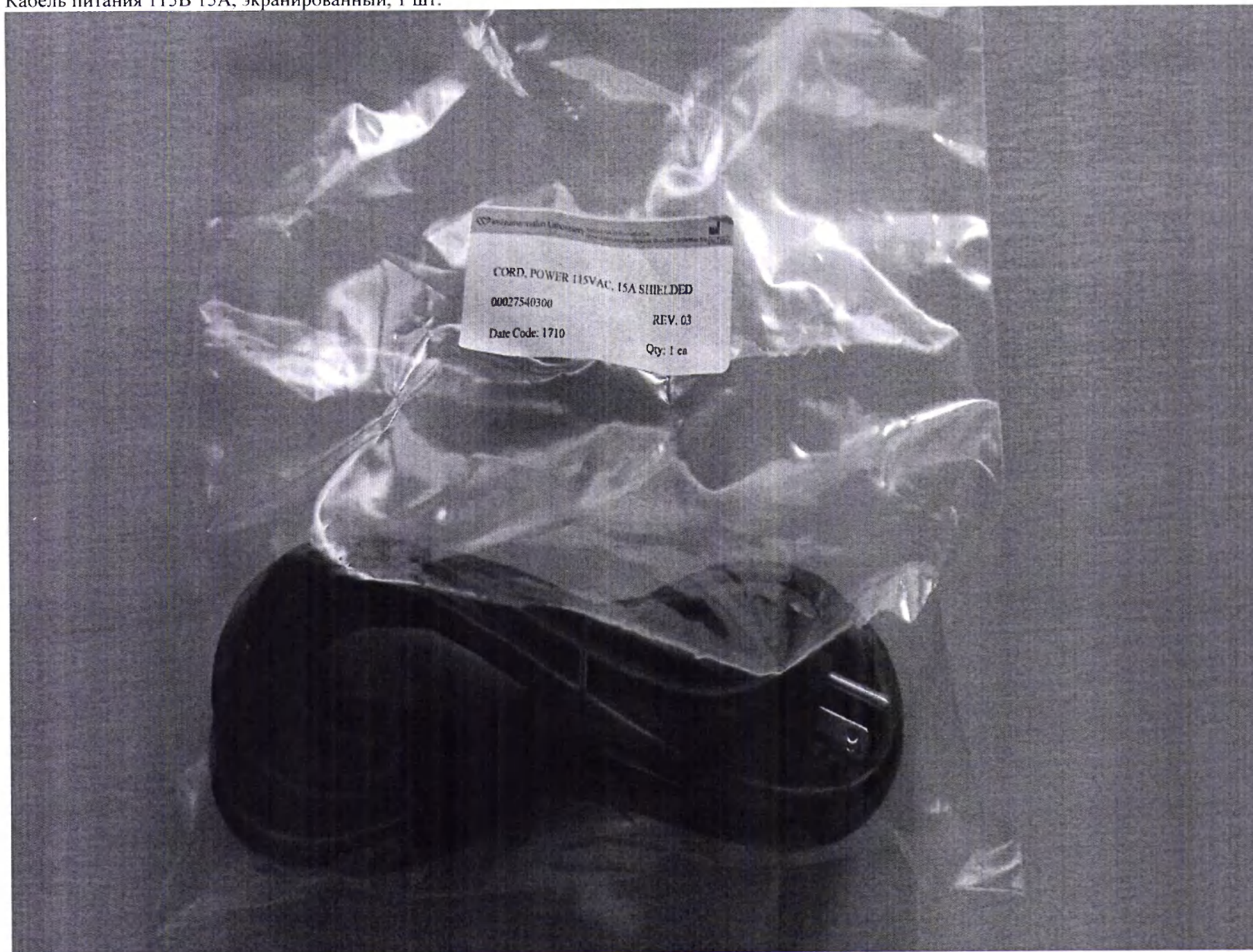
Предохранители на 5А, 10 шт.

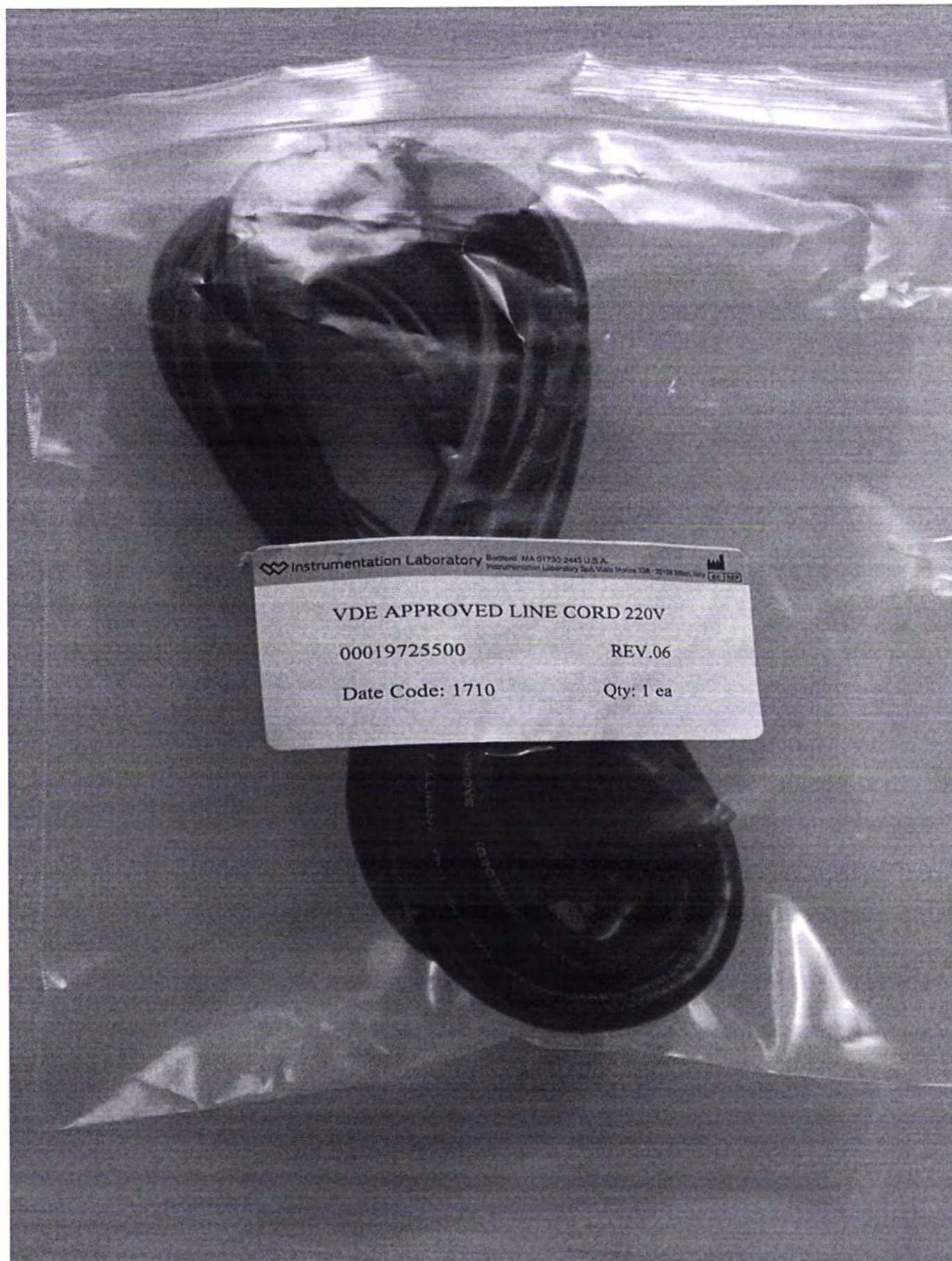


Предохранители на 10А, 10 шт.



Кабель питания 115В 15А, экранированный, 1 шт.





Instrumentation Laboratory
Burlington, MA 01730 2445 U.S.A.
Instrumentation Laboratory SpA Viale Marconi 138 - 20138 Milano, Italy

VDE APPROVED LINE CORD 220V

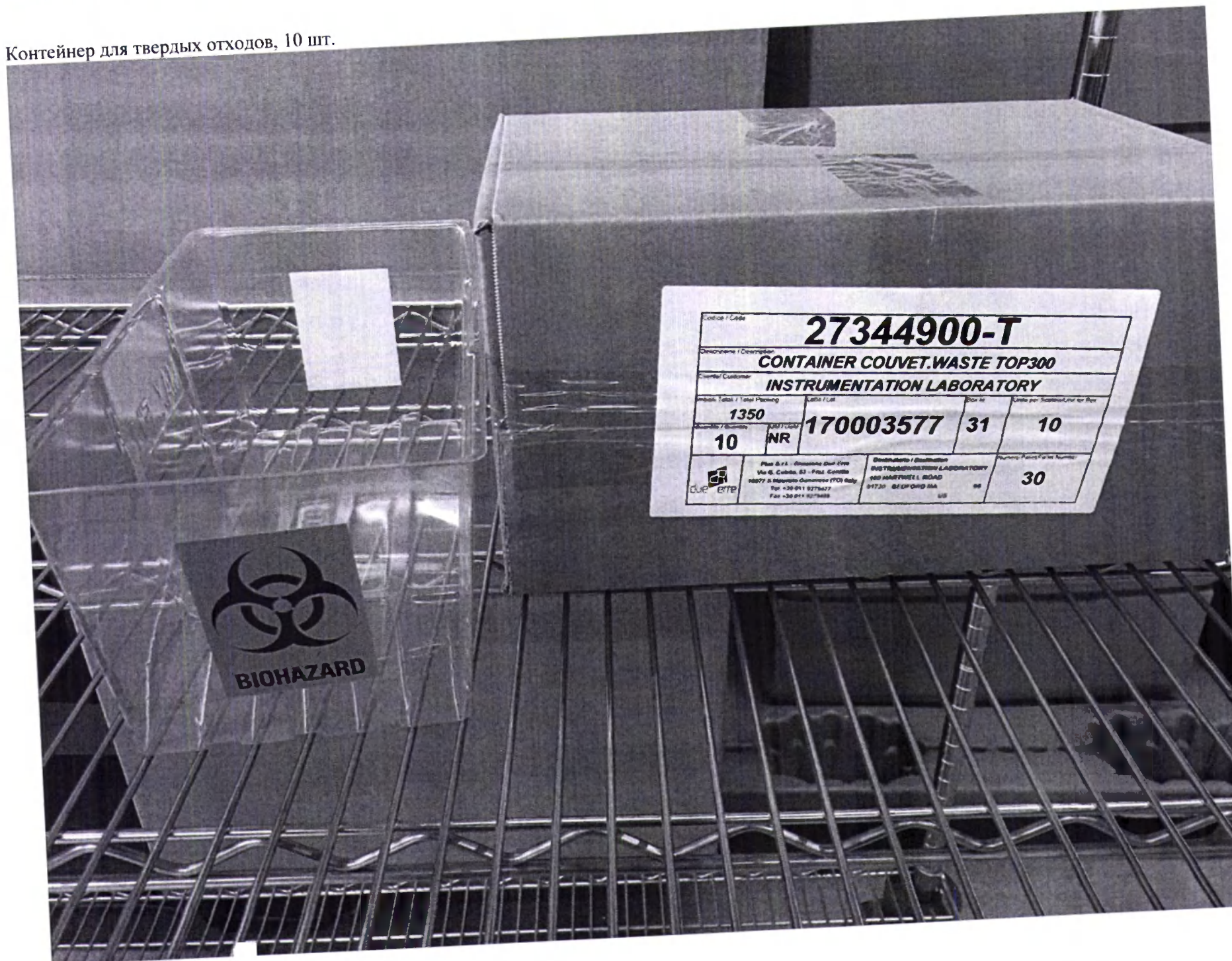
00019725500

REV.06

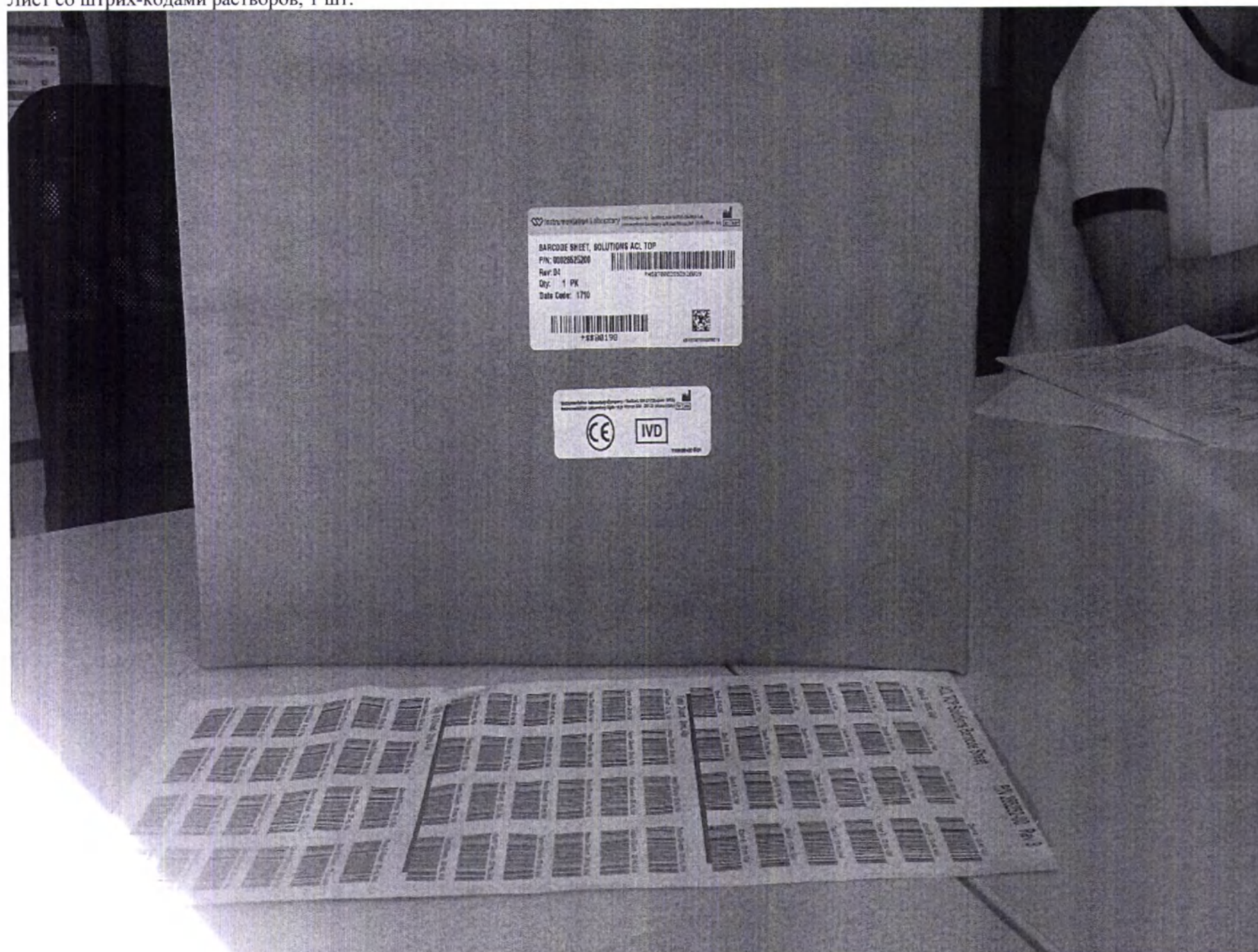
Date Code: 1710

Qty: 1 ea

Контейнер для твердых отходов, 10 шт.

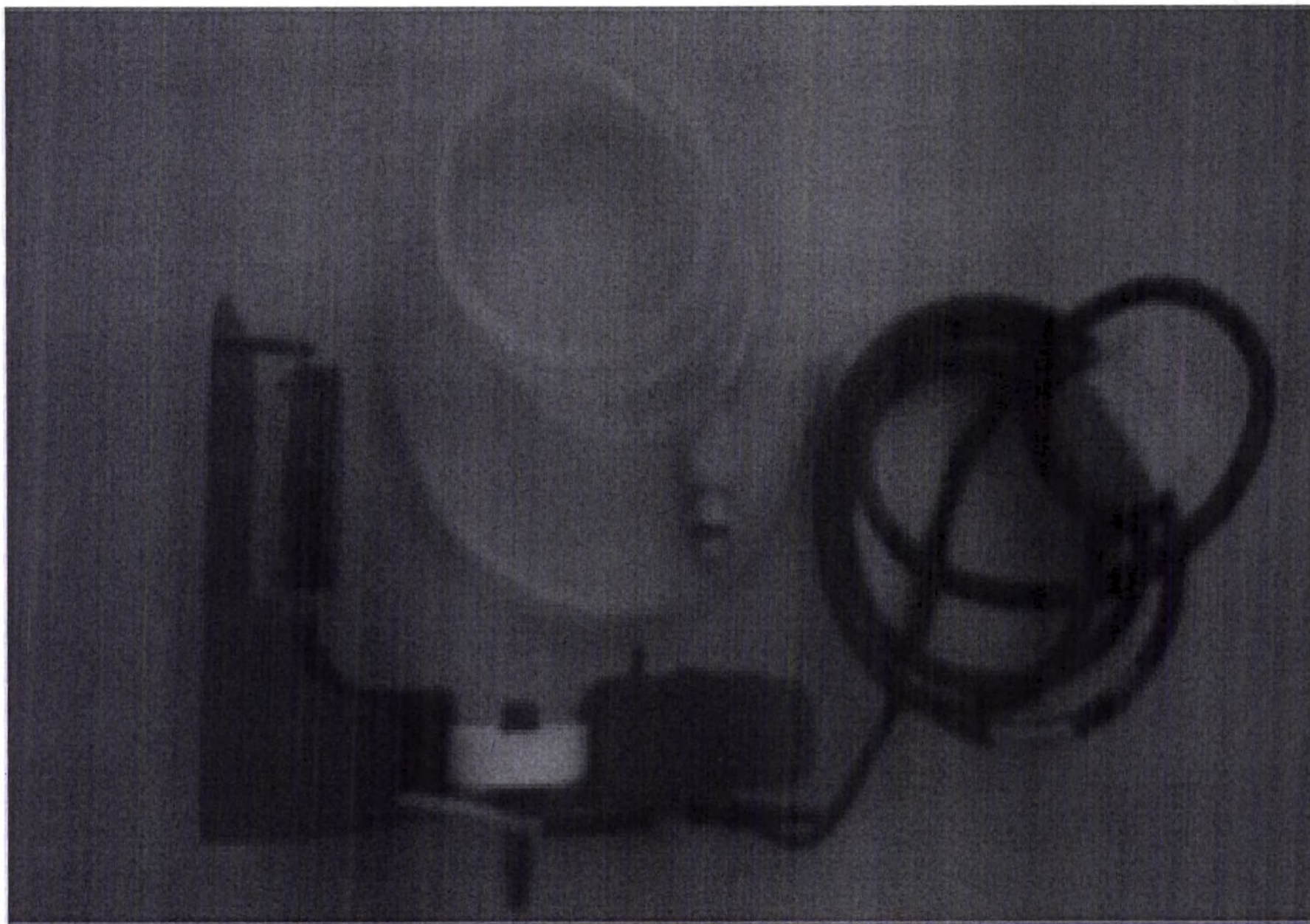


Лист со штрих-кодами растворов, 1 шт.

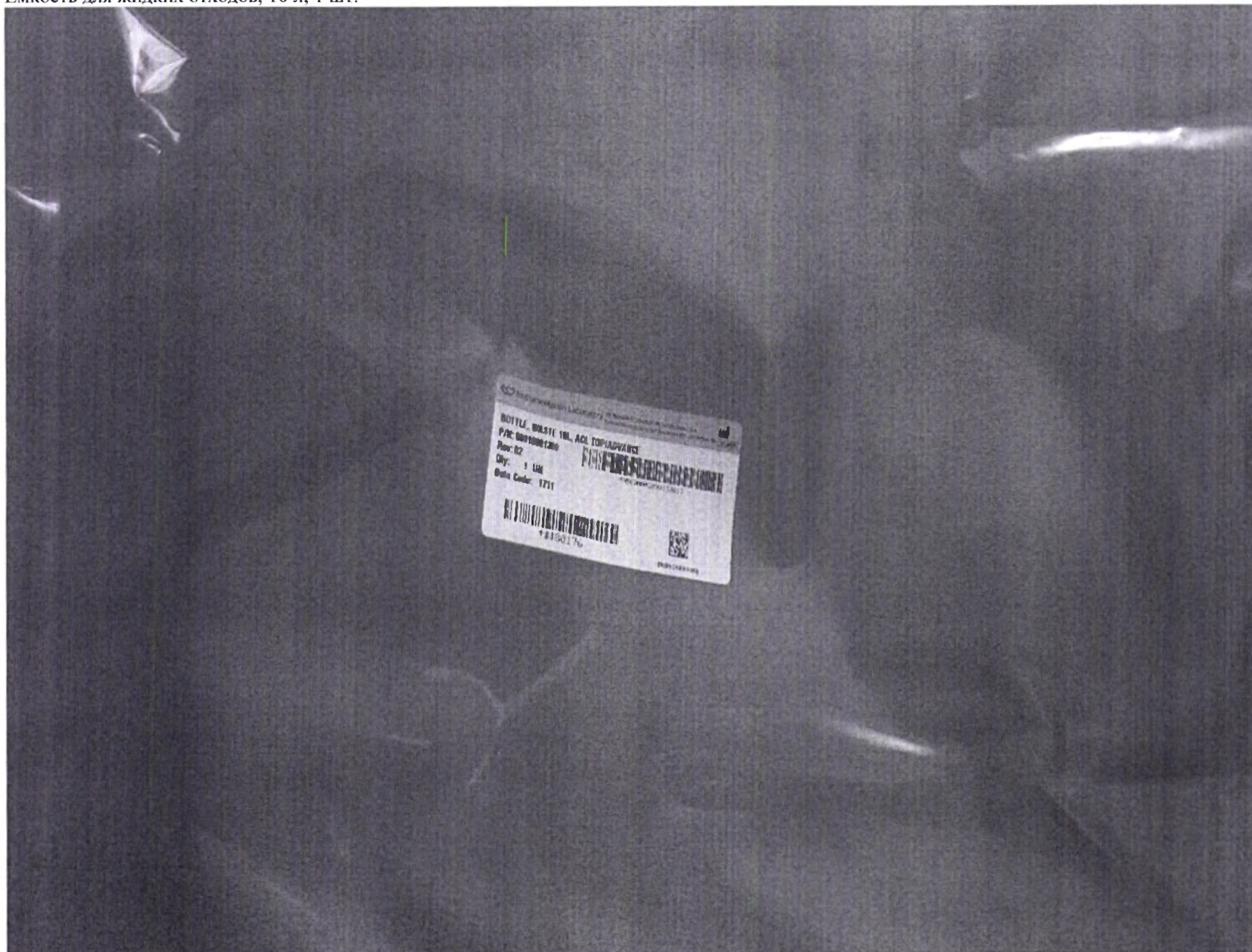


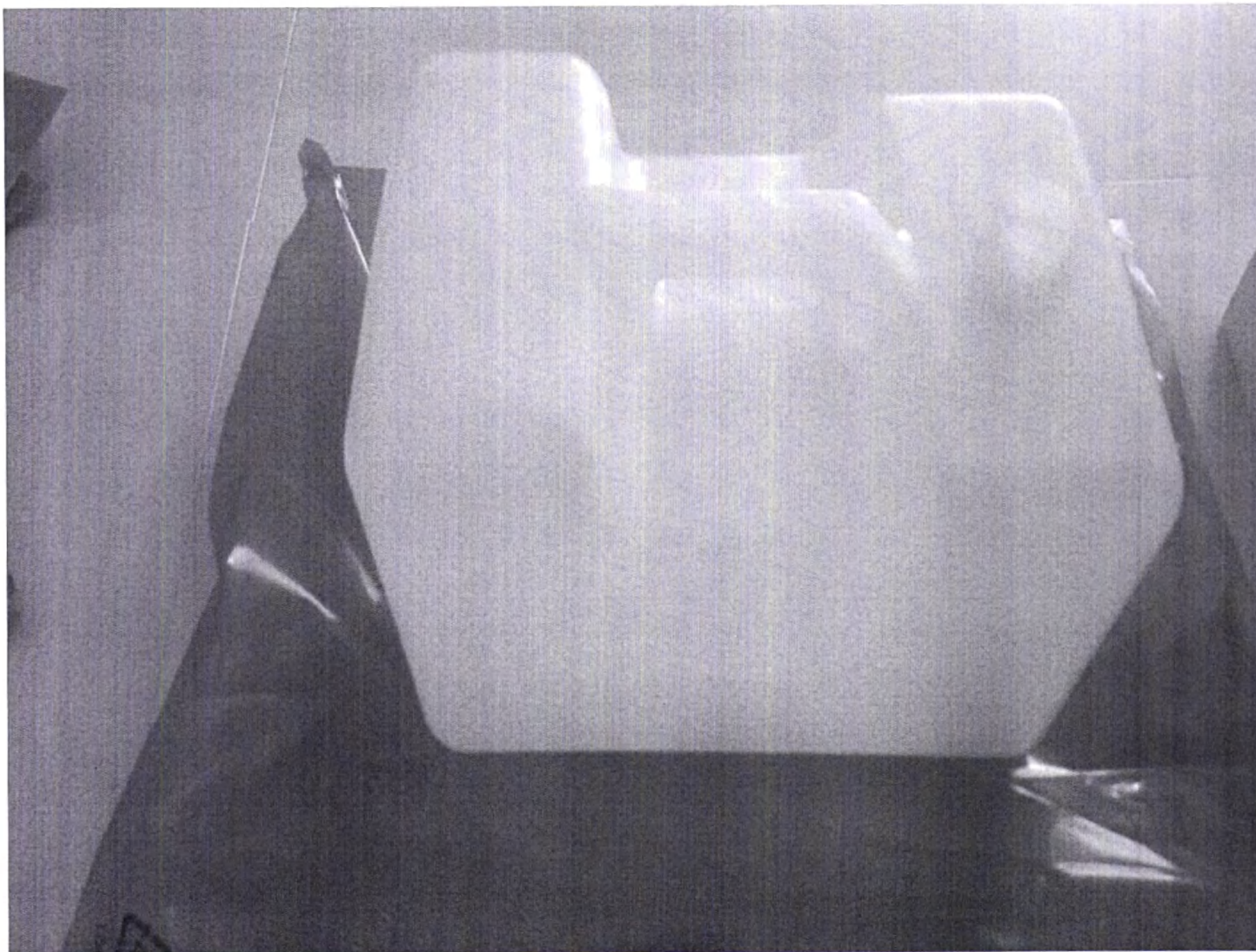
Датчик контейнера для жидких отходов, 1 шт.



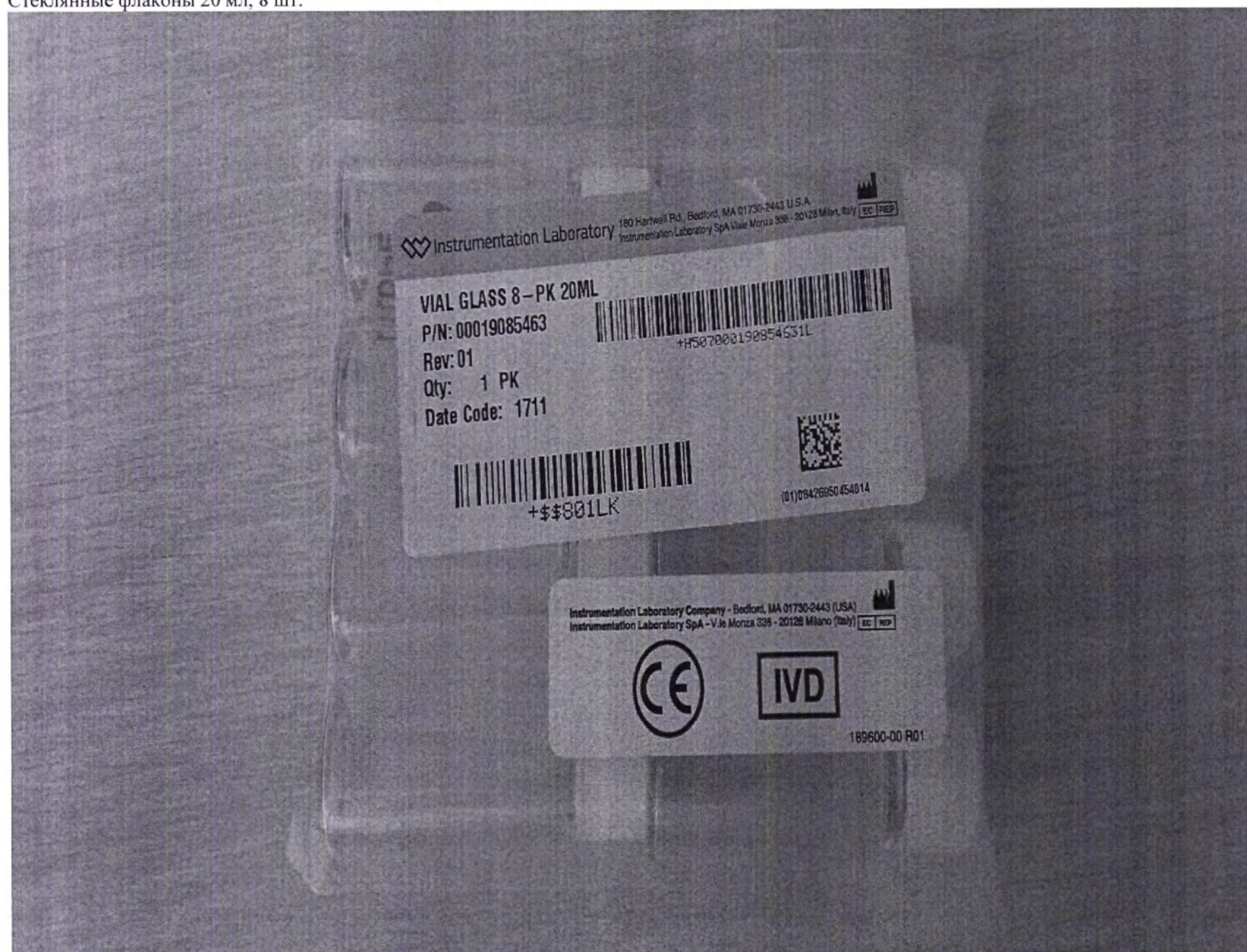


Емкость для жидких отходов, 10 л, 1 шт.





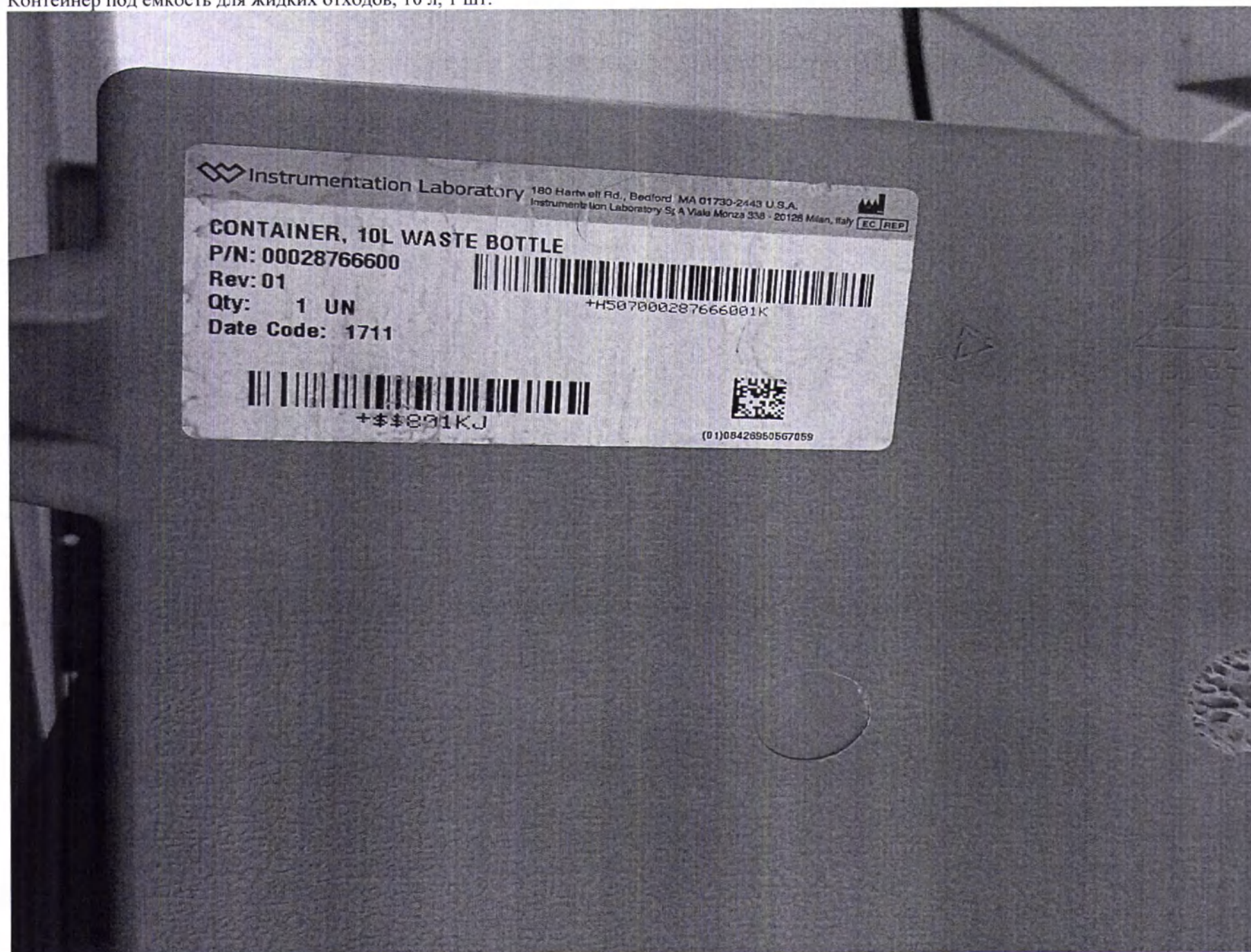
Стеклянные флаконы 20 мл, 8 шт.



Адаптеры под штативы для образцов: адаптеры для аликвотных пробирок, 5 шт.; адаптеры для педиатрических пробирок, 5шт.

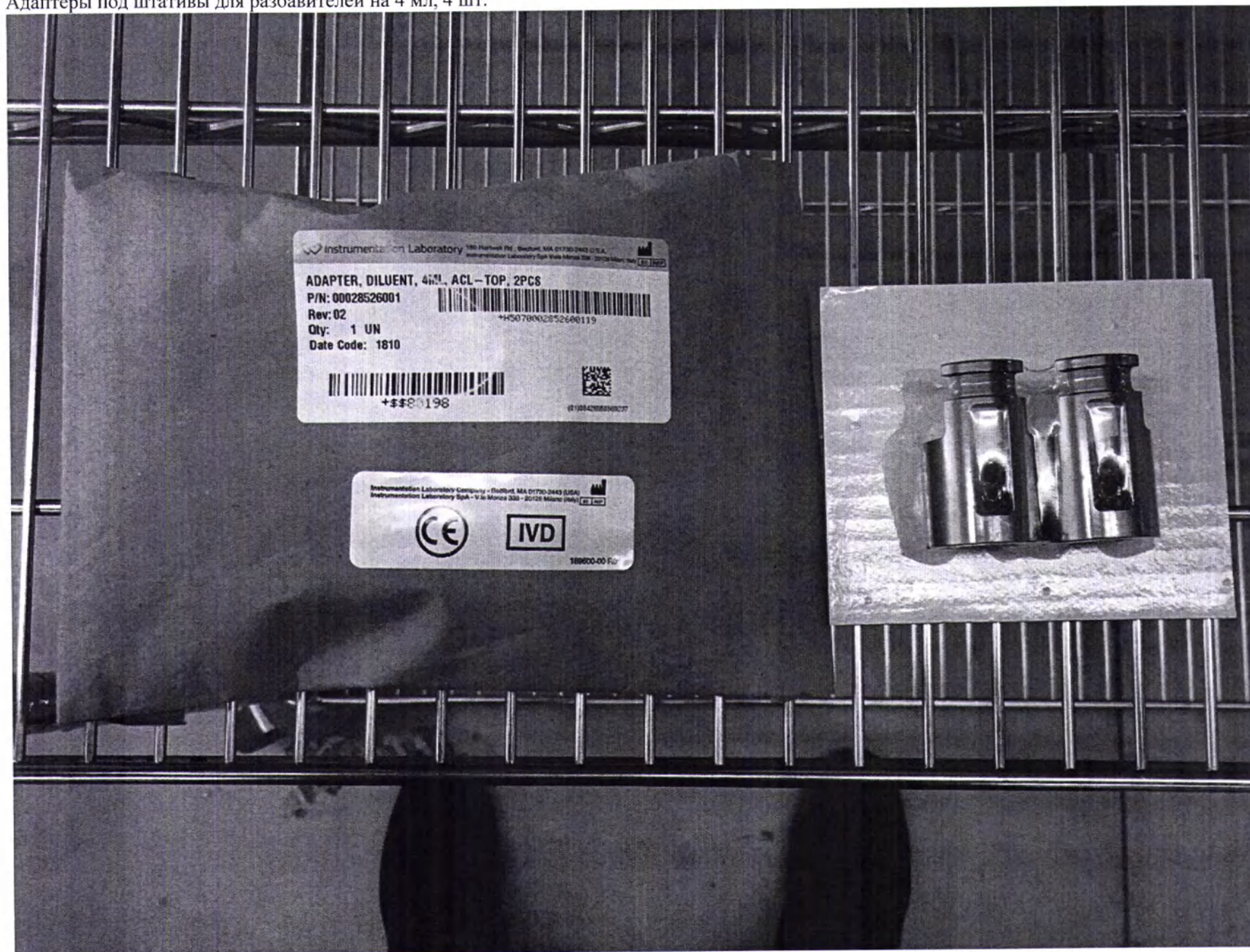


Контейнер под емкость для жидких отходов, 10 л, 1 шт.

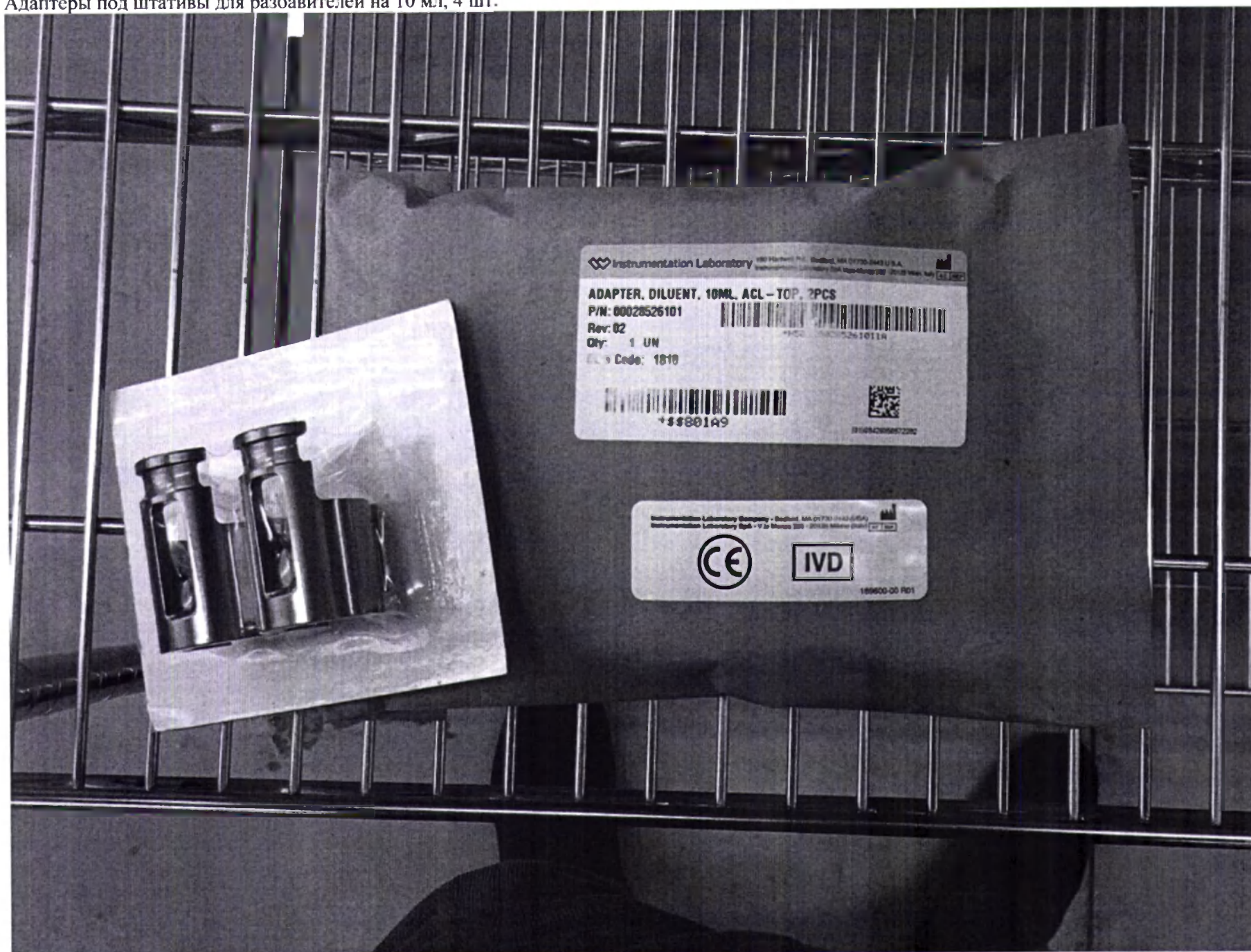




Адаптеры под штативы для разбавителей на 4 мл, 4 шт.



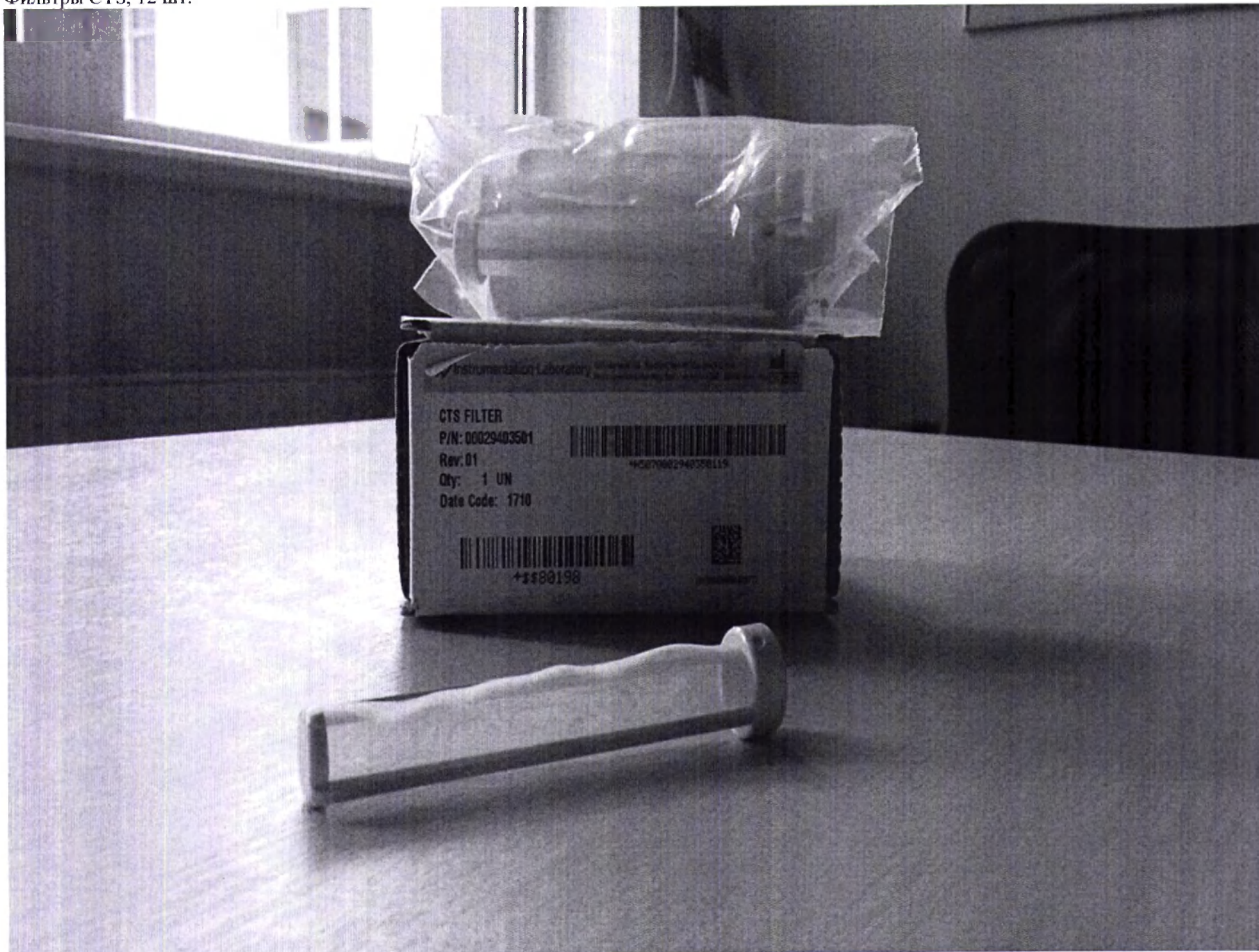
Адаптеры под штативы для разбавителей на 10 мл, 4 шт.



Адаптеры под штативы для разбавителей на 20 мл, 4 шт.



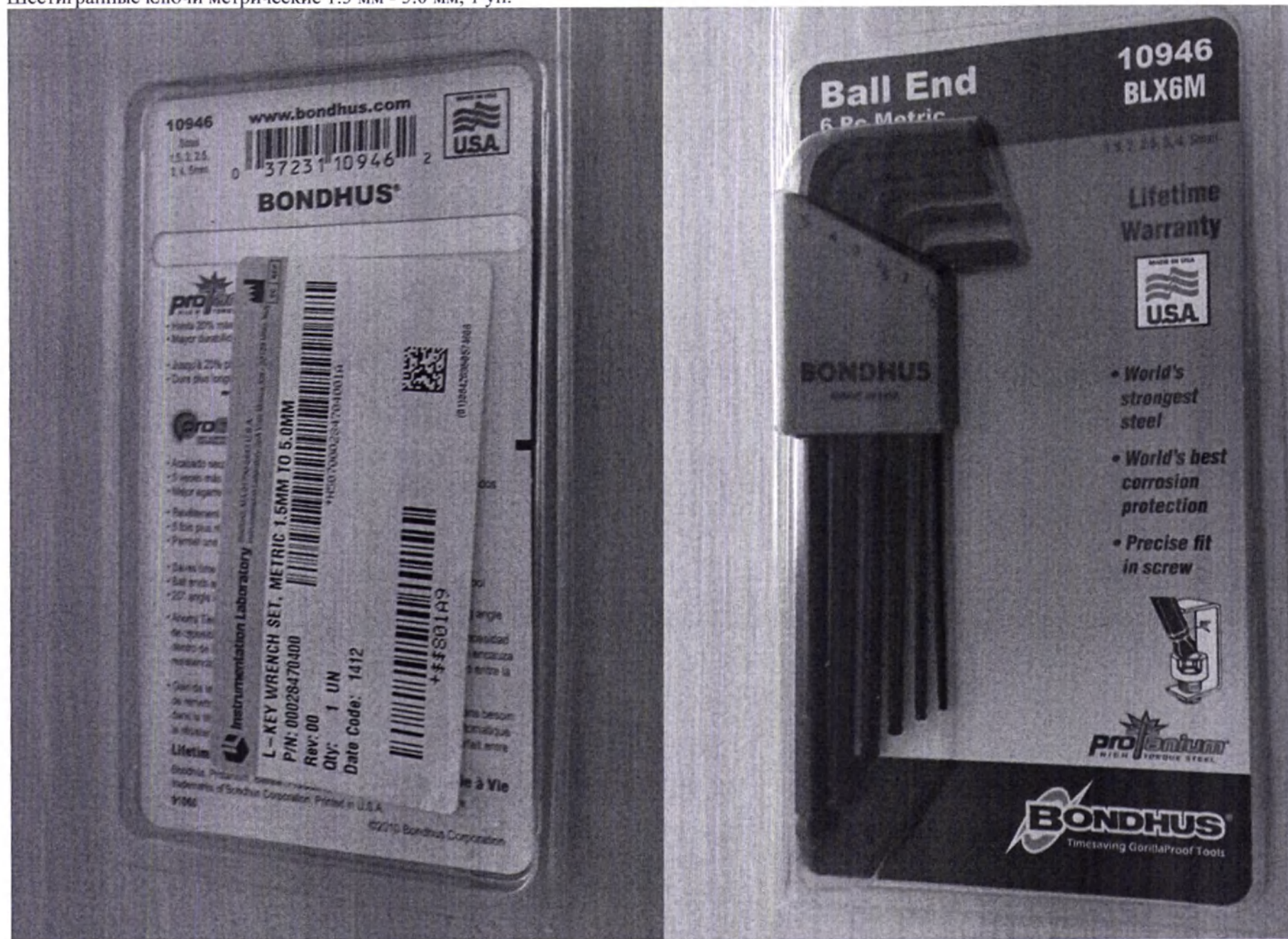
Фильтры CTS, 12 шт.



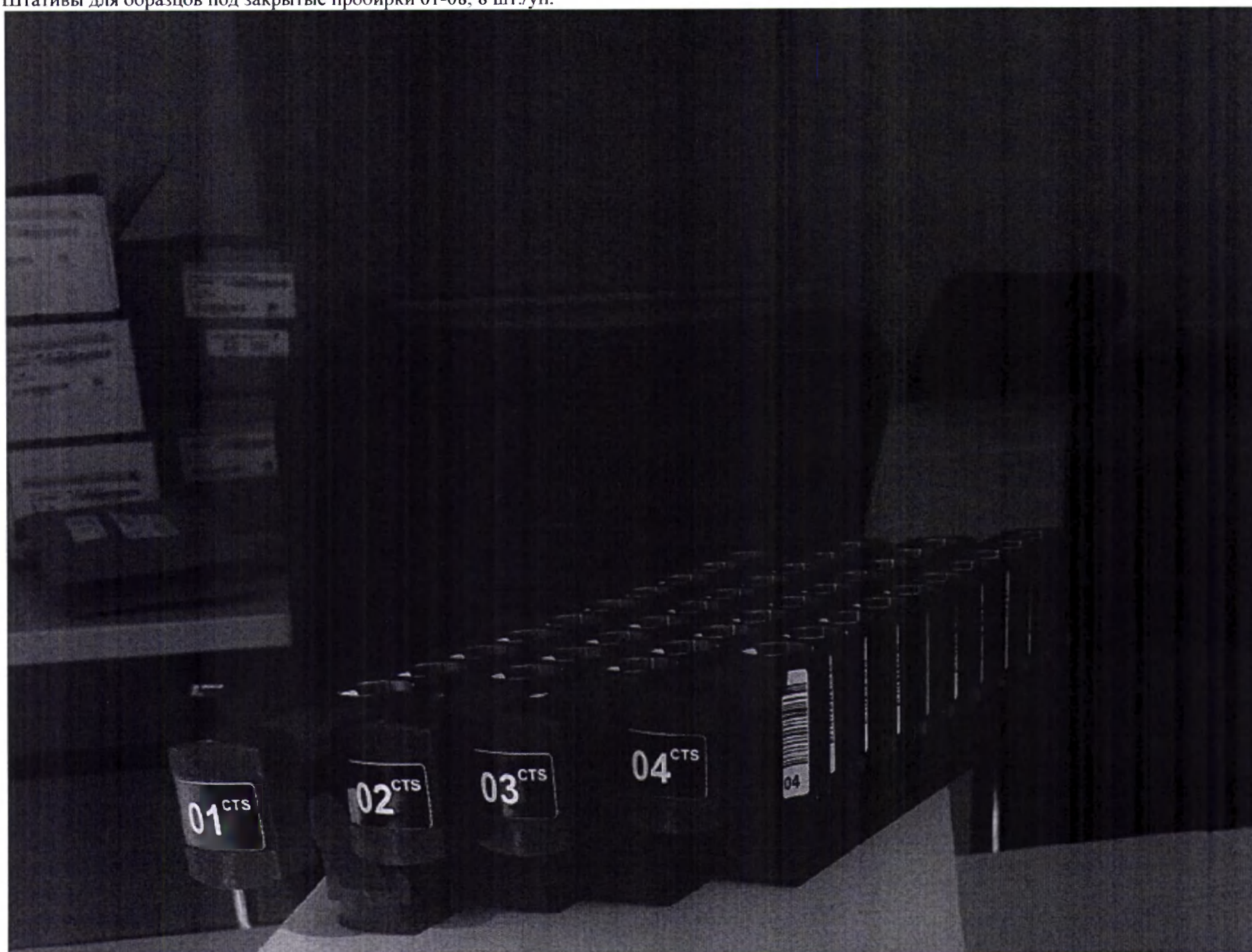
Набор для замены прокалывателя CTS: прокалыватель, 1 шт.; винт, 1 шт.; кольца, 6 шт. (при необходимости)



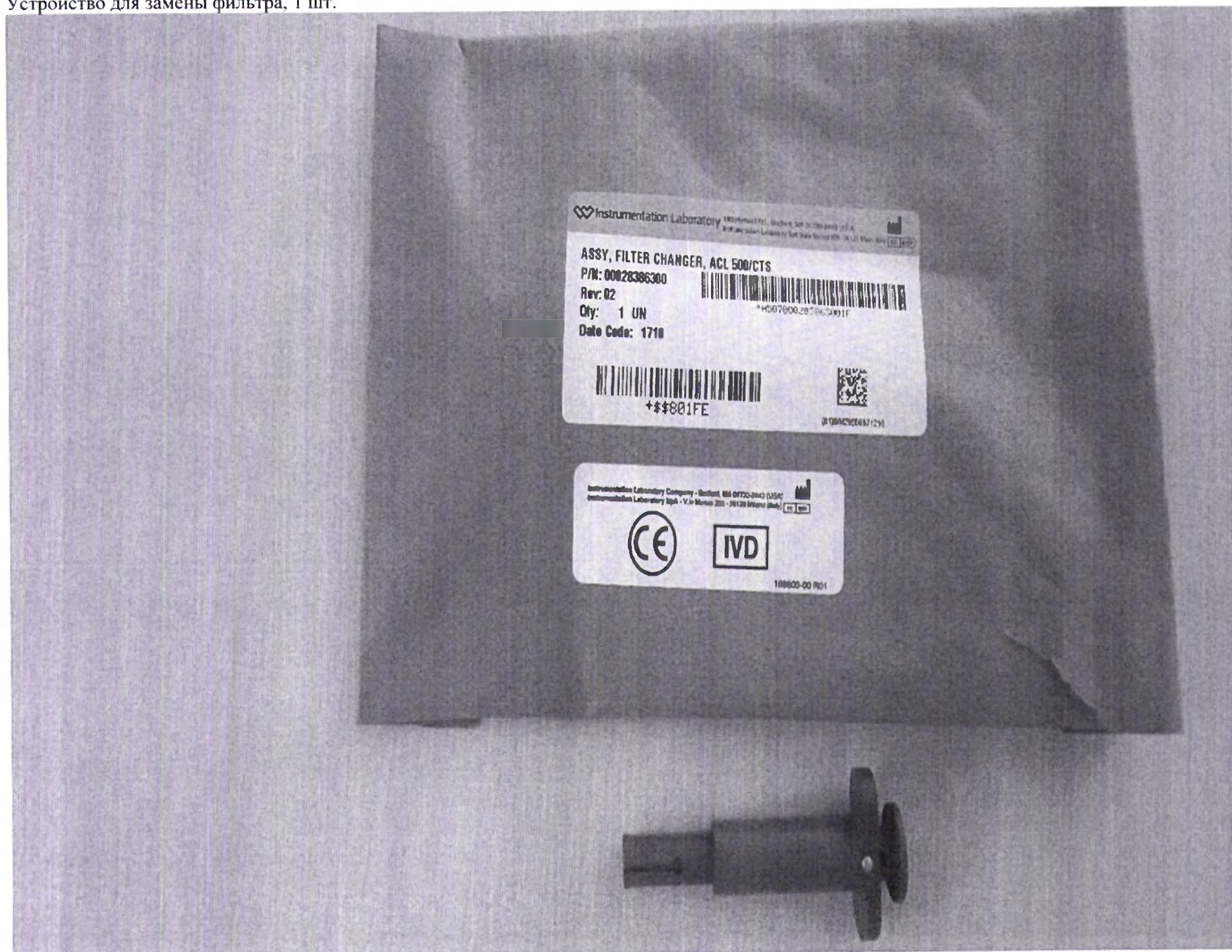
Шестигранные ключи метрические 1.5 мм - 5.0 мм, 1 уп.



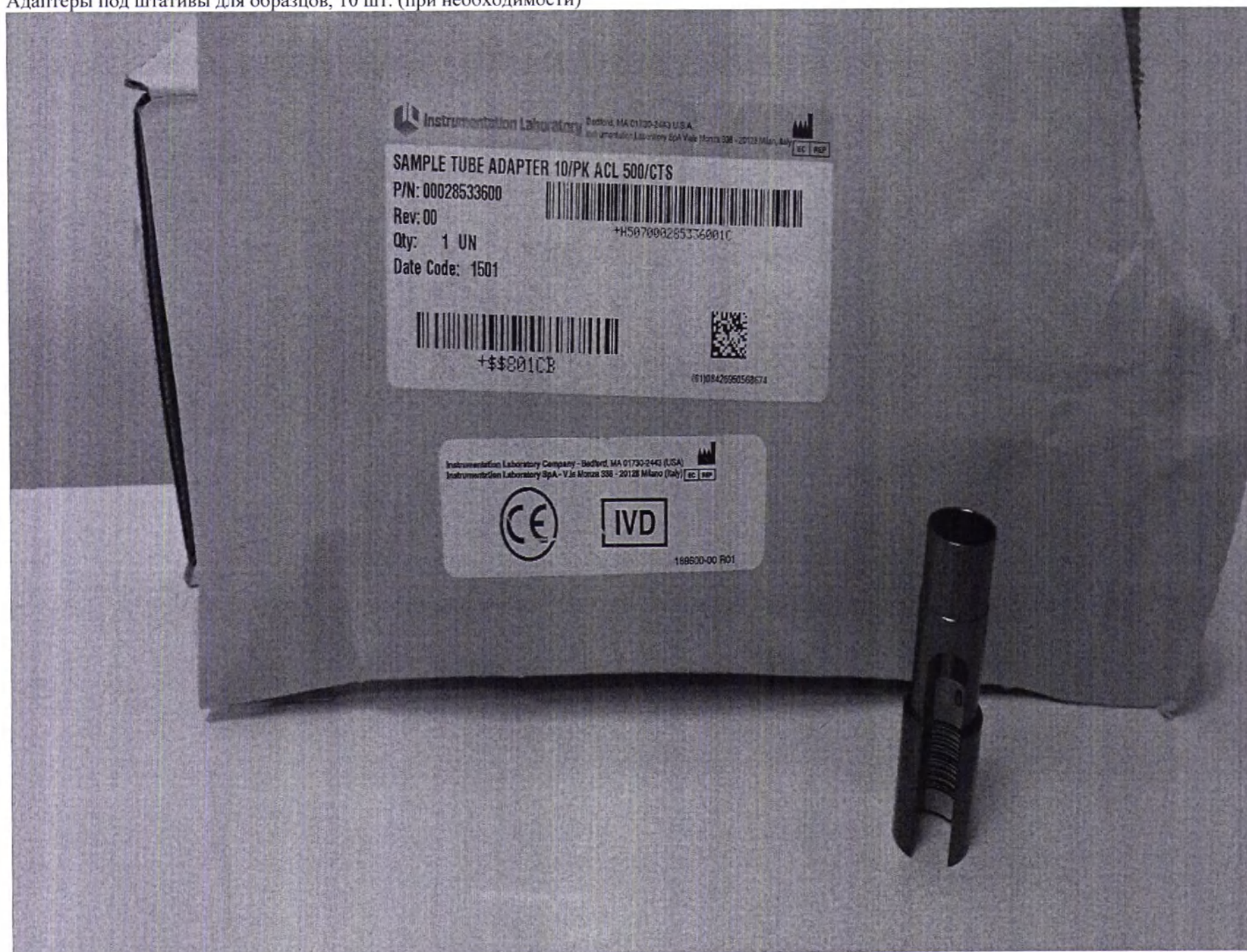
Штативы для образцов под закрытые пробирки 01-08, 8 шт./уп.



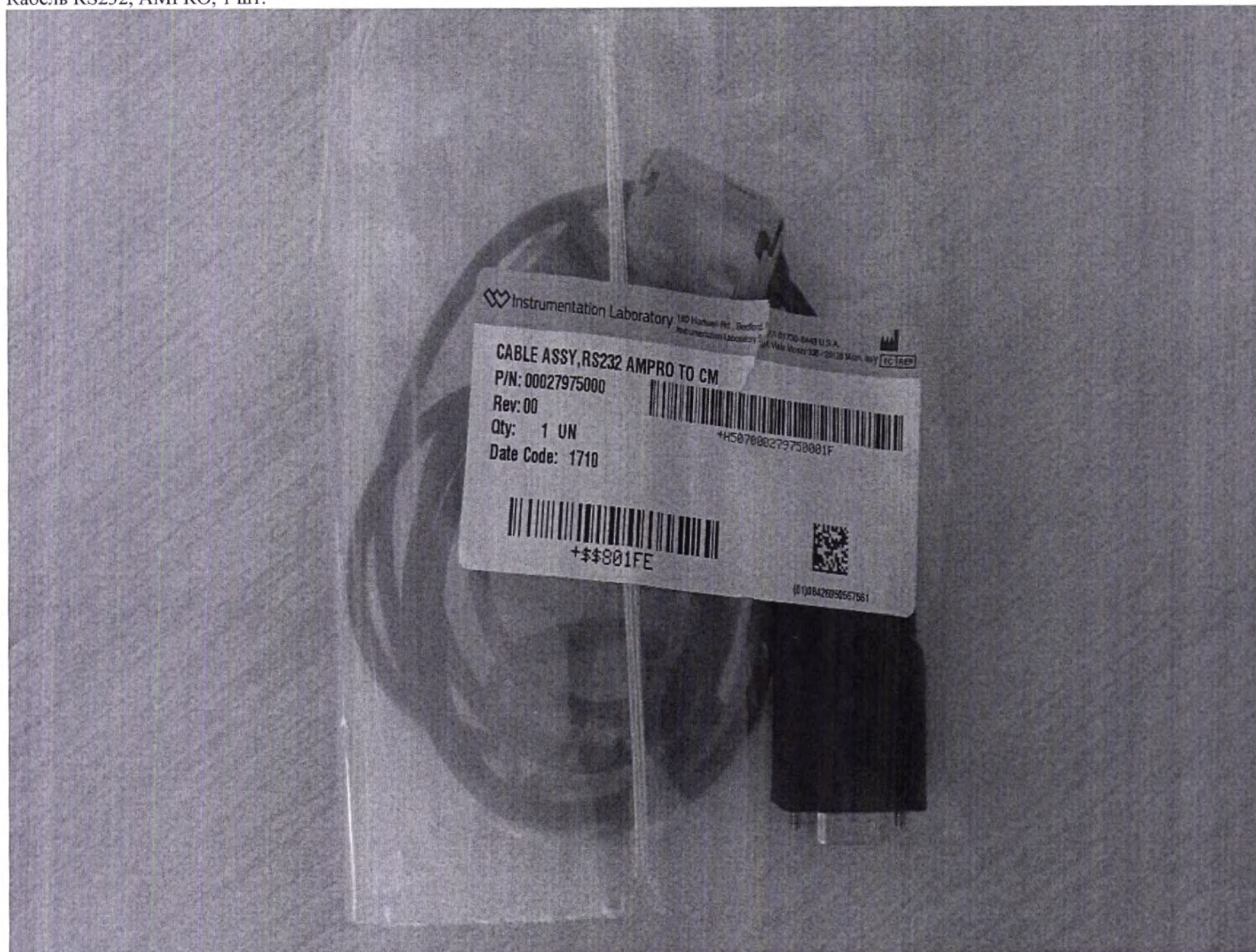
Устройство для замены фильтра, 1 шт.



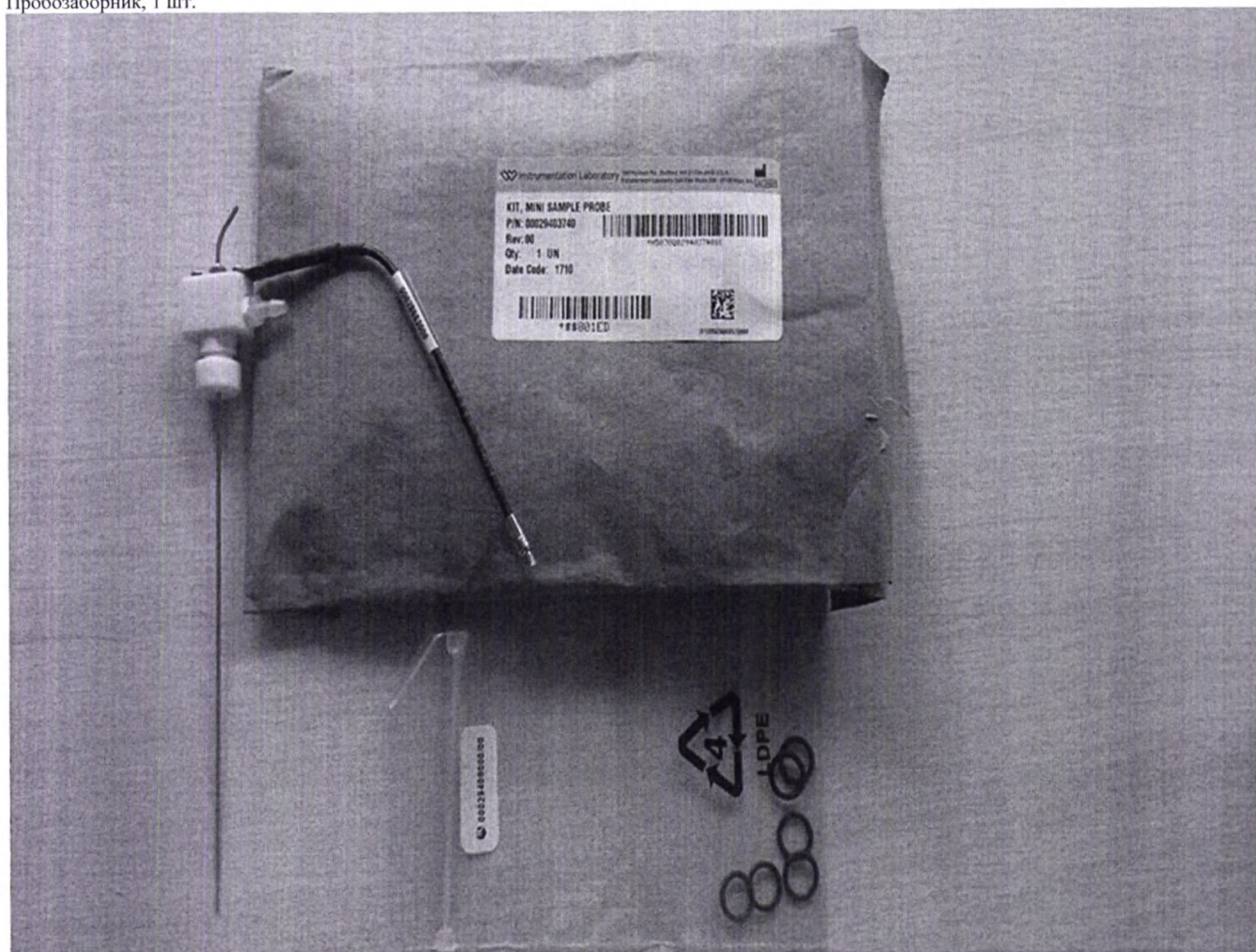
Адаптеры под штативы для образцов, 10 шт. (при необходимости)



Кабель RS232, AMPRO, 1 шт.

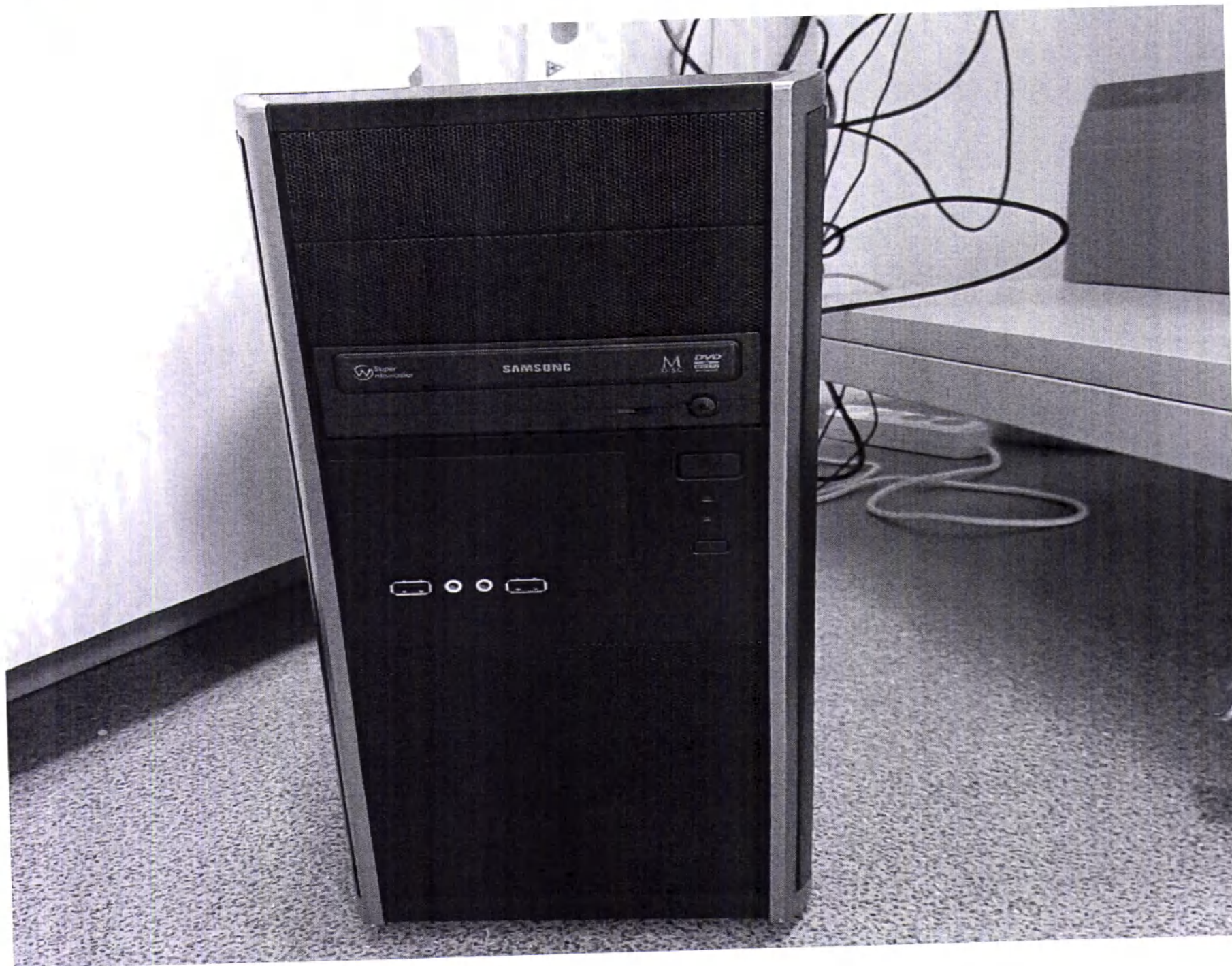


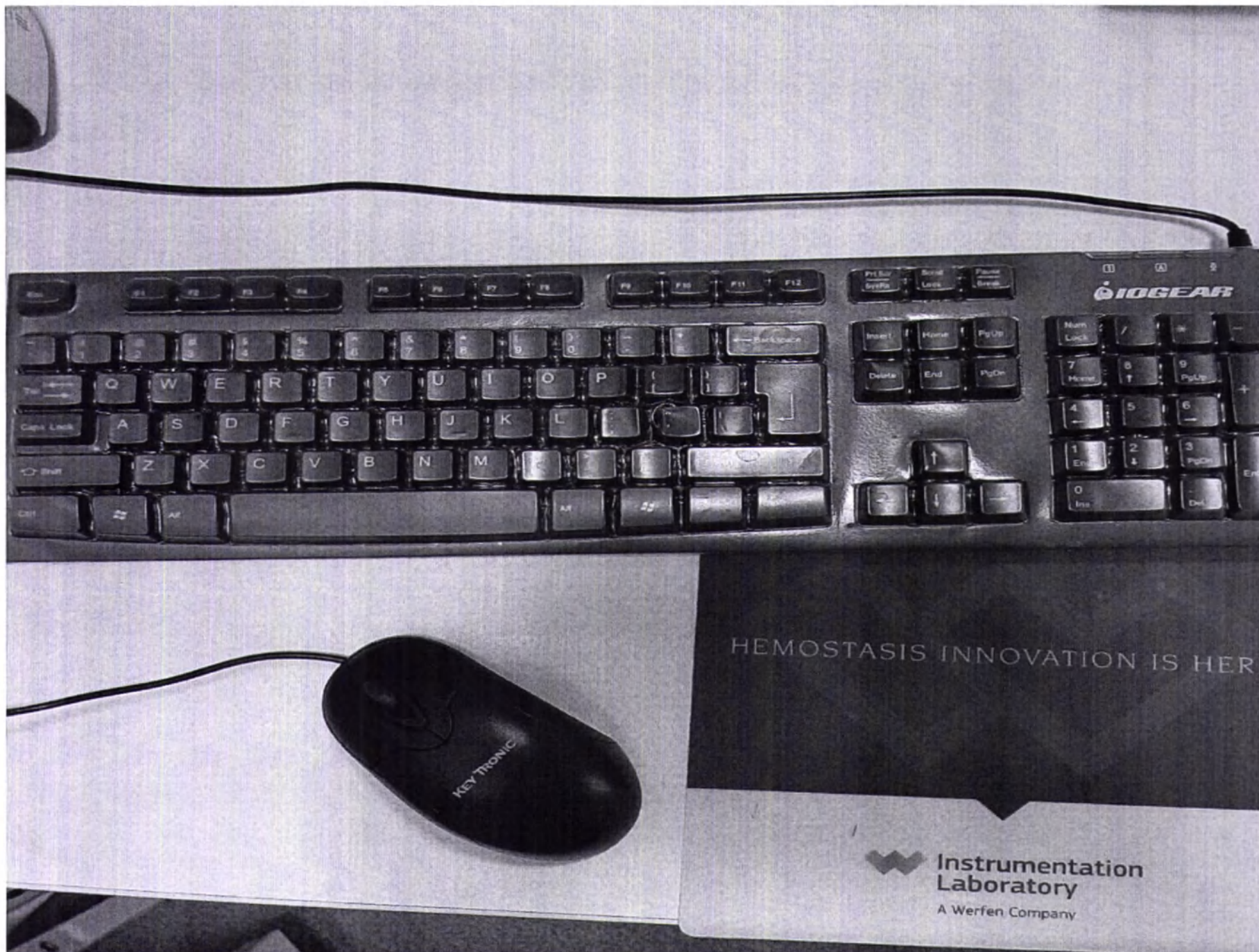
Пробозаборник, 1 шт.











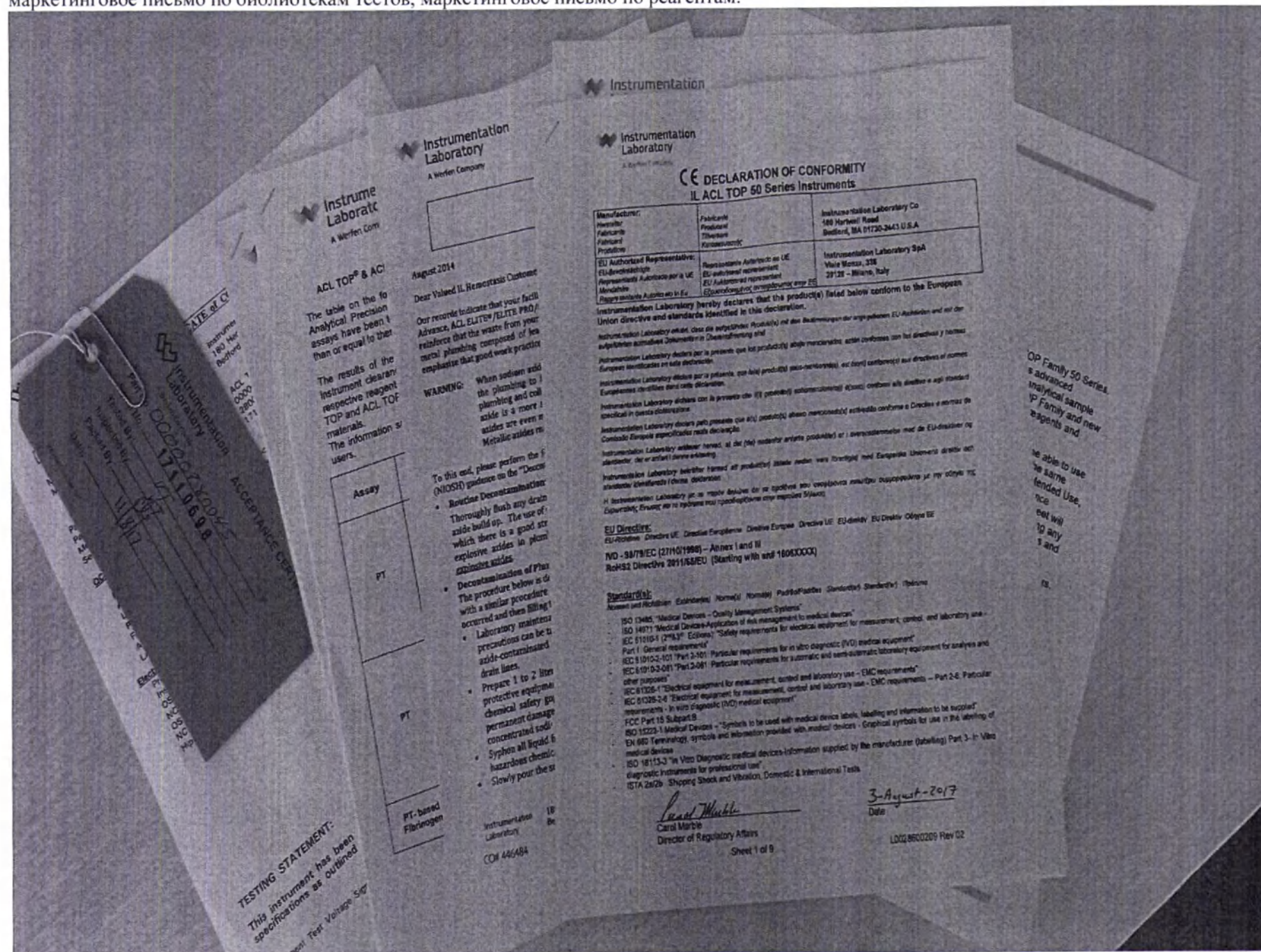
HEMOSTASIS INNOVATION IS HERE

 **Instrumentation
Laboratory**
A Werfen Company

Интегрированный стол (представлен с моделью анализатора ACL TOP 550 CTS)



Документация: декларация соответствия, сертификат соответствия, спецификация точности измерений, письмо-уведомление про Азид натрия, маркетинговое письмо по библиотекам тестов, маркетинговое письмо по реагентам.



February, 2016

ACL TOP Family 50 Series with Software Release V6.1.0, Parameters P-18.1.00 and User Manual (On Line Help) V6.1.0

Dear Valued ACL TOP™ Customer,

Welcome to the ACL TOP Family 50 Series of Analyzers. The ACL TOP Family 50 Series are the newest members of the ACL TOP Family: the best-in-class analyzers for the hemostasis laboratory. These high performance consolidated workstations are for routine and specialty assays: Clotting, Chromogenic and Latex-Immunoassay with pre-analytical sample integrity checks and advanced audit trail and accreditation support tools. They are part of Instrumentation Laboratory's commitment to develop and introduce products that meet the needs of today's demanding hemostasis laboratory. The ACL TOP Family 50 Series is configured with Software V6.1.0, Parameters P-18.1.00, and User Manual (On Line Help) V6.1.0 and available to select regions worldwide.

The ACL TOP Family 50 Series includes the following analyzers:

ACL TOP 350 CTS	Part Number: 00000280065
ACL TOP 550 CTS	Part Number: 00000280045
ACL TOP 750	Part Number: 00000280015
ACL TOP 750 CTS	Part Number: 00000280055
ACL TOP 750 LAS	Part Number: 00000280035

All models of the ACL TOP Family 50 Series offer:

- Same quality results
- Same comprehensive reagent portfolio
- Same powerful and intuitive software
- Same features and usability
- Same assay-specific sample checks
- Same advanced lab accreditation support tools

Software Version 6.1.0 with Parameters P-18.1.00 includes the following parameter files:

- Liquid Anti-Xa [Anti-Xa]
- Antithrombin Liquid [AT LIQ]
- APCR V with APC [APCR V+]
- APCR V without APC [APCR V-]
- APTT Syn Phospholip [APTT-SP]
- APTT SynthASil [APTT-SS]
- D-Dimer HS 500 [DDHS 500]
- D-Dimer HS [DDHS]
- D-Dimer [DD]
- Factor II-RP [FII-RP]
- Factor II- ReadiPlasTin [FIIRead]
- Factor II-RP-8 [FII-RP-8]
- Factor IX-SS [FIX-SS]
- Factor V- ReadiPlasTin [FVRead]
- Factor V-RP-8 [FVRP-8]
- Factor VIII-SS [FVIII-SS]
- Factor VIII-SS with normal vWF [F8vF-SS]
- Factor VII-RP [FVII-RP]
- Factor VII-RP-8 [FVII-RP-8]
- Factor VII- ReadiPlasTin [FVIIRead]
- Factor V-RP [FV-RP]
- Factor X HS Plus [FX-HS+]
- Factor X -RP [FX-RP]
- FX ReadiPlasTin [FXRead]
- Factor XI-SS [FXI-SS]
- Factor XII-SS [FXII-SS]
- Factor VIII-SP [FVIII-SP]
- Factor IX-SP [FIX-SP]
- Factor XI-SP [FXI-SP]
- Factor XII-SP [FXII-SP]
- Fib RecombiPlasTin [Fib-RP]



**Instrumentation
Laboratory**

A Werfen Company

November, 2014

Dear Valued ACL TOP 50 customer,

Instrumentation Laboratory is pleased to announce the launch of the new ACL TOP Family 50 Series. The ACL TOP Family 50 Series offer low- to high- volume hemostasis laboratories advanced automation of routine to specialty assays with the added benefit of integrated pre-analytical sample integrity checks, and advanced laboratory accreditation support tools. The ACL TOP Family and new ACL TOP Family 50 Series will be able to use the same comprehensive portfolio of reagents and produce the same quality results.

Since the new ACL TOP Family 50 Series evolved from the ACL TOP Family, you will be able to use the same comprehensive portfolio of HemosIL reagents, calibrators and controls using the same assigned values as listed on the insert sheets for the ACL TOP Family. In addition, the Intended Use, Reagent Storage/Stability, Limitations/Interfering Substances, Expected Values, Performance Characteristics, and any other instrument specific claims on any HemosIL reagent insert sheet will apply to both the ACL TOP Family and the ACL TOP Family 50 Series. Therefore, when using any HemosIL reagent on the ACL TOP Family 50 Series analyzer, please use the assigned values and claims listed on the insert sheet for the ACL TOP Family.

IL is committed to delivering innovative and practical solutions to meet the needs of our customers. The features of the new ACL TOP Family 50 Series will minimize the risk of errors and enhance quality assurance leading to better patient care. Thank you for choosing IL as a partner in Hemostasis testing.

Please contact your local representative if you have any questions.

Sincerely,

Catherine Quirbach Ph.D.

Group Product Manager, Hemostasis Reagents

Instrumentation Laboratory

CO#446005

00027503098 R00

180 Hartwell Road, Bedford, MA 01730 781-861-0710 www.ilus.com



**Instrumentation
Laboratory**
A Werfen Company

**IL HEMOSTASIS SYSTEMS
URGENT SAFETY NOTIFICATION**

August 2014

Dear Valued IL Hemostasis Customer:

Our records indicate that your facility has in use one or more IL Hemostasis Systems: ACL TOP® Family, ACL Futura/ACL Advance, ACL ELITE®/ELITE PRO/8/9/10000, ACL Classic (100-7000) and ACL AcuStar. This notification is intended to reinforce that the waste from your IL Hemostasis System contains sodium azide that may potentially form explosives in metal plumbing composed of lead, brass, tin, copper or zinc or containing solder in the plumbing system and to emphasize that good work practices should be followed to mitigate the risk of explosion.

WARNING: When sodium azide preservative in reagents is disposed down the drain, it can react with the metals in the plumbing to form insoluble metallic azides, such as copper and lead azide, which settle in the plumbing and collect in traps, threads, etc. These metallic azides are highly explosive. For example, lead azide is a more sensitive primary explosive than nitroglycerine and copper azide and other metallic azides are even more explosive and are considered too sensitive to be used commercially as explosives. Metallic azides may explode if subjected to friction, heat, shock or by reaction with other chemicals.

To this end, please perform the following steps taken directly from the National Institute of Occupational Safety and Health (NIOSH) guidance on the "Decontamination Procedures for Azide Contaminated Plumbing" (1976):

- **Routine Decontamination:**
Thoroughly flush any drain used for waste disposal with copious amounts of water several times a day to prevent azide build up. The use of copper- and lead-free lines between the point of discharge of azide and the nearest pipe in which there is a good stream of water, or the use of azide-free reagents, may prevent future accumulation of explosive azides in plumbing. **NOTE: These measures will NOT decontaminate plumbing already containing explosive azides.**
- **Decontamination of Plumbing Containing Explosive Azides:**
The procedure below is designed to decontaminate a drain trap. Longer lengths of drain lines can be decontaminated with a similar procedure after plugging the drain below the point at which any azide contamination is likely to have occurred and then filling the entire length of pipe with 10% sodium hydroxide solution.
 - Laboratory maintenance workers, especially plumbers, should be alerted to the azide hazard so that proper precautions can be taken. Violent explosions have resulted when plumbers have attempted to penetrate blocked azide-contaminated drainage systems with a flexible metal probe (snake) or to cut or saw azide-contaminated drain lines.
 - Prepare 1 to 2 liters of 10% sodium hydroxide solution (100 g NaOH per liter of water). Wear appropriate protective equipment when preparing and handling this corrosive material including gloves, protective clothing, chemical safety goggles and face shield. Contact with eyes or skin will cause severe burns and may cause permanent damage. Carefully read and follow the manufacturer's safety instructions and instructions for diluting concentrated sodium hydroxide or sodium hydroxide solid in water.
 - Syphon all liquid from the trap and drain using a soft rubber or plastic hose. Use proper precautions against any hazardous chemicals which may be present.
 - Slowly pour the sodium hydroxide solution into the trap.

Instrumentation Laboratory
180 Hartwell Road
Bedford, MA 01730

Tel 781-861-0710

www.ilus.com

CO# 446484

Page 1 of 2

L0019014800 R03



Instrumentation Laboratory

A Werfen Company

ACL TOP® & ACL TOP Family 50 Series Analytical Precision Performance Requirements

The table on the following pages reflects the current ACL TOP and ACL TOP Family 50 Series Analytical Precision Performance Requirements. The released parameters for each of the noted assays have been tested by Instrumentation Laboratory, and the imprecision data generated is less than or equal to these requirements.

The results of the internal testing have been submitted to the respective governing bodies for instrument clearance where the reagent is sold, and is also published in the insert sheets of the respective reagent products. Those published values reflect the testing performed on specific ACL TOP and ACL TOP Family 50 Series instruments using specific lots of reagent, calibrator, and control materials.

The information supplied here can serve as a guide to ACL TOP and ACL TOP Family 50 Series users.

Assay	Reagent	Result Unit	Control	Within Run Imprecision (%CV)	Total Imprecision (%CV)
PT	PT-Fib HS + PT-Fibrinogen	Seconds	HemosIL® Normal Control	≤ 2.0	≤ 3.0
			HemosIL Normal Control 1	≤ 2.0	≤ 3.0
			HemosIL Low Abnormal Control	≤ 3.0	≤ 4.0
			HemosIL Abnormal Control 2	≤ 3.0	≤ 4.0
			HemosIL High Abnormal Control	≤ 5.0	≤ 8.0
			HemosIL Abnormal Control 3	≤ 5.0	≤ 8.0
PT	RecombiPlasTin 2G ReadiPlasTin	Seconds	HemosIL® Normal Control	≤ 3.0	≤ 3.0
			HemosIL Normal Control 1	≤ 3.0	≤ 3.0
			HemosIL Low Abnormal Control	≤ 4.0	≤ 4.0
			HemosIL Abnormal Control 2	≤ 4.0	≤ 4.0
			HemosIL High Abnormal Control	≤ 5.0	≤ 8.0
			HemosIL Abnormal Control 3	≤ 5.0	≤ 8.0
PT-based Fibrinogen	PT-Fib HS + PT-Fibrinogen	mg/dL	HemosIL Normal Control	≤ 10.0	≤ 12.0
			HemosIL Normal Control 1	≤ 10.0	≤ 12.0



**Instrumentation
Laboratory**

A Werfen Company

For North America Customers Only

September 19, 2016

Dear Valued ACL TOP Family 50 Series customer,

When using any HemosIL reagent on the ACL TOP Family 50 Series analyzer, please use the assigned values and the claims listed on the insert sheet for the ACL TOP Family. Since the ACL TOP Family 50 Series evolved from the ACL TOP Family, you will be able to use the same comprehensive portfolio of HemosIL reagents, calibrators and controls. The claims for Intended Use, Reagent Storage/Stability, Limitations/Interfering Substances, Expected Values on a HemosIL reagent insert sheet will apply for both the ACL TOP Family and the ACL TOP Family 50 Series.

In addition, Instrumentation Laboratory performed additional precision and method comparison studies to achieve 510k clearance. While the HemosIL labeling is being updated, the corresponding Precision and Method Comparison data for ACL TOP 50 Series from the current 510k cleared assays are listed in this letter for your reference.

Please share this information with your laboratory staff and retain a copy of this letter for your records. Thank you for choosing IL as a partner in Hemostasis testing.

Please contact your local representative if you have any questions.

Sincerely,

Catherine Quirbach Ph.D.

Group Product Manager, Hemostasis Reagents
Instrumentation Laboratory

Part No. 00000280045
 Serial No. 17110698
 Test By: VF
 Inspected By: VF
 Approved By: VF
 Date: 11/8/17

Instrumentation Laboratory
 ACCEPTANCE CERTIFICATE

Certificate of COMPLIANCE

Instrumentation Laboratory
 180 Hartwell Road
 Bedford, MA US 01730

ACL TOP 550 CTS SYSTEM
 00000280045
 2800.45 ACL TOP 550 CTS
 17110698

V	1.7 %	0.7	PASS
V	3.2 %	1.2	PASS
V	1.7 %	1.2	PASS
V	3.0 %	2.6	PASS
V	3.0 %	1.2	PASS
V	6.0 %	1.4	PASS
V	2.3 %	1.1	PASS
V	10.0 %	6.8	PASS
V	0.200 Ohm	0.070	PASS
V	2 MOhm	734	PASS
0.1 .. 1000.0 μ A	524.1	PASS	
0.1 .. 500.0 μ A	265.3	PASS	
0.1 .. 1000.0 μ A	530.4	PASS	
0.1 .. 500.0 μ A	268.7	PASS	
2.00 .. 10.00 mA	4.21	PASS	

TESTING STATEMENT:

This instrument has been certified to meet all applicable electrical and analytical specifications as outlined in Instrumentation Laboratory's final test and QC procedures.

Instrument Test Voltage Signature: JNUON

Date: 11/03/2017

QC Signature: SYI

Date: 11/07/2017

CO # 464252

Sheet 1 of 1

Part No. 00028766200 Rev 1B

CE DECLARATION OF CONFORMITY
IL ACL TOP 50 Series Instruments

Manufacturer: Hersteller Fabricante Fabricant Produttore	Fabricante Produtor Tilvorkare Κατασκευαστής	Instrumentation Laboratory Co 180 Hartwell Road Bedford, MA 01730-2443 U.S.A
EU Authorized Representative: EU-Bevollmächtigte Representante Autorizado por la UE Mandataire Representante Autorizzato in Eu	Representante Autorizado na UE EU-authorized representative EU Auktoriserad representant Εξουσιοδοτημένος αντιπρόσωπος στην ΕΕ	Instrumentation Laboratory SpA Viale Monza, 338 20128 - Milano, Italy

Instrumentation Laboratory hereby declares that the product(s) listed below conform to the European Union directive and standards identified in this declaration.

Instrumentation Laboratory erklärt, dass die aufgeführten Produkt(e) mit den Bestimmungen der angegebenen EU-Richtlinien und mit den aufgeführten normativen Dokumenten in Übereinstimmung sind.

Instrumentation Laboratory declara por la presente que los producto(s) abajo mencionados, están conformes con las directivas y normas Europeas identificadas en esta declaración.

Instrumentation Laboratory déclare par la présente, que le(s) produit(s) sous-mentionné(s), est (sont) conforme(s) aux directives et normes Européennes identifiées dans cette déclaration.

Instrumentation Laboratory dichiara con la presente che il(l) prodotto(i) sottoelencato(i) è(sono) conforme alla direttiva e agli standard specificati in questa dichiarazione.

Instrumentation Laboratory declara pelo presente que o(s) produto(s) abaixo mencionado(s) está/estão conforme a Directiva e normas da Comissão Europeia especificadas nesta declaração.

Instrumentation Laboratory erklærer herved, at det (de) nedenfor anførte produkt(er) er i overensstemmelse med de EU-direktiver og standarder, der er anført i denne erklæring.

Instrumentation Laboratory bekräftar härmed att produkt(er) listade nedan, vara förenliga med Europeiska Union-ens direktiv och standarder identifierade i denna deklaration.

Η Instrumentation Laboratory με τα παρόν δηλώνει ότι τα προϊόντα που αναφέρονται κατωτέρω συμμορφούνται με την οδηγία της Ευρωπαϊκής Ένωσης και τα πρότυπα που προσδιορίζονται στην παρούσα δήλωση.

EU Directive:

EU-Richtlinie Directive UE Directive Européenne Direttiva Europea Directiva UE EU-direktiv EU Direktiv Οδηγία ΕΕ

IVD - 98/79/EC (27/10/1998) - Annex I and III

RoHS2 Directive 2011/65/EU (Starting with sn# 1606XXXX)

Standard(s):

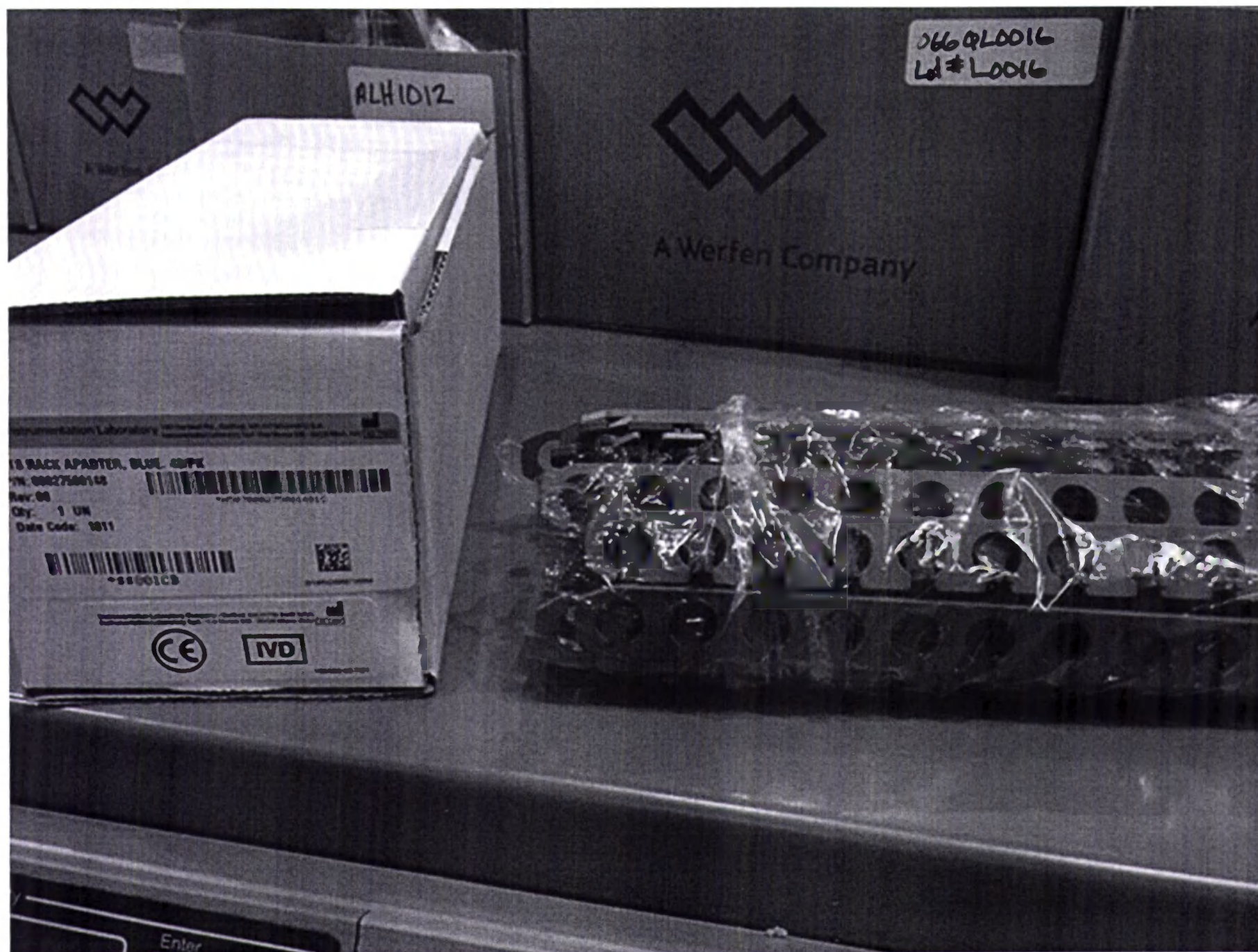
Normen und Richtlinien Estándar(es) Norme(s) Norma(s) Padrão/Padrões Standard(er) Standard(er) Πρότυπα

- ISO 13485, "Medical Devices - Quality Management Systems"
- ISO 14971 "Medical Devices-Application of risk management to medical devices"
- IEC 61010-1 (2nd & 3rd Editions) "Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements"
- IEC 61010-2-101 "Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment"
- IEC 61010-2-081 "Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes"
- IEC 61328-1 "Electrical equipment for measurement, control and laboratory use - EMC requirements"
- IEC 61328-2-6 "Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment"
- FCC Part 15 Subpart B
- ISO 15223-1 Medical Devices - "Symbols to be used with medical device labels, labelling and information to be supplied"
- EN 980 Terminology, symbols and information provided with medical devices - Graphical symbols for use in the labelling of medical devices
- ISO 18113-3 "In Vitro Diagnostic medical devices-Information supplied by the manufacturer (labelling) Part 3- In Vitro diagnostic instruments for professional use"
- ISTA 2a/2b Shipping Shock and Vibration, Domestic & International Tests.

Carol Marble
Carol Marble
Director of Regulatory Affairs

3-August-2017
Date

Адаптеры для CTS штативов, голубые, 48 шт. (при необходимости)



Адаптеры для CTS штативов, голубые, 96 шт. (при необходимости)



Адаптеры для аликвотных пробирок, 10 шт. (при необходимости)



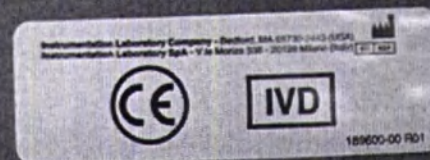
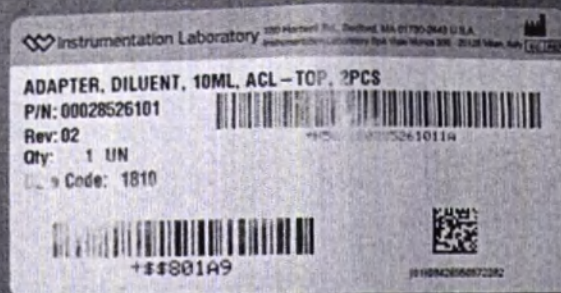
Адаптеры для микропробирок, 10 шт. (при необходимости)



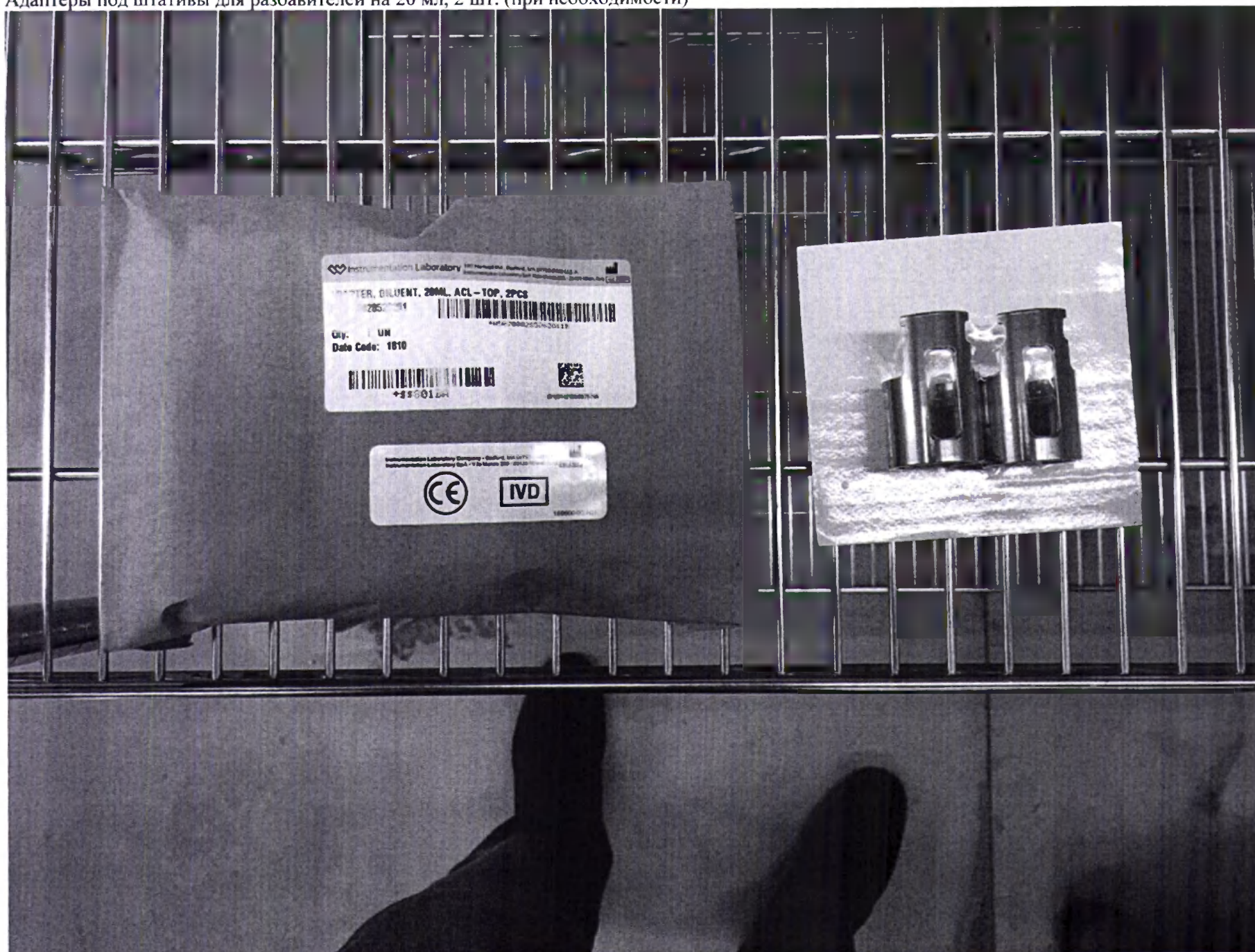
Адаптеры для педиатрических пробирок, 10 шт. (при необходимости)



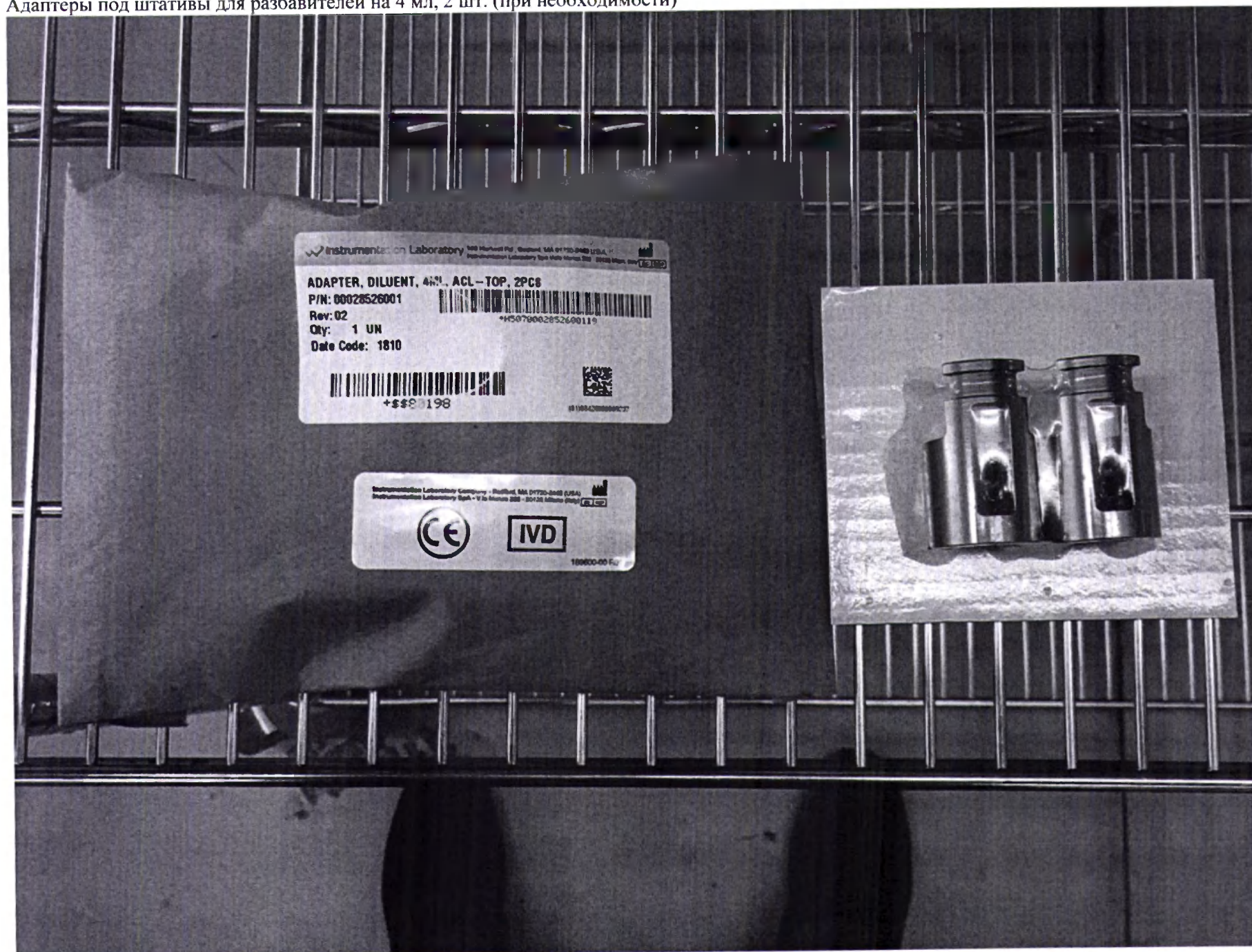
Адаптеры под штативы для разбавителей на 10 мл, 2 шт. (при необходимости)



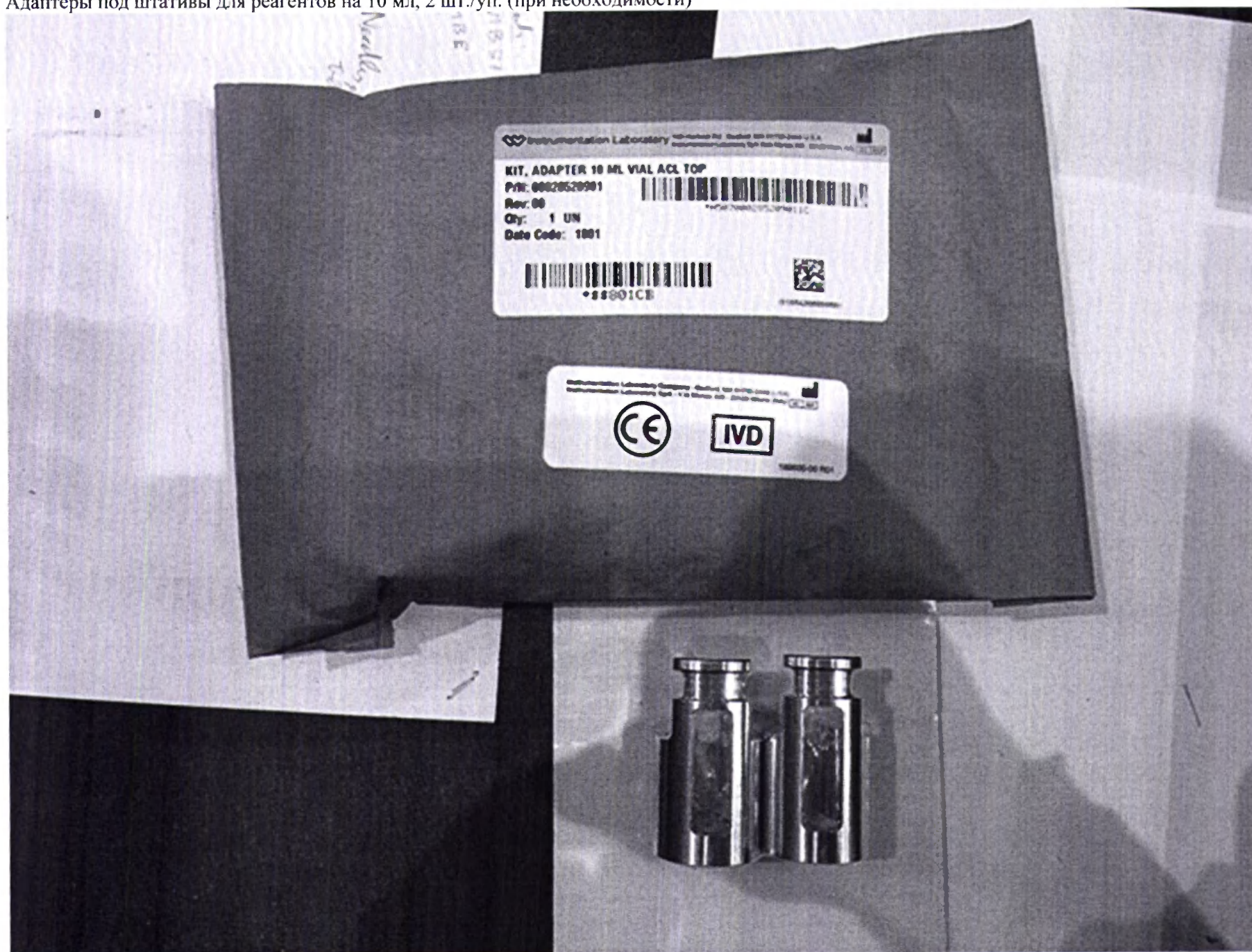
Адаптеры под штативы для разбавителей на 20 мл, 2 шт. (при необходимости)



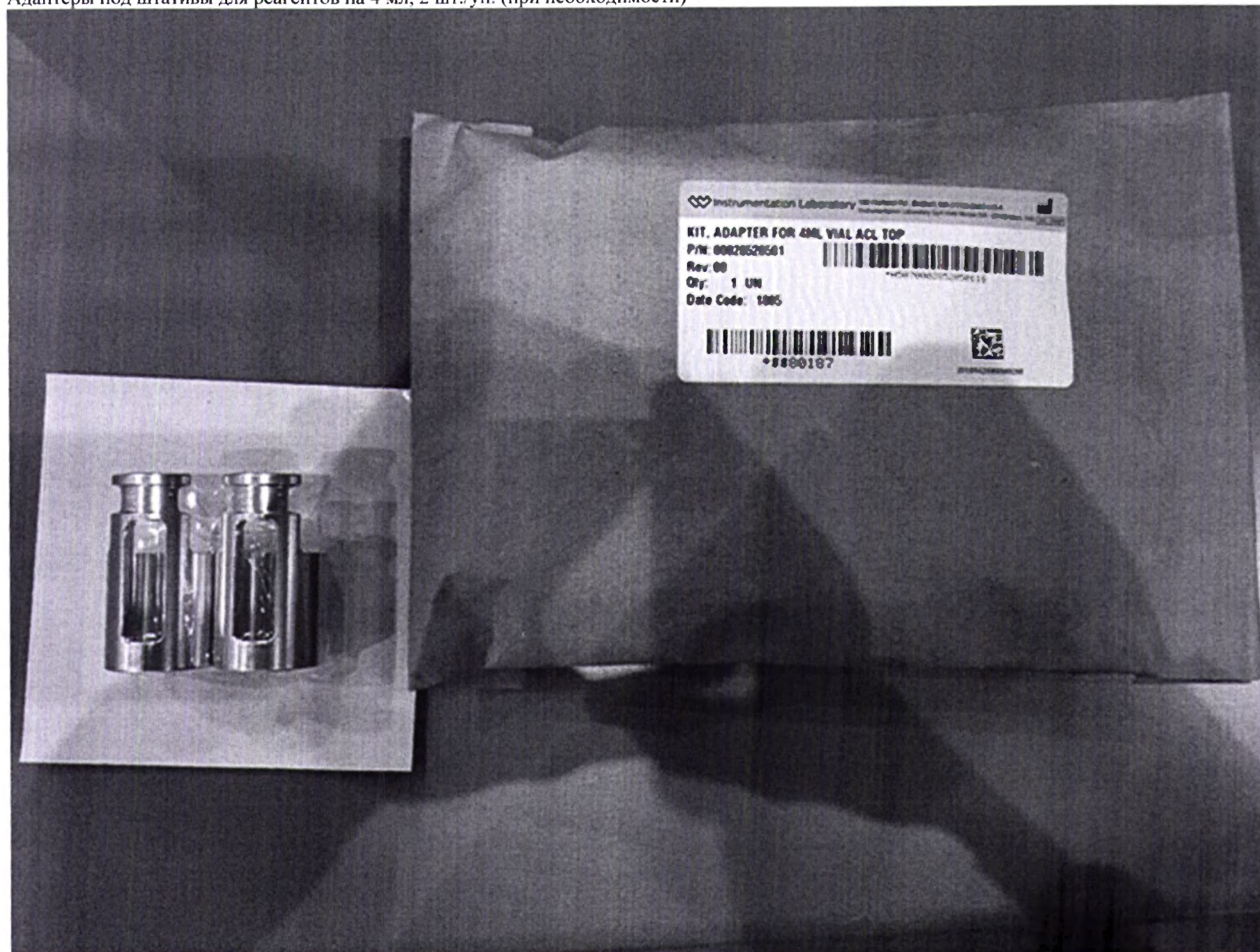
Адаптеры под штативы для разбавителей на 4 мл, 2 шт. (при необходимости)



Адаптеры под штативы для реагентов на 10 мл, 2 шт./уп. (при необходимости)



Адаптеры под штативы для реагентов на 4 мл, 2 шт./уп. (при необходимости)



Вентилятор для охлаждения реагентов, ACL TOP 500/550 CTS, 1 шт. (при необходимости)



Внешний 2D считыватель штрих-кода, 1 шт.

ACTOP

ACL Top 2D USB Bar Code Reader

REF 00028210900



CE



(01)08426950925576

(21)180608-011

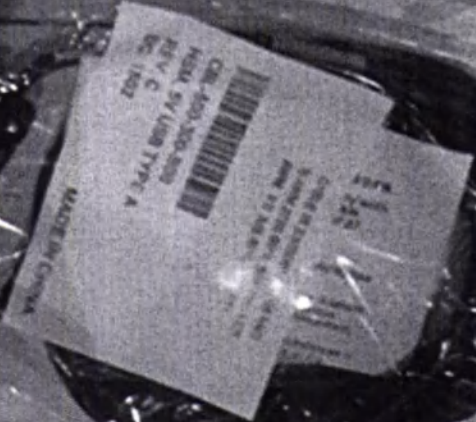
Part 15 of the FCC rules.
This device is subject to the following two conditions:
1. This device must not cause harmful interference and
2. This device must accept any interference received, including interference that may cause undesired operation.
Additional conditions include: UL, CE,
FCC, and C-TICK, and Canadian ICES 003.

COMPLIES WITH EMC 89/336/EEC LVD 73/23/EEC

Instrumentation Laboratory
Instrumentation Laboratory Company, Bedford, MA 01730-1043, U.S.A.
Instrumentation Laboratory Ltd., Watlington, Oxford, OX12 0JN, U.K.
www.instrumentation-lab.com

00028210900

Honeywell



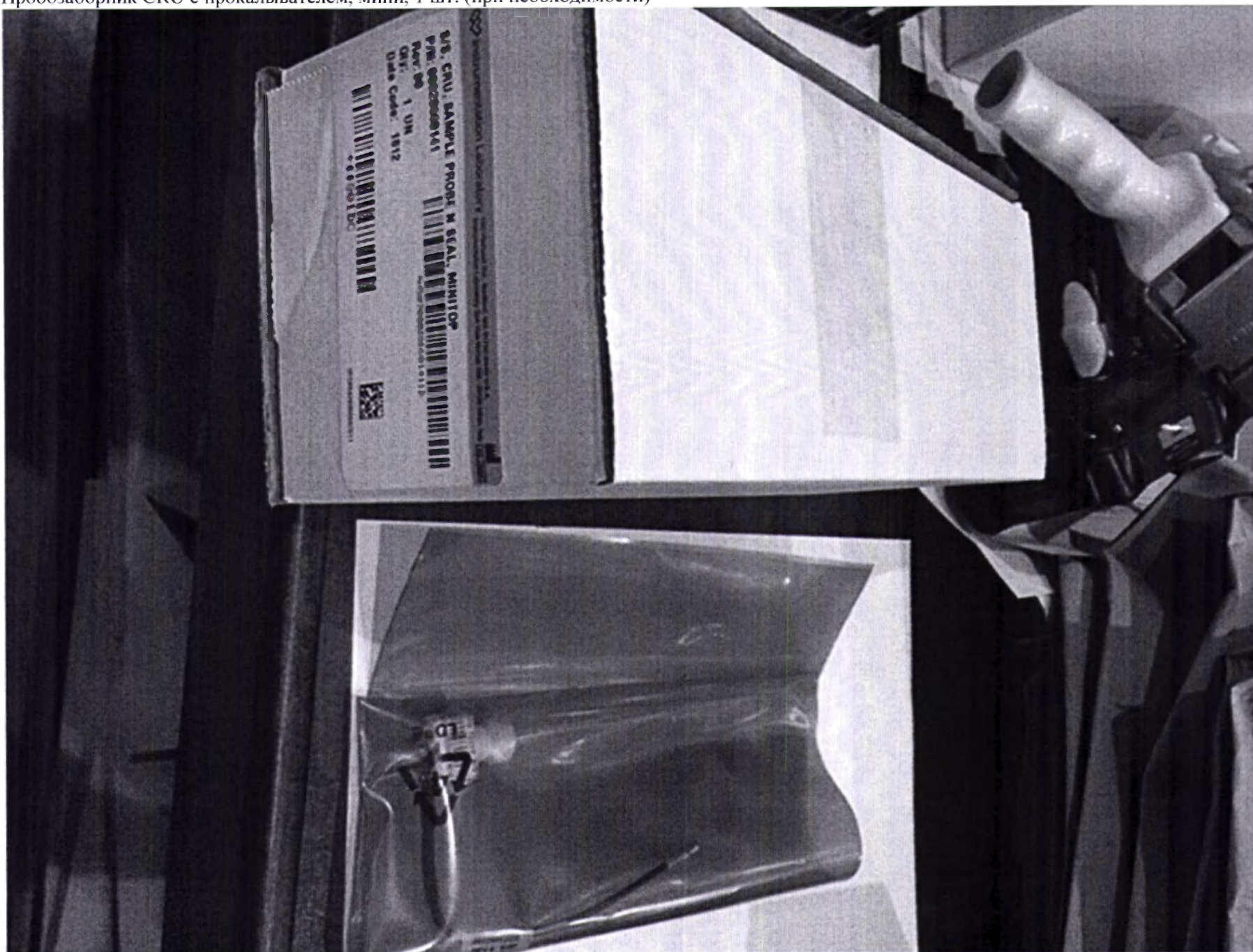




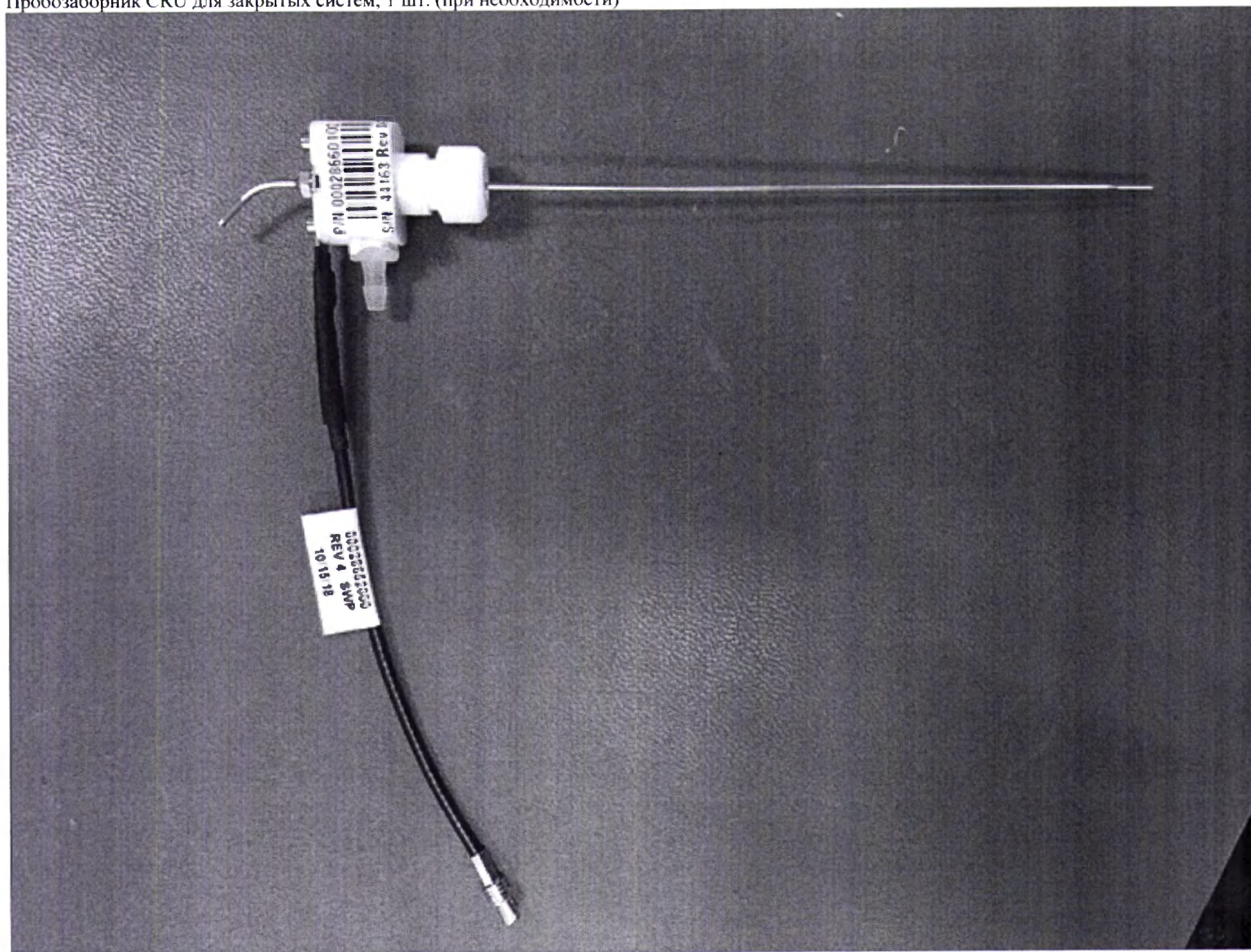
Наконечники для шприца, 250 мкл, 1 уп. (при необходимости)



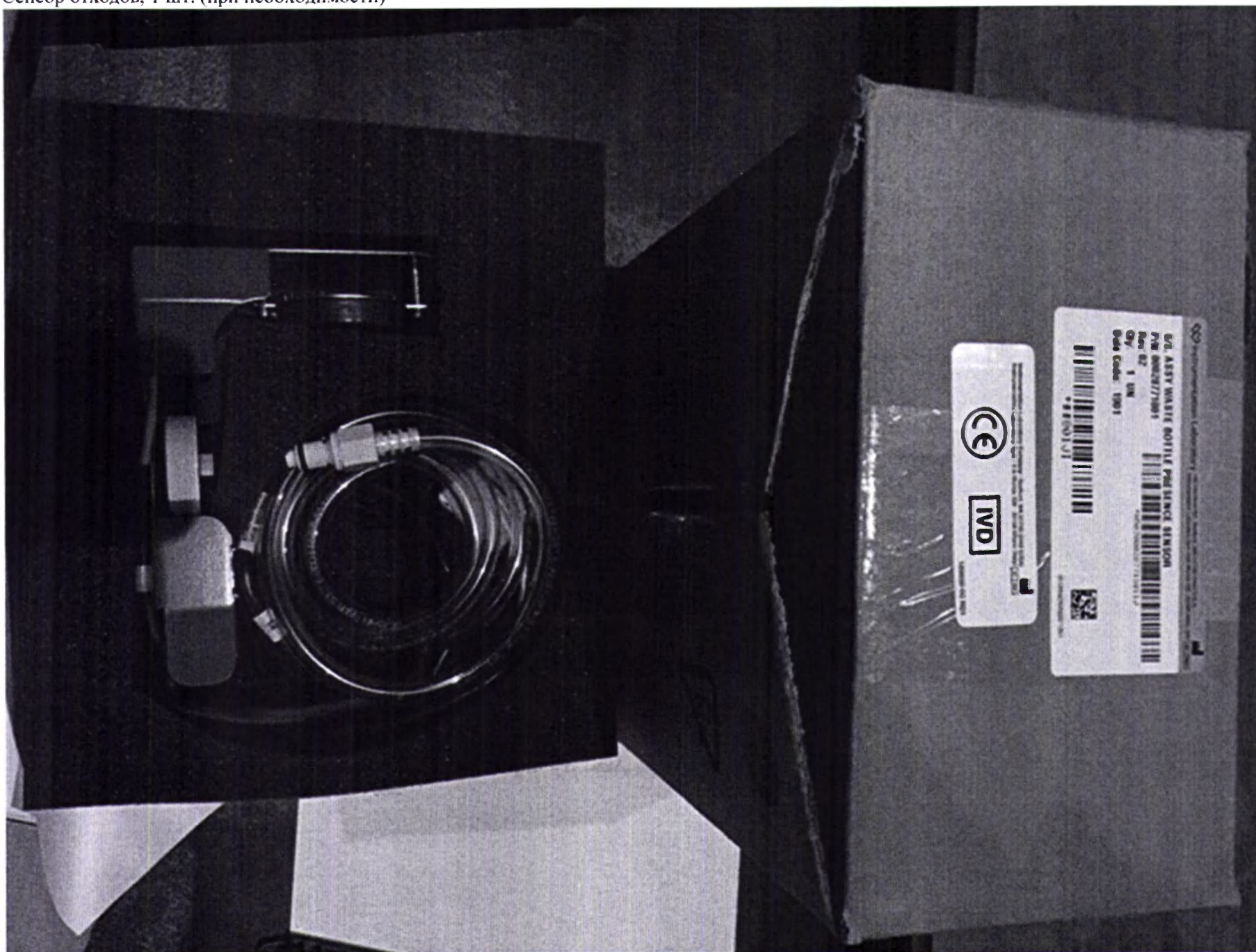
Пробозаборник CRU с прокалывателем, мини, 1 шт. (при необходимости)



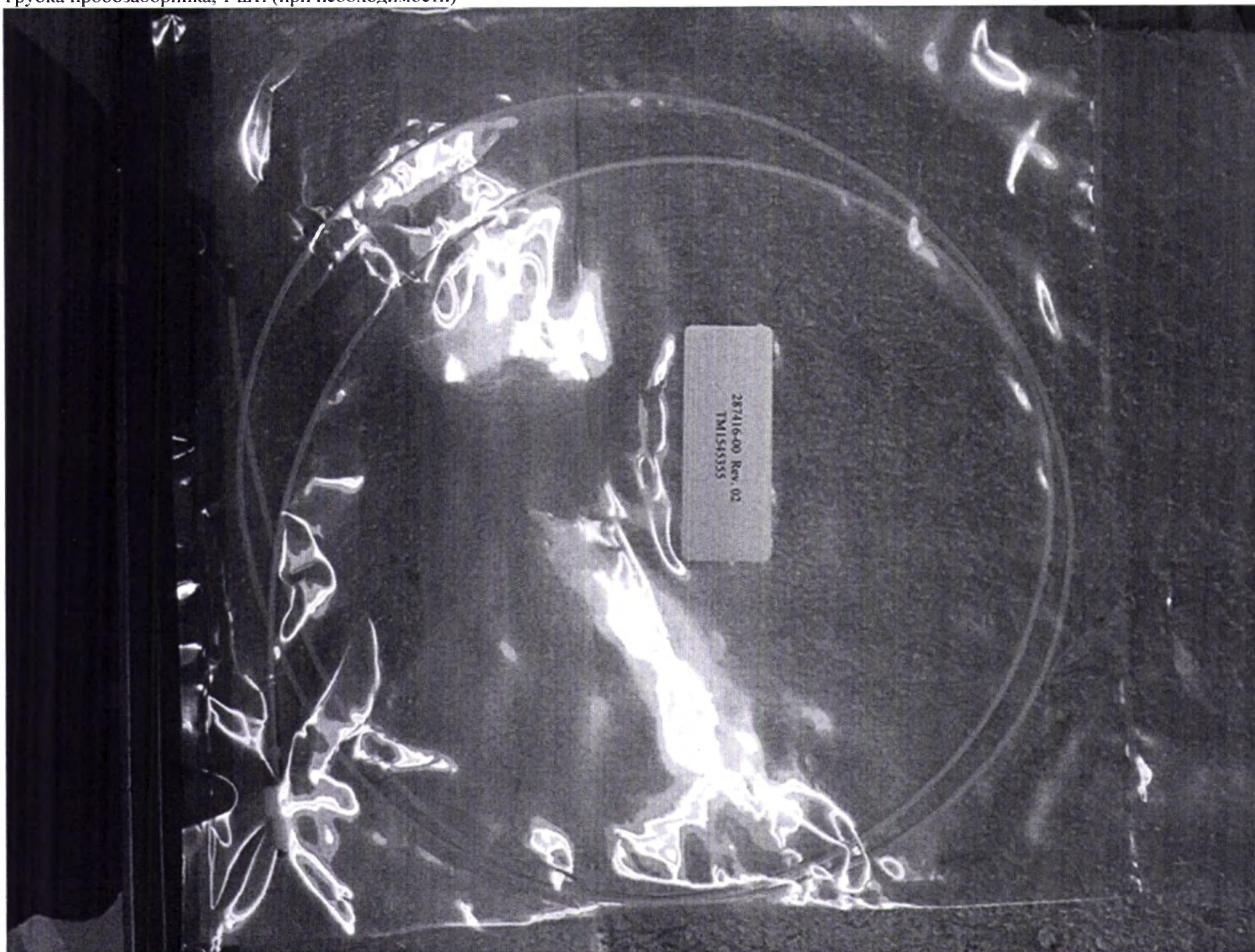
Пробозаборник CRU для закрытых систем, 1 шт. (при необходимости)



Сенсор отходов, 1 шт. (при необходимости)



Трубка пробозаборника, 1 шт. (при необходимости)



Шприц PE PSD4, 250 мкл. 1 шт. (при необходимости)

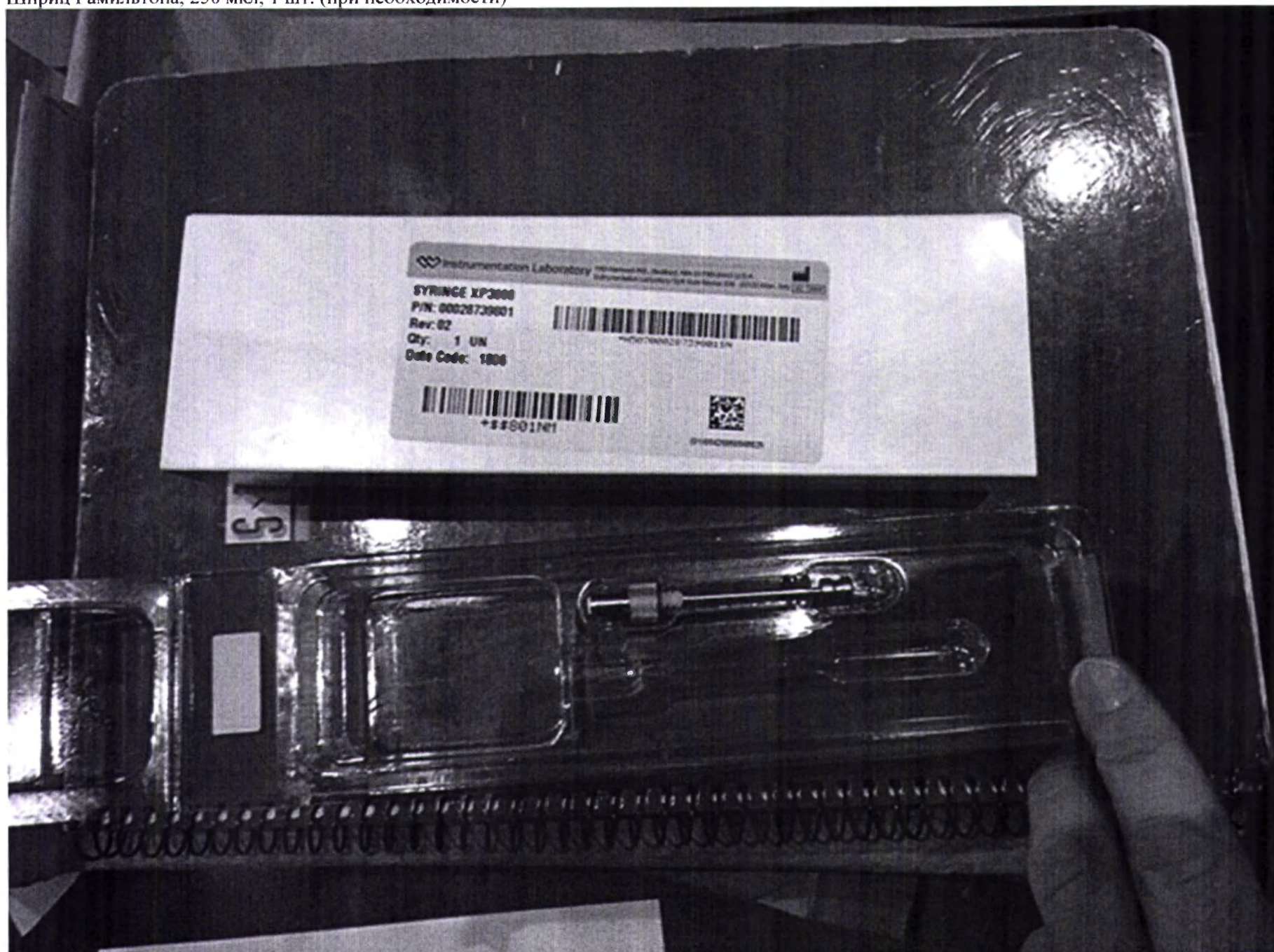
Syringe Drive Motor

REV-B

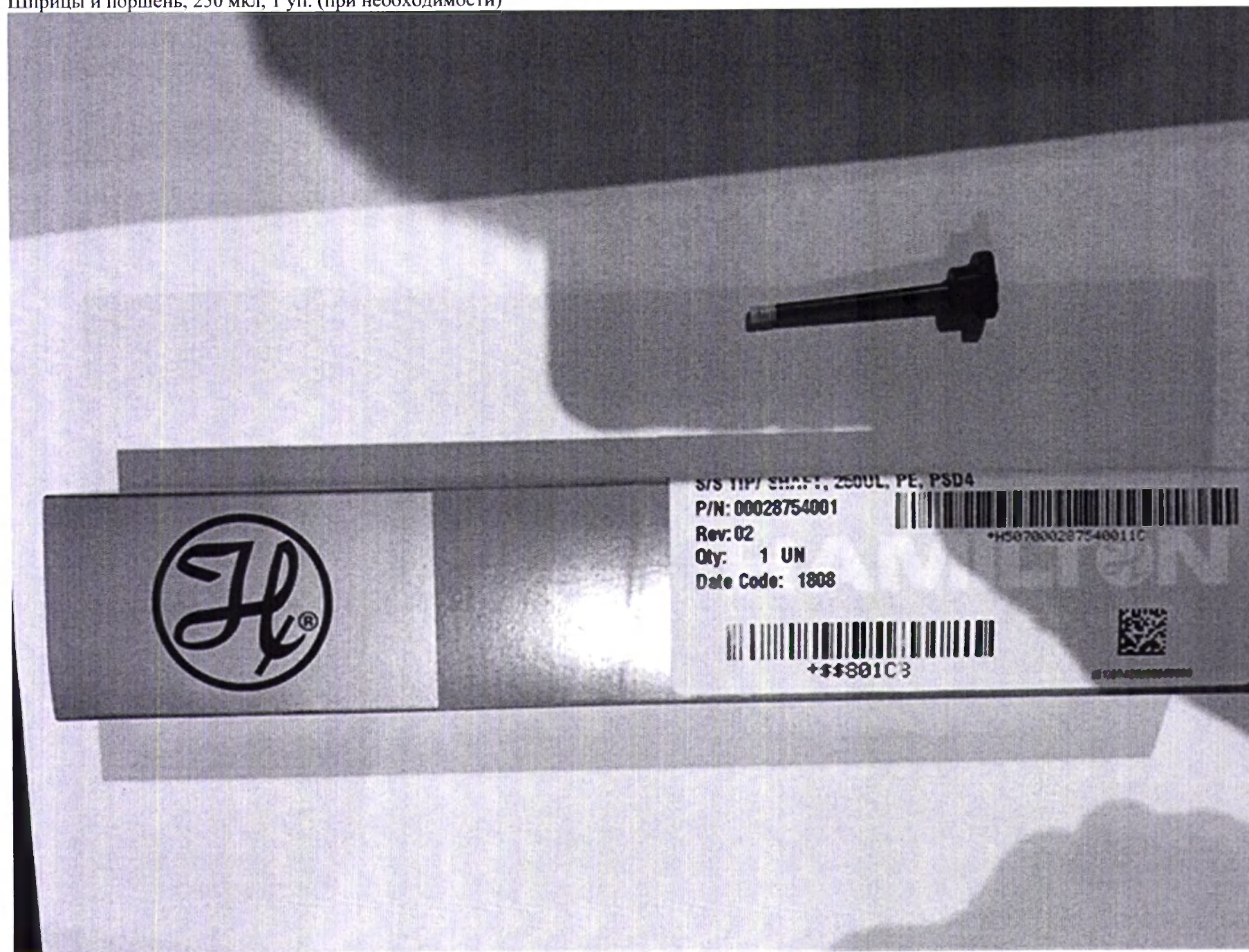
HAMILTON

Syringe

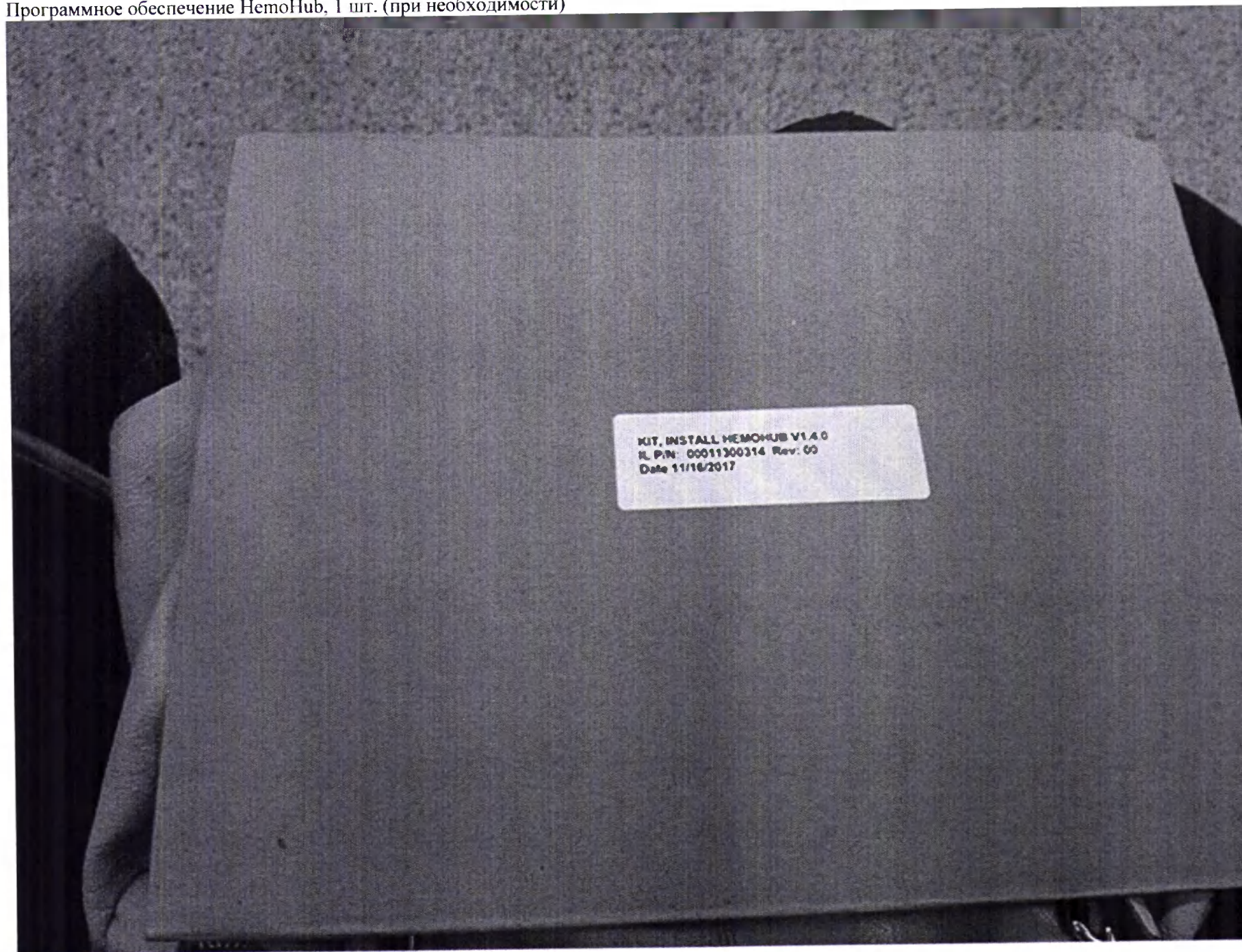
Шприц Гамильтона, 250 мкл, 1 шт. (при необходимости)



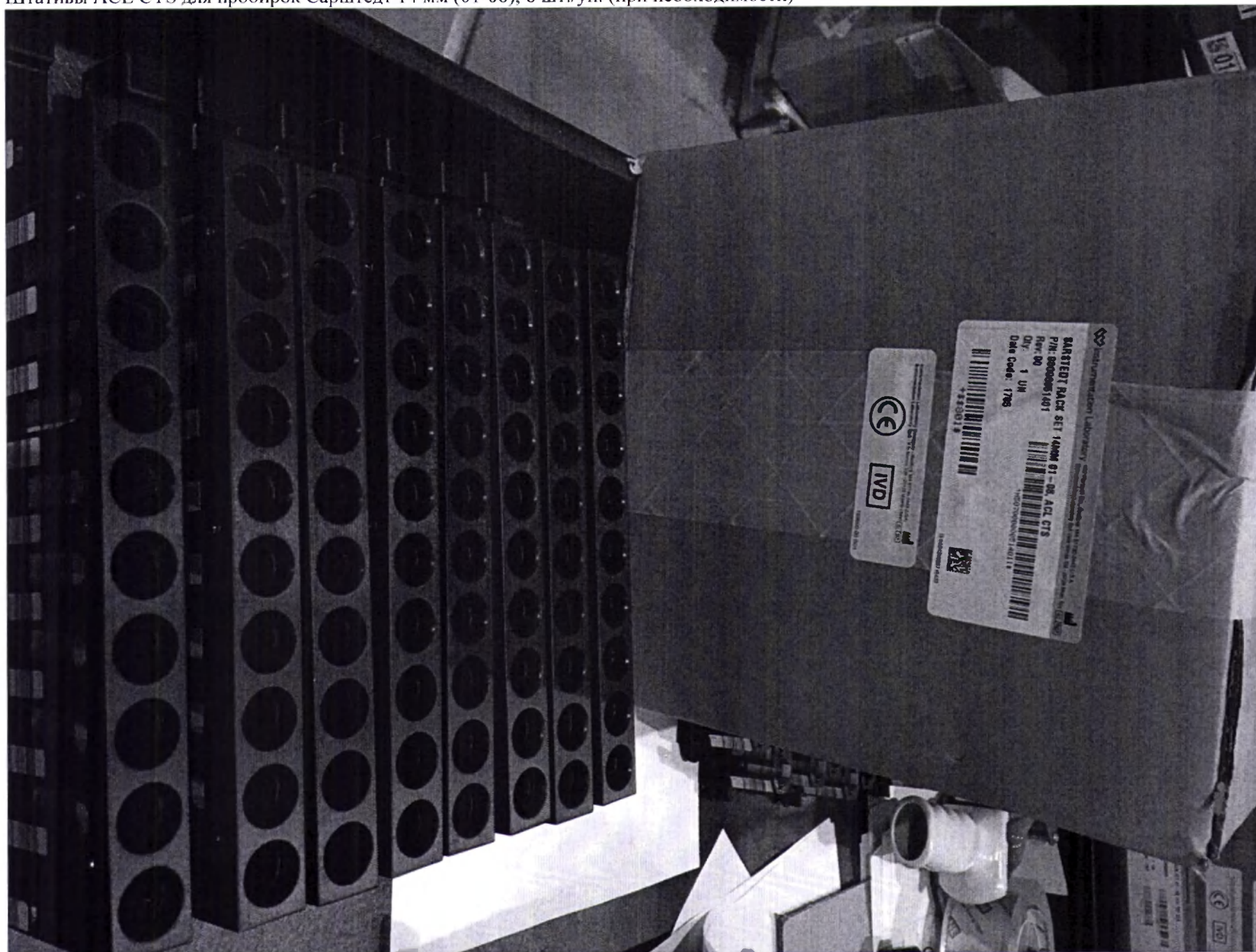
Шприцы и поршень, 250 мкл, 1 уп. (при необходимости)



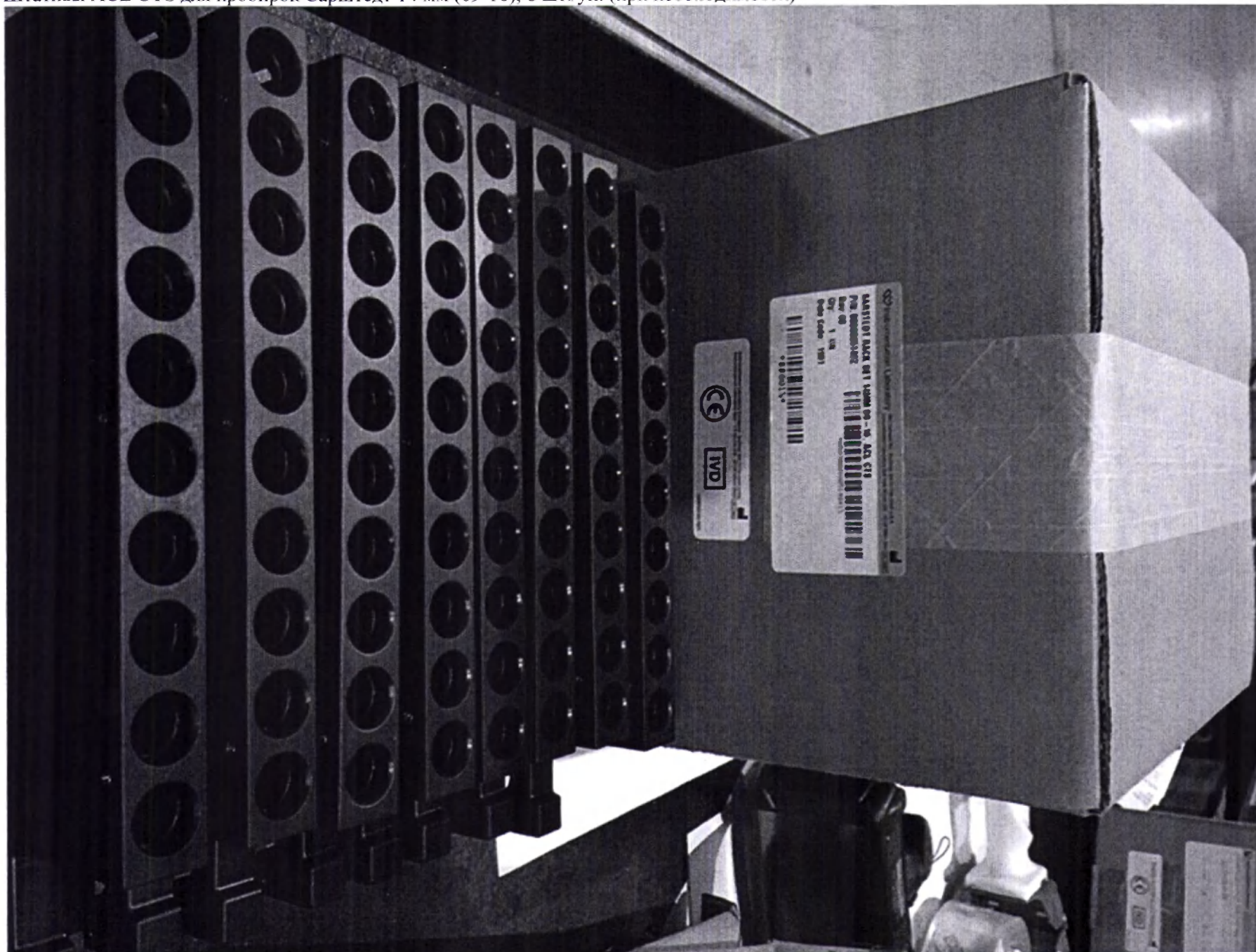
Программное обеспечение НетоHub, 1 шт. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 14 мм (01-08), 8 шт./уп. (при необходимости)



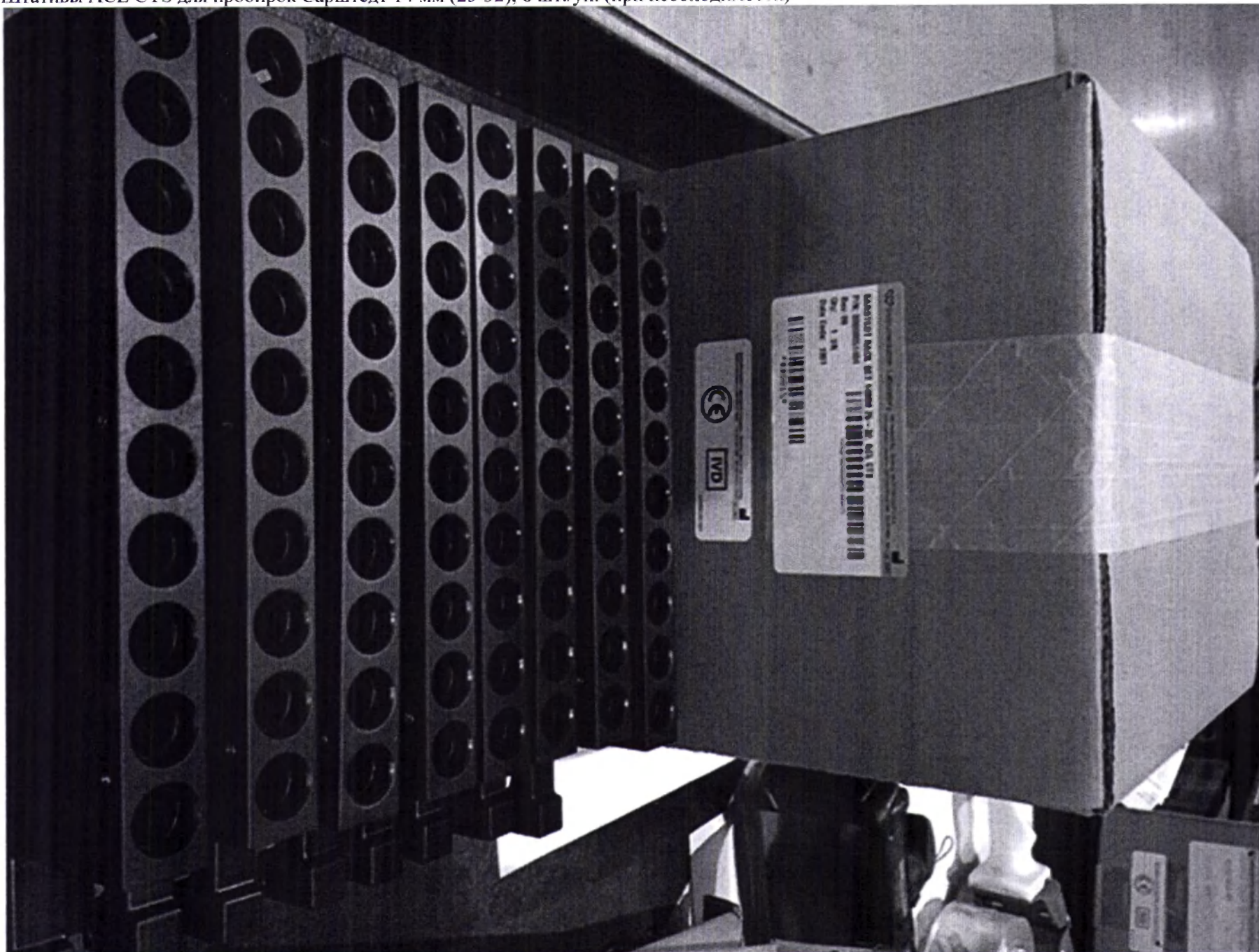
Штативы ACL CTS для пробирок Сарштедт 14 мм (09-16), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Саршедт 14 мм (17-24), 8 шт./уп. (при необходимости)



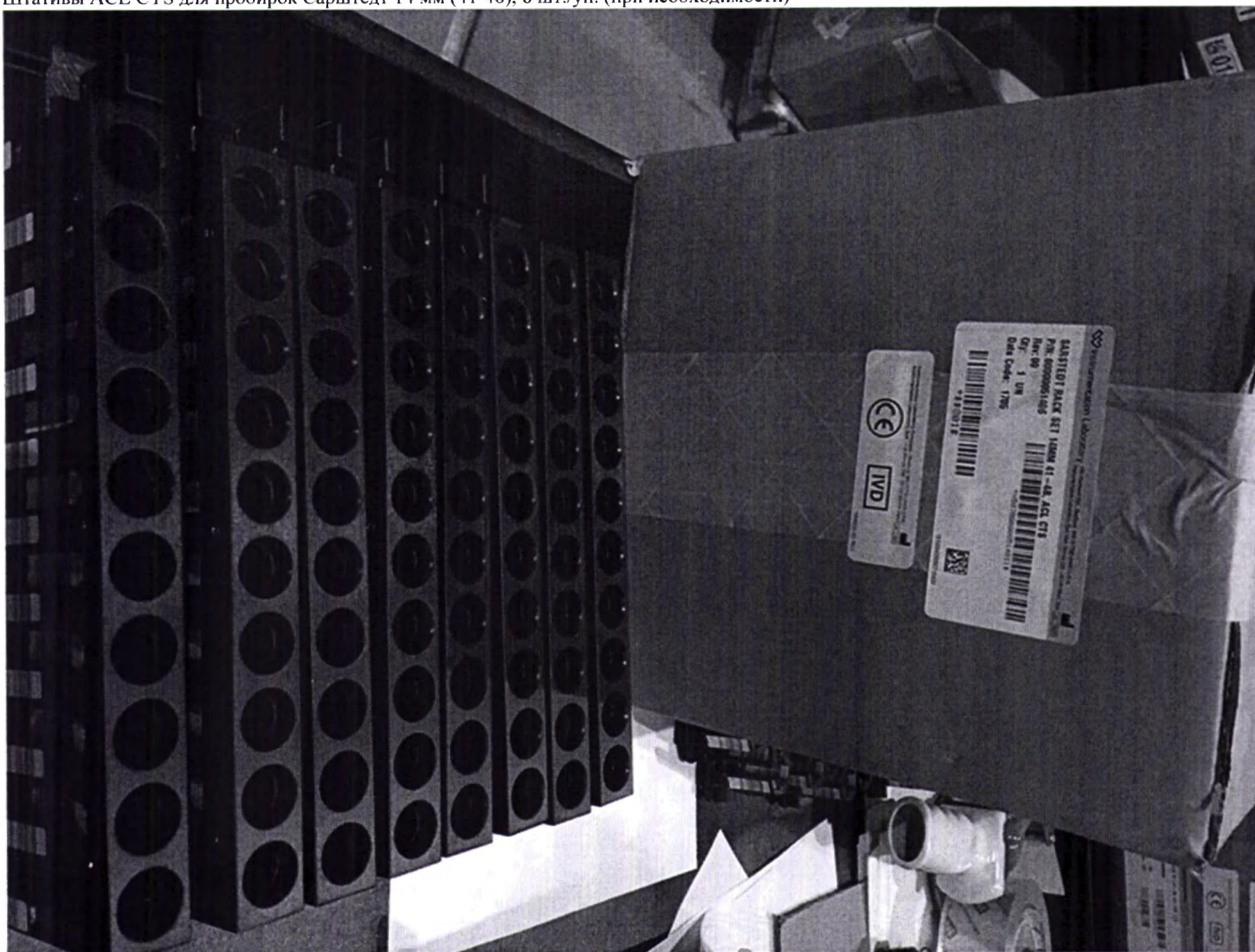
Штативы ACL CTS для пробирок Сарштедт 14 мм (25-32), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 14 мм (33-40), 8 шт./уп. (при необходимости)



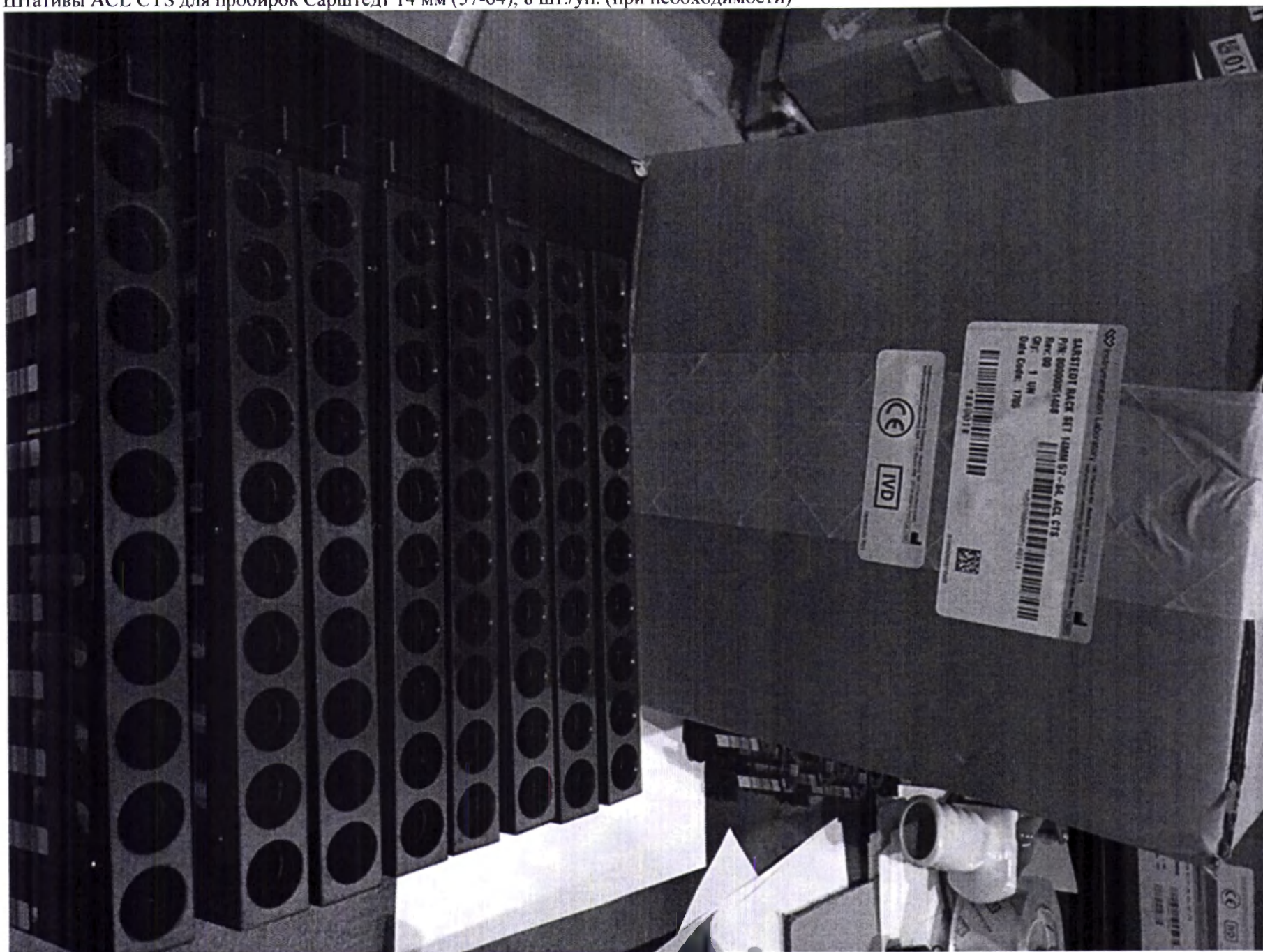
Штативы ACL CTS для пробирок Сарштедт 14 мм (41-48), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 14 мм (49-56), 8 шт./уп. (при необходимости)



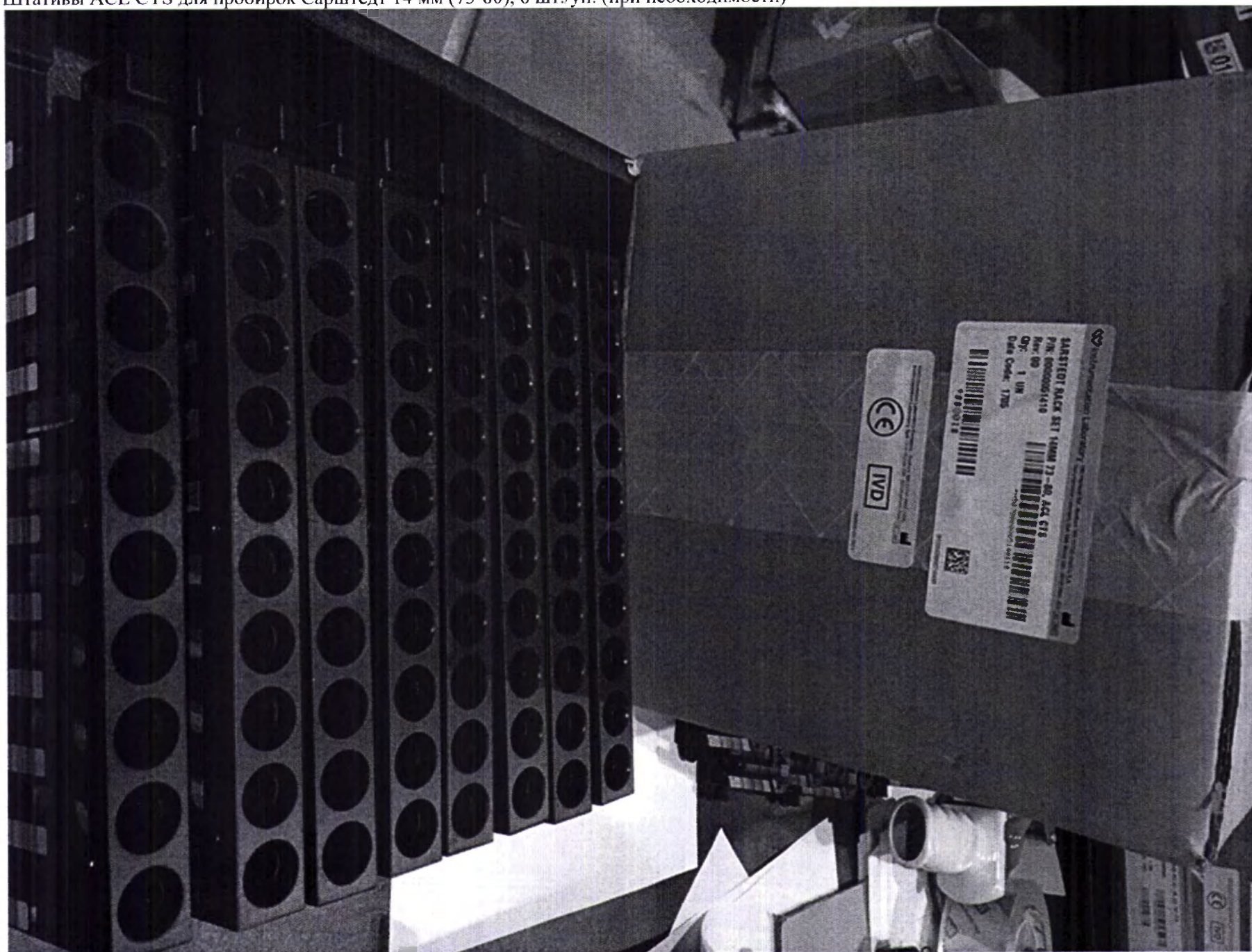
Штативы ACL CTS для пробирок Сарштедт 14 мм (57-64), 8 шт./уп. (при необходимости)



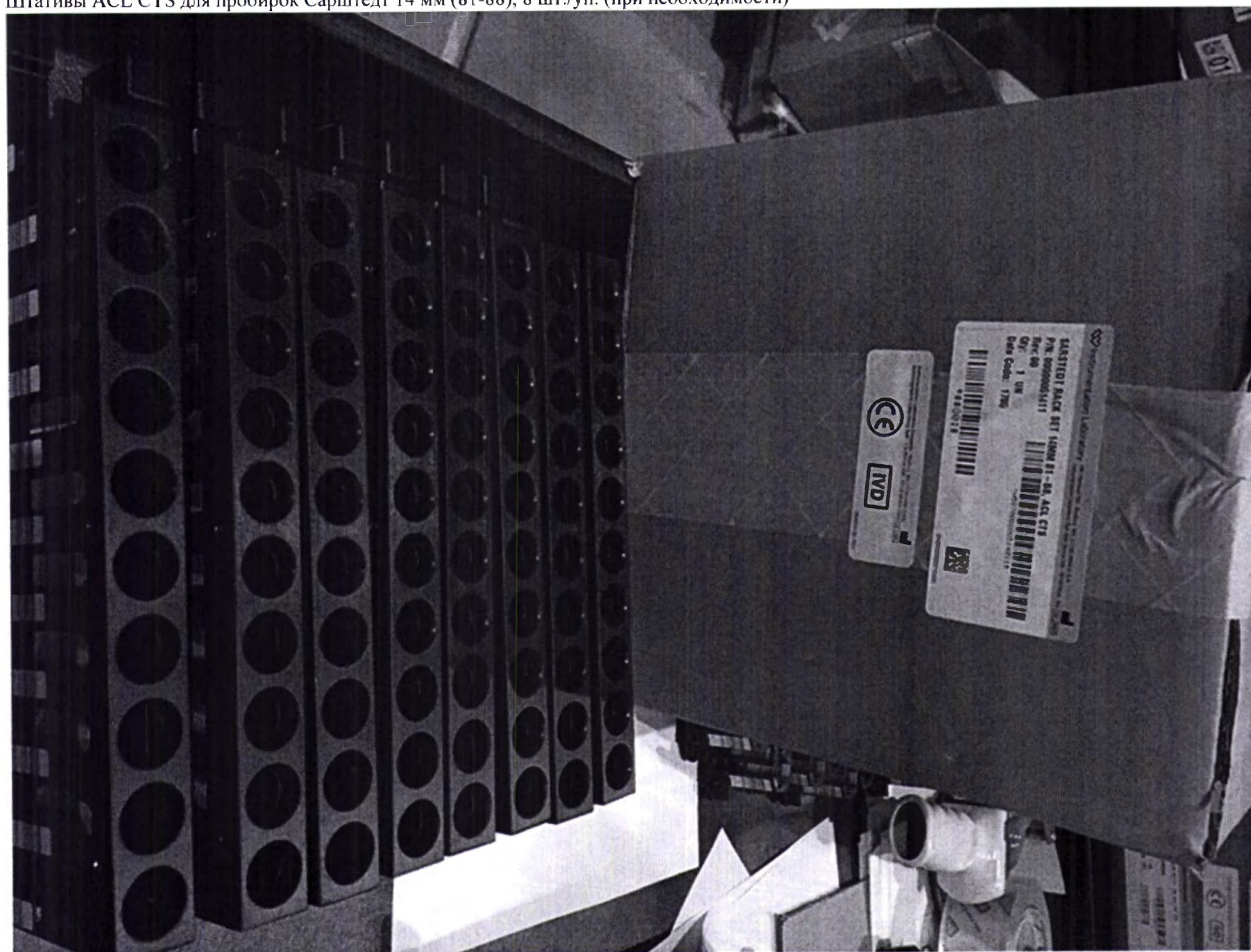
Штативы ACL CTS для пробирок Саршедт 14 мм (65-72), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Саршедт 14 мм (73-80), 8 шт./уп. (при необходимости)



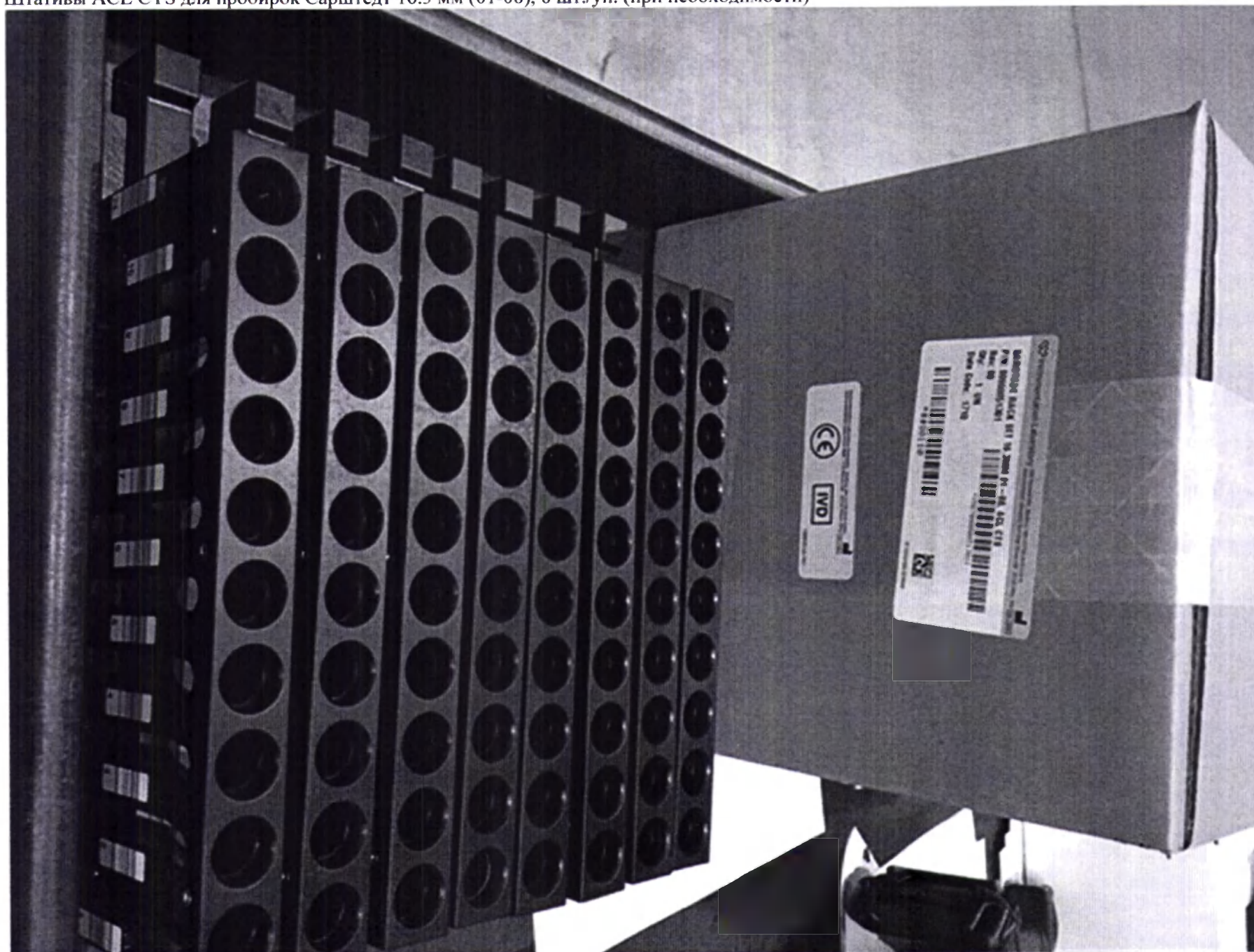
Штативы ACL CTS для пробирок Сарштедт 14 мм (81-88), 8 шт./уп. (при необходимости)



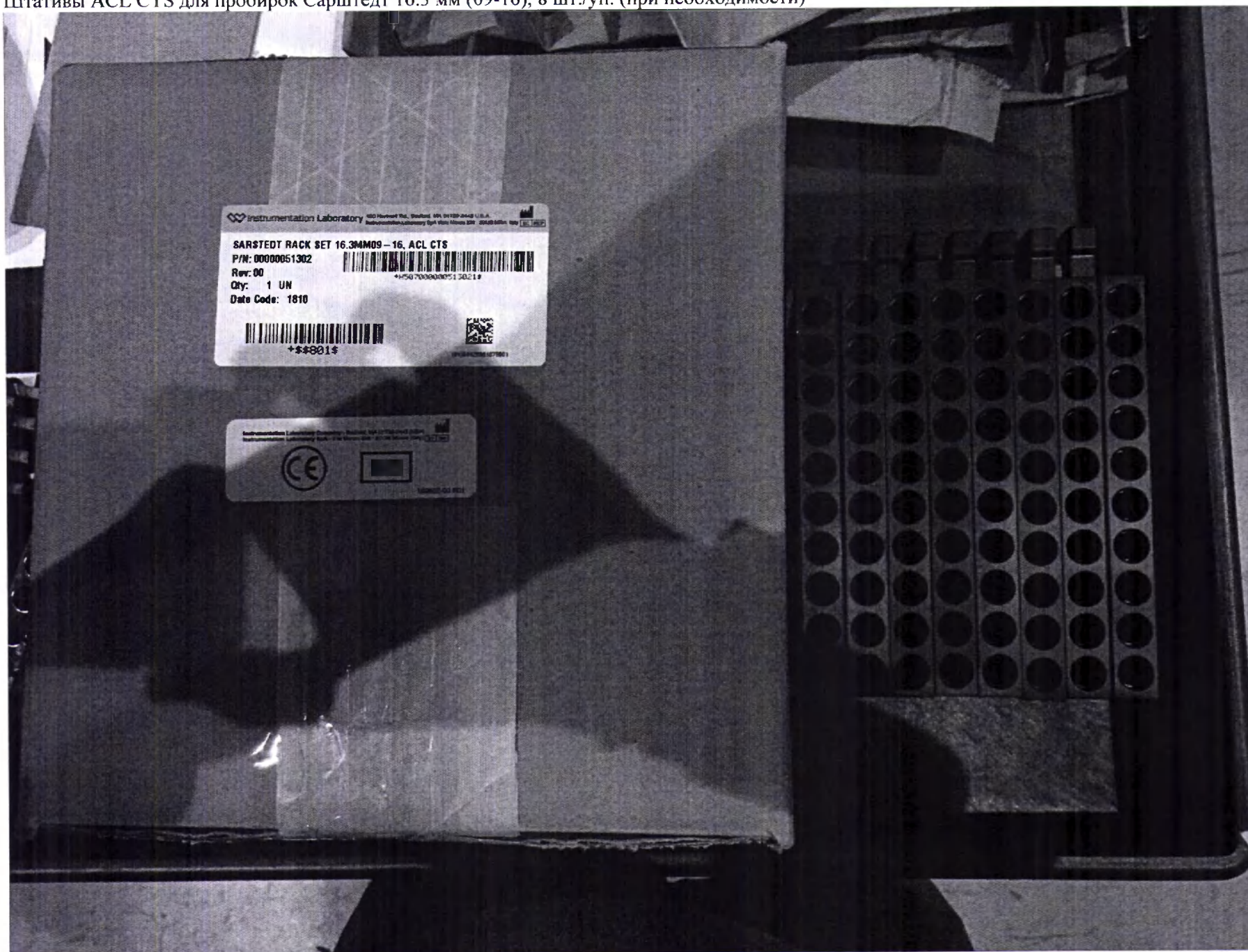
Штативы ACL CTS для пробирок Сарштедт 14 мм (89-96), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 16.3 мм (01-08), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 16.3 мм (09-16), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 16.3 мм (17-24), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Саршедт 16.3 мм (25-32), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Саршедт 16.3 мм (33-40), 8 шт./уп. (при необходимости)



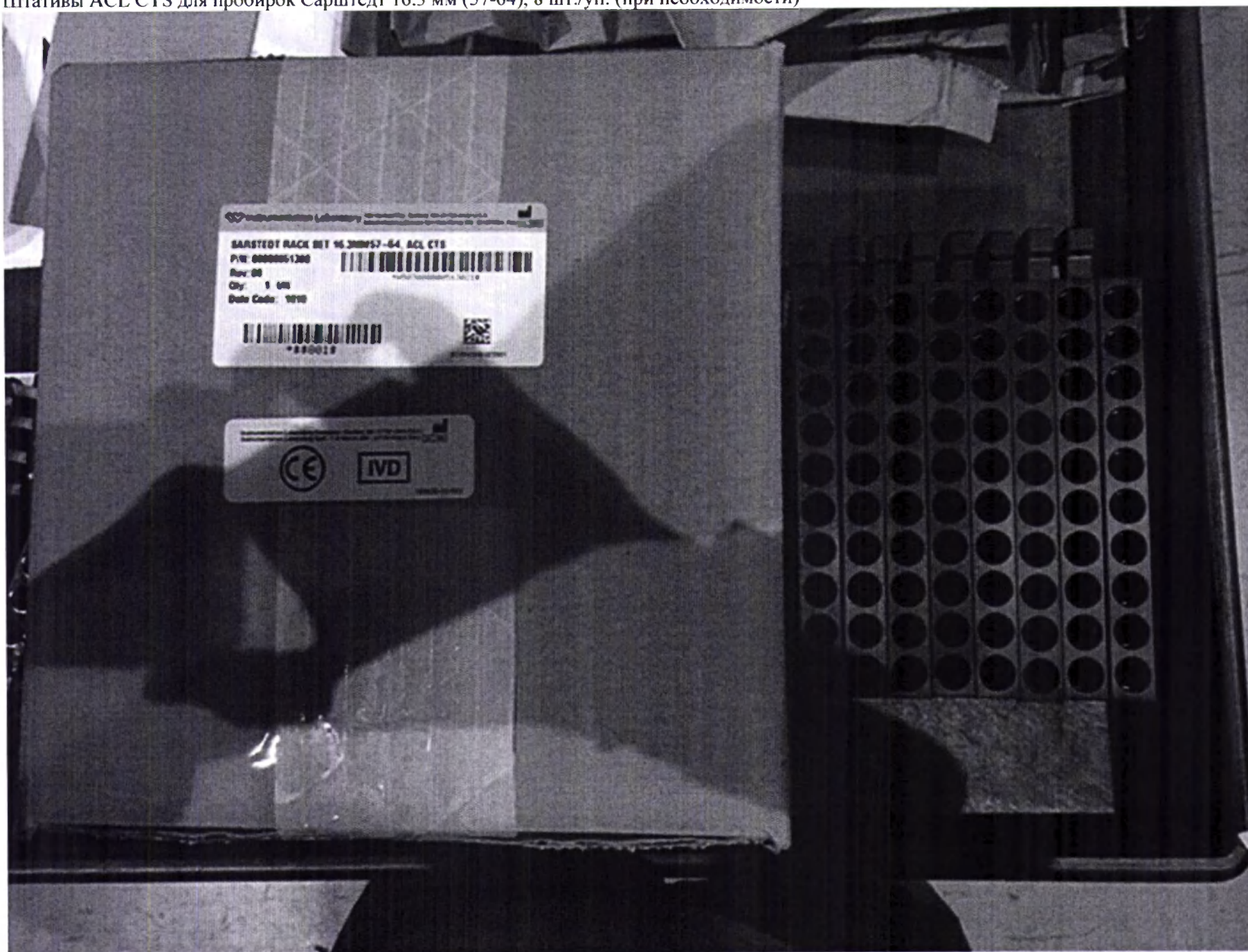
Штативы ACL CTS для пробирок Саршедт 16.3 мм (41-48), 8 шт./уп. (при необходимости)



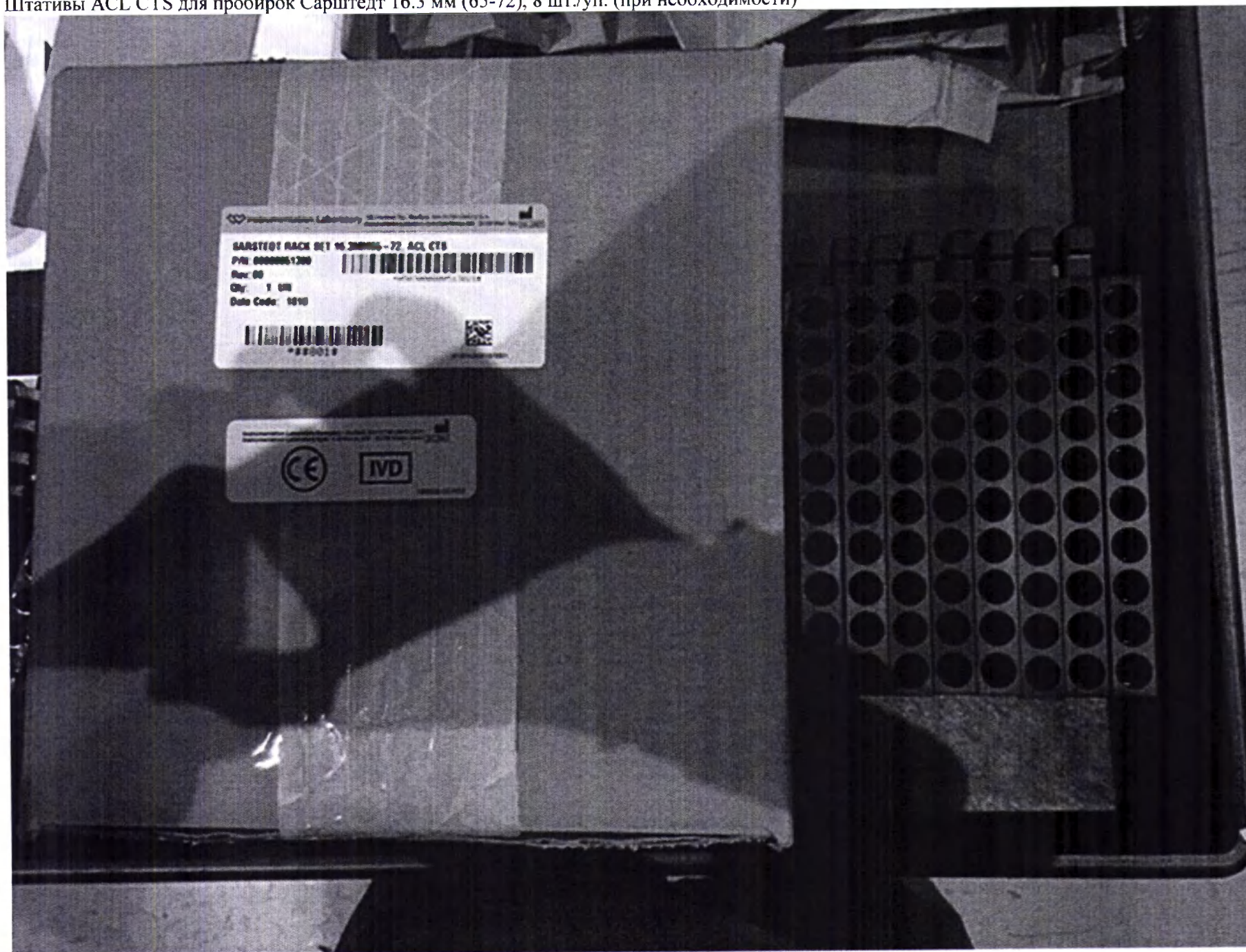
Штативы ACL CTS для пробирок Сарштедт 16.3 мм (49-56), 8 шт./уп. (при необходимости)



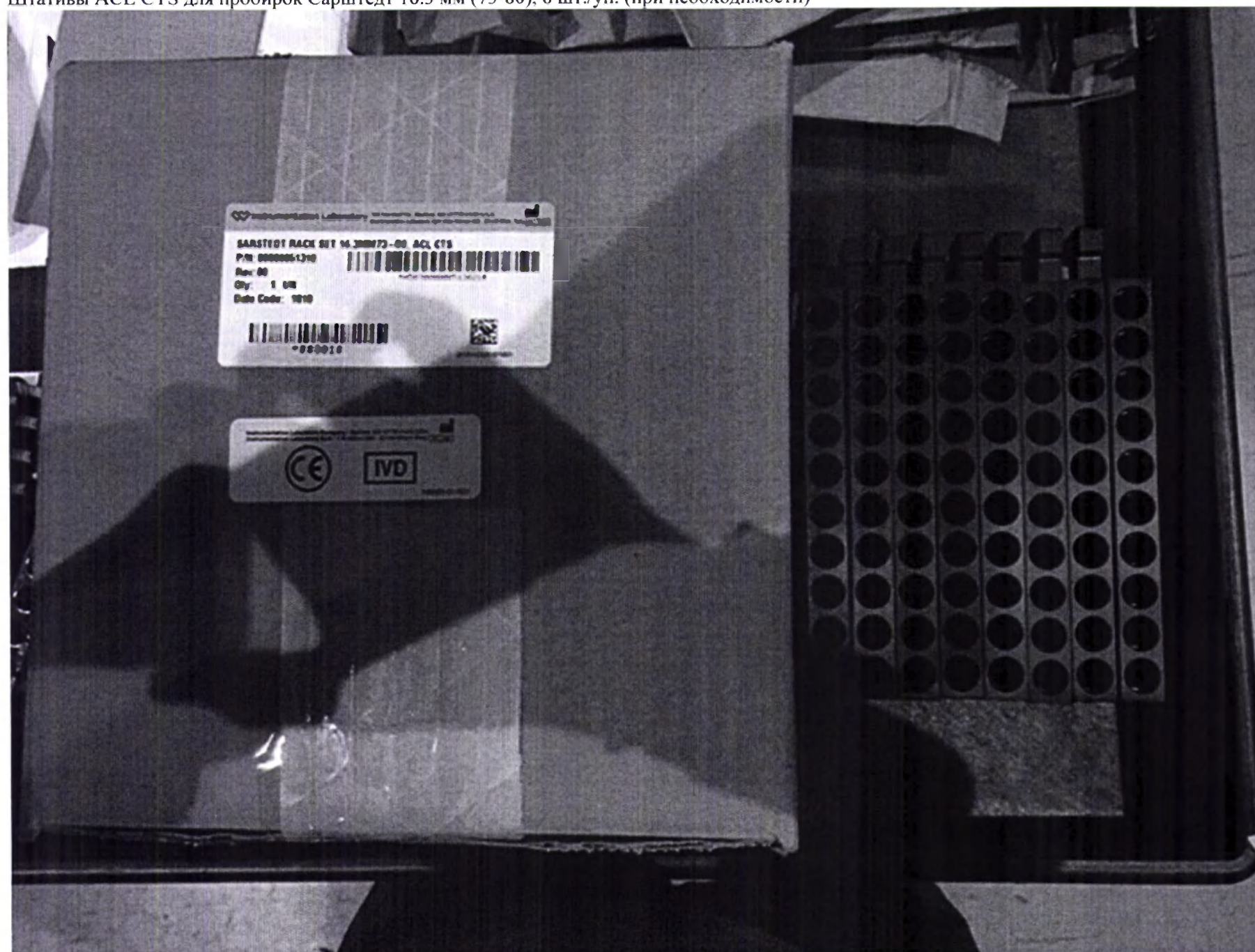
Штативы ACL CTS для пробирок Сарштедт 16.3 мм (57-64), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 16.3 мм (65-72), 8 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 16.3 мм (73-80), 8 шт./уп. (при необходимости)



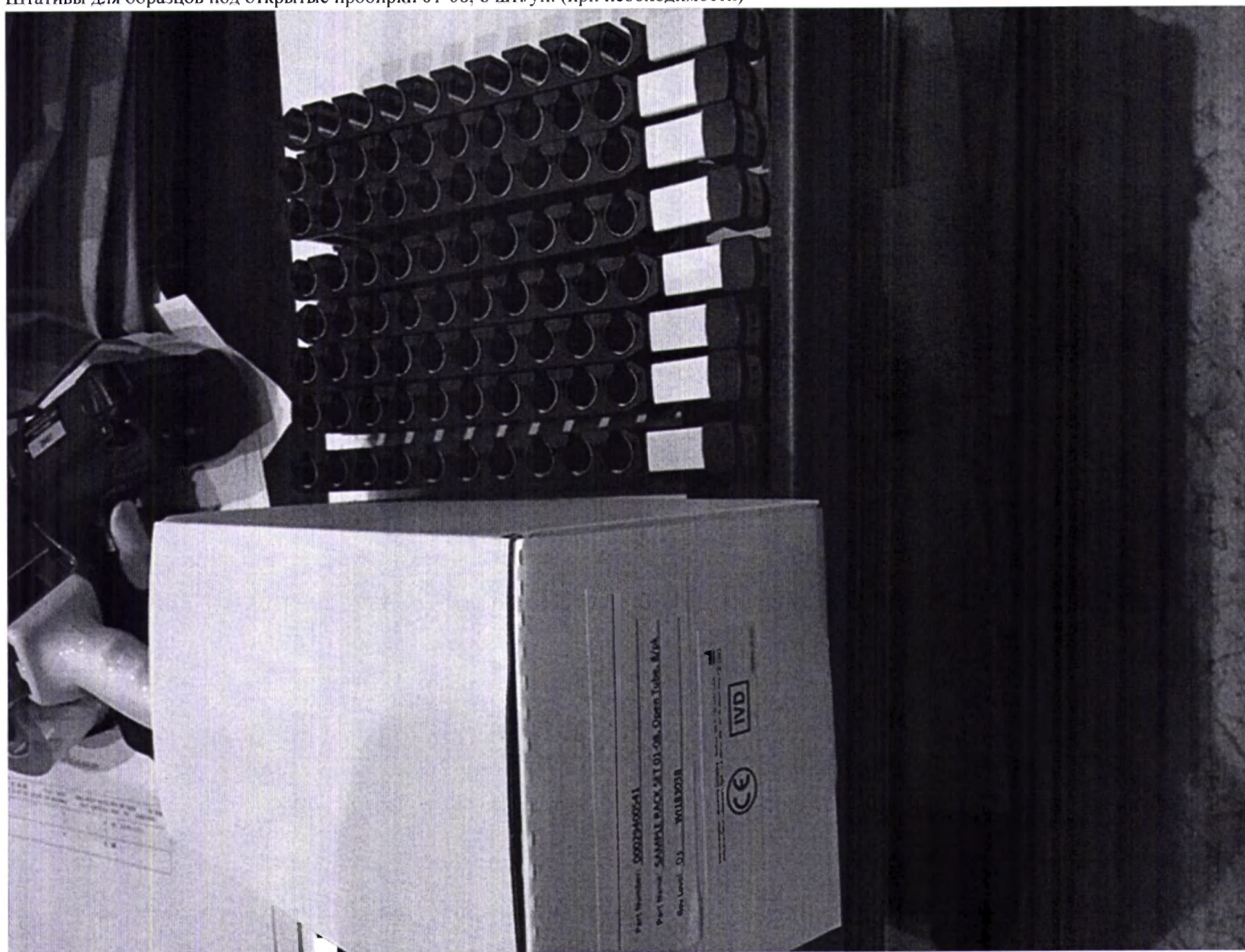
Штативы ACL CTS для пробирок Сарштедт 16.3 мм (81-88), 8 шт./уп. (при необходимости)



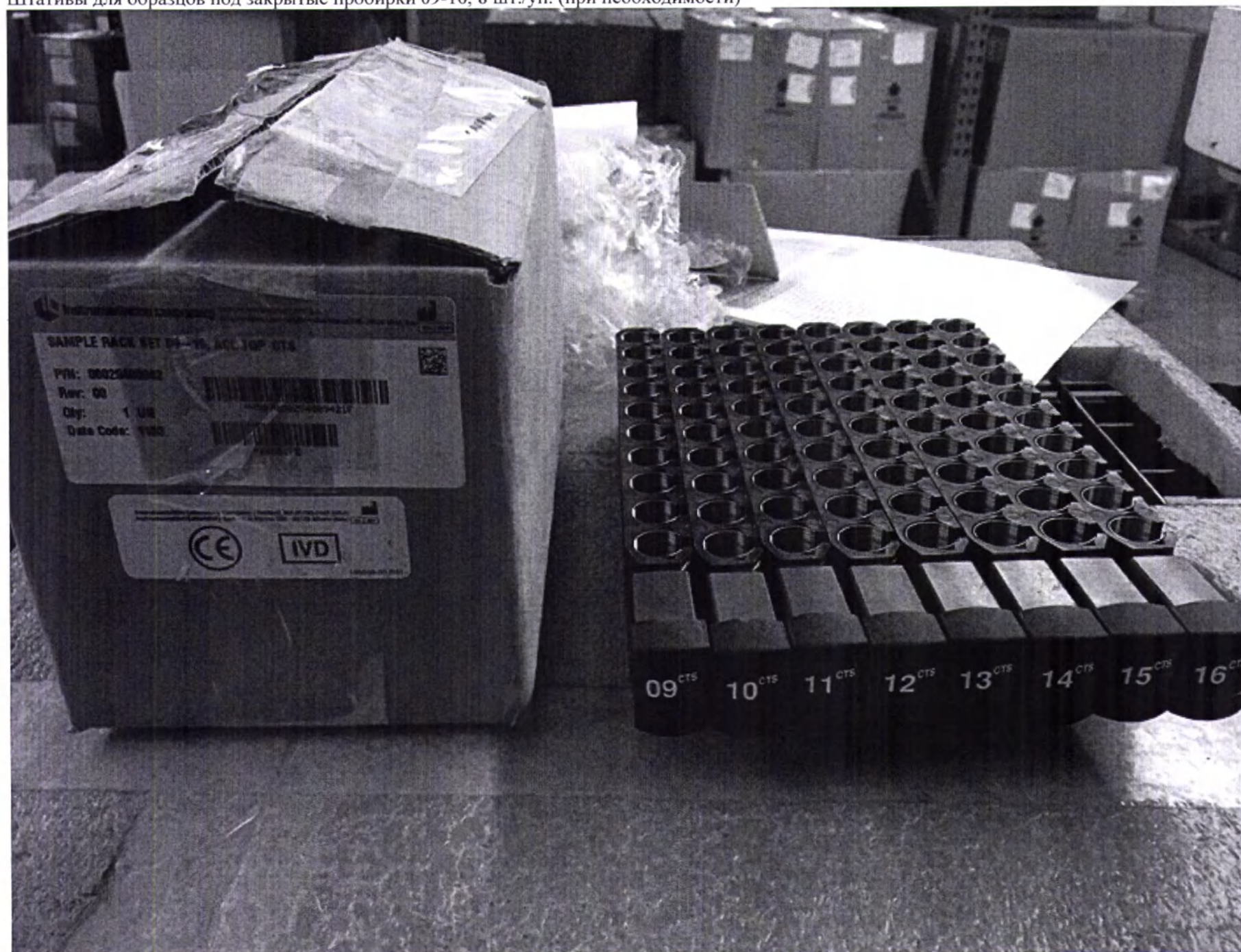
Штативы ACL CTS для пробирок Сарштедт 16.3 мм (89-96), 8 шт./уп. (при необходимости)



Штативы для образцов под открытые пробирки 01-08, 8 шт./уп. (при необходимости)



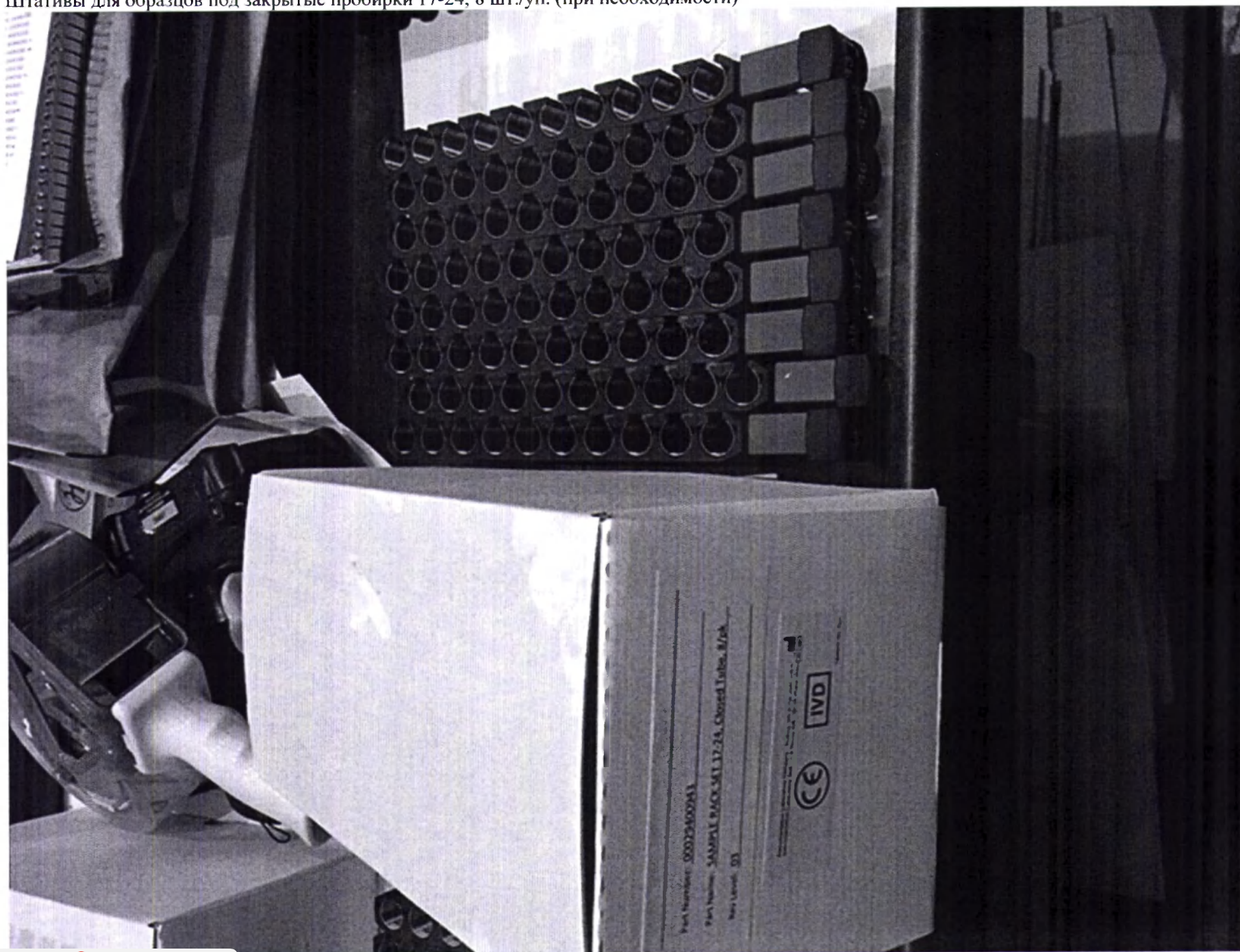
Штативы для образцов под закрытые пробирки 09-16, 8 шт./уп. (при необходимости)



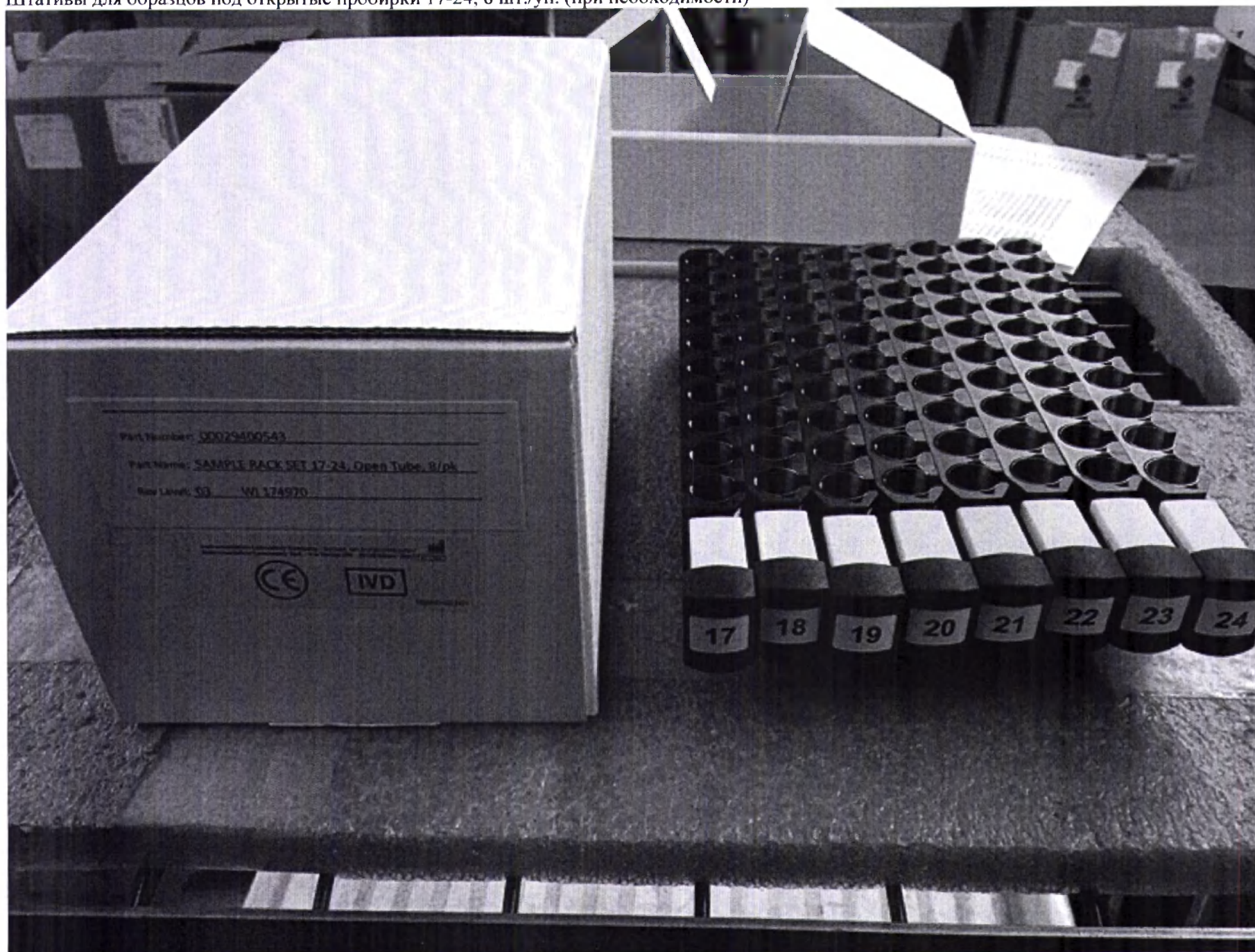
Штативы для образцов под открытые пробирки 09-16, 8 шт./уп. (при необходимости)



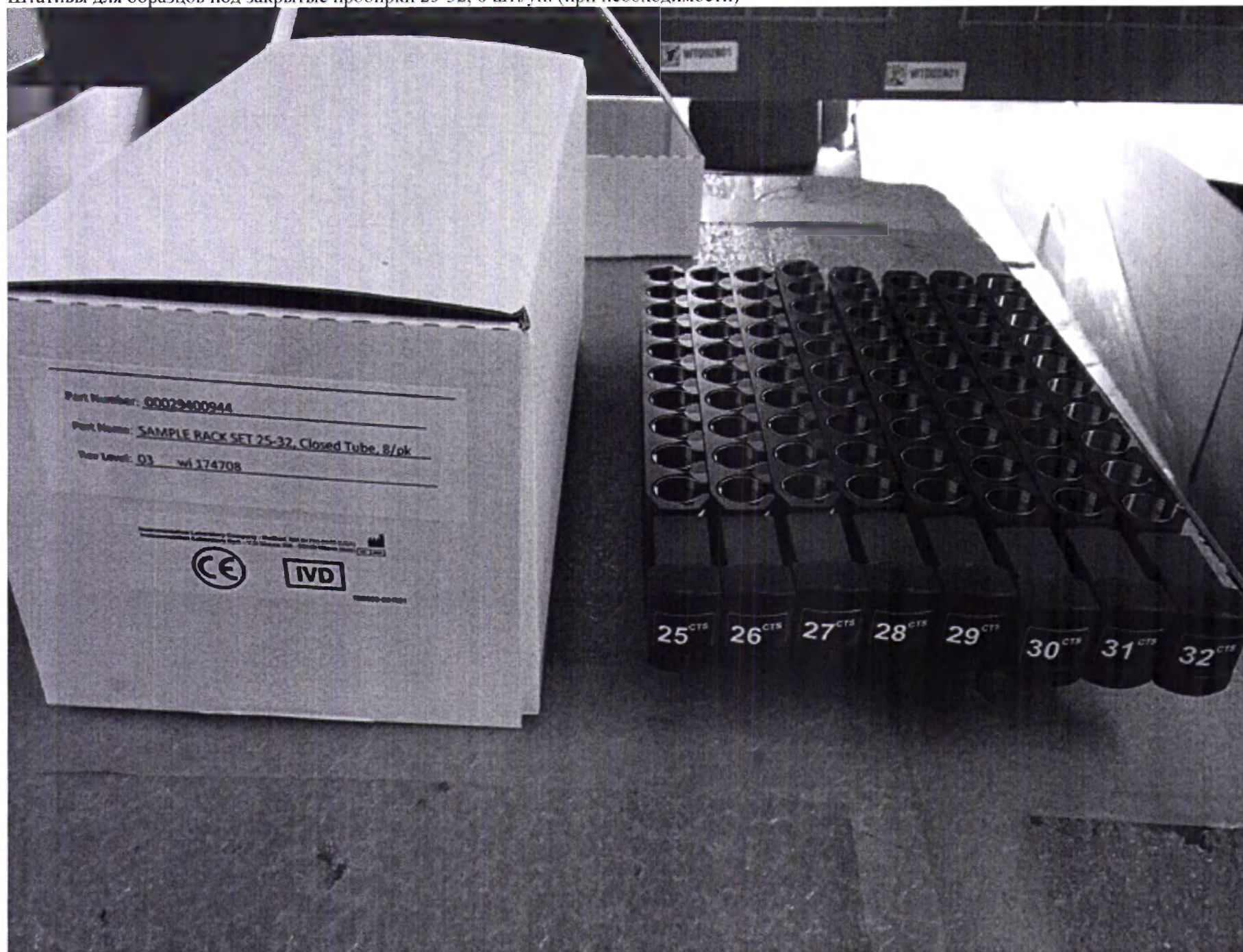
Штативы для образцов под закрытые пробирки 17-24, 8 шт./уп. (при необходимости)



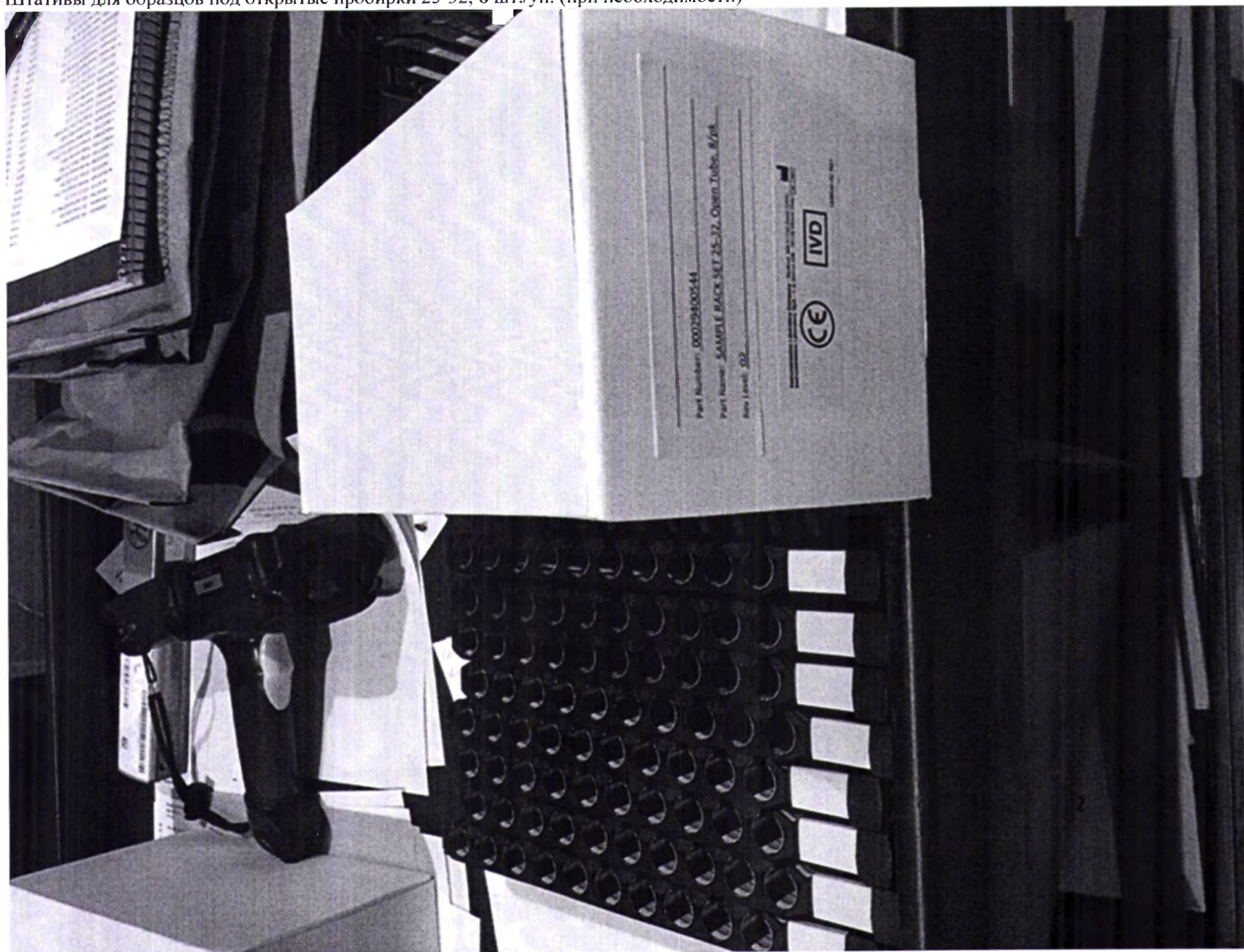
Штативы для образцов под открытые пробирки 17-24, 8 шт./уп. (при необходимости)



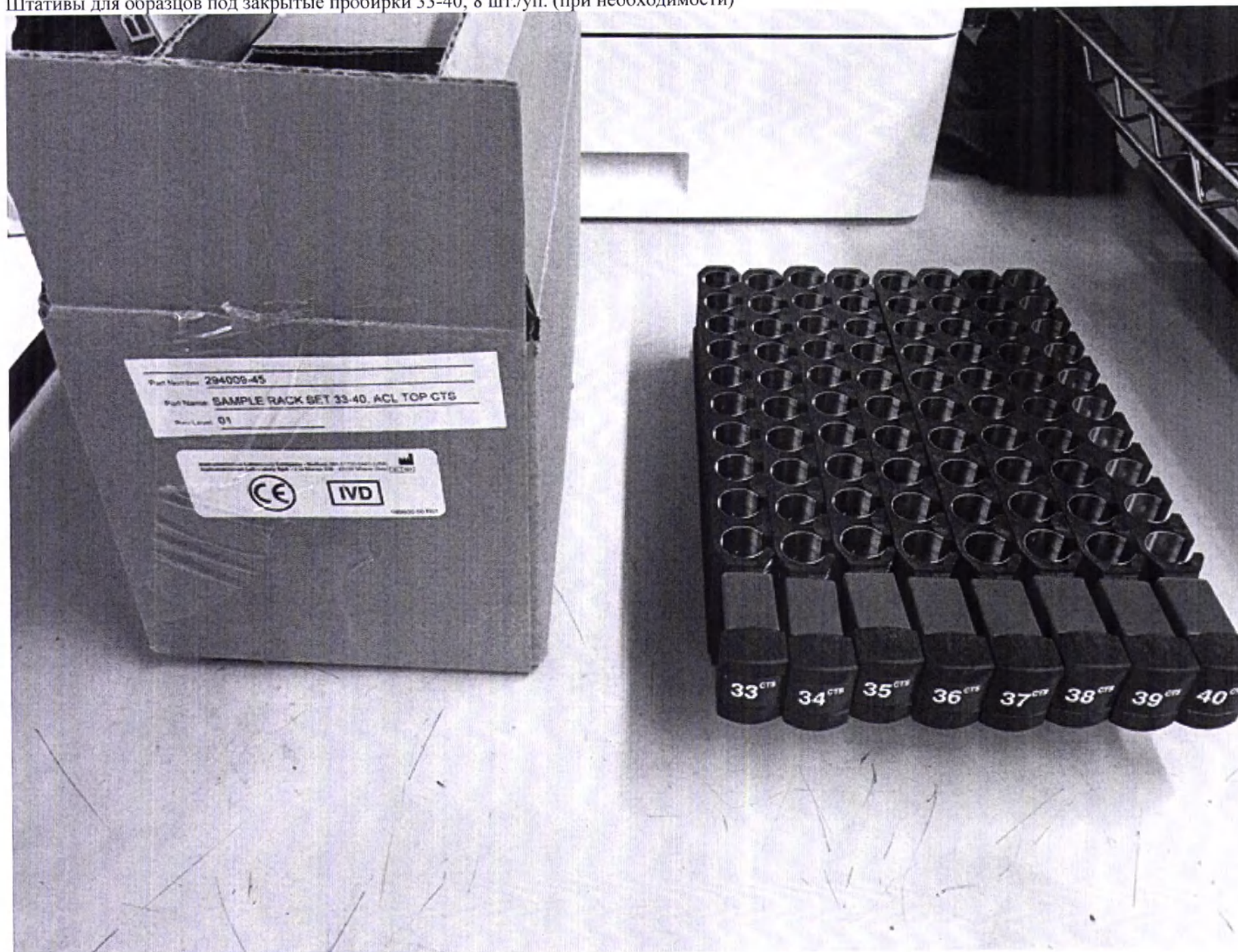
Штативы для образцов под закрытые пробирки 25-32, 8 шт./уп. (при необходимости)



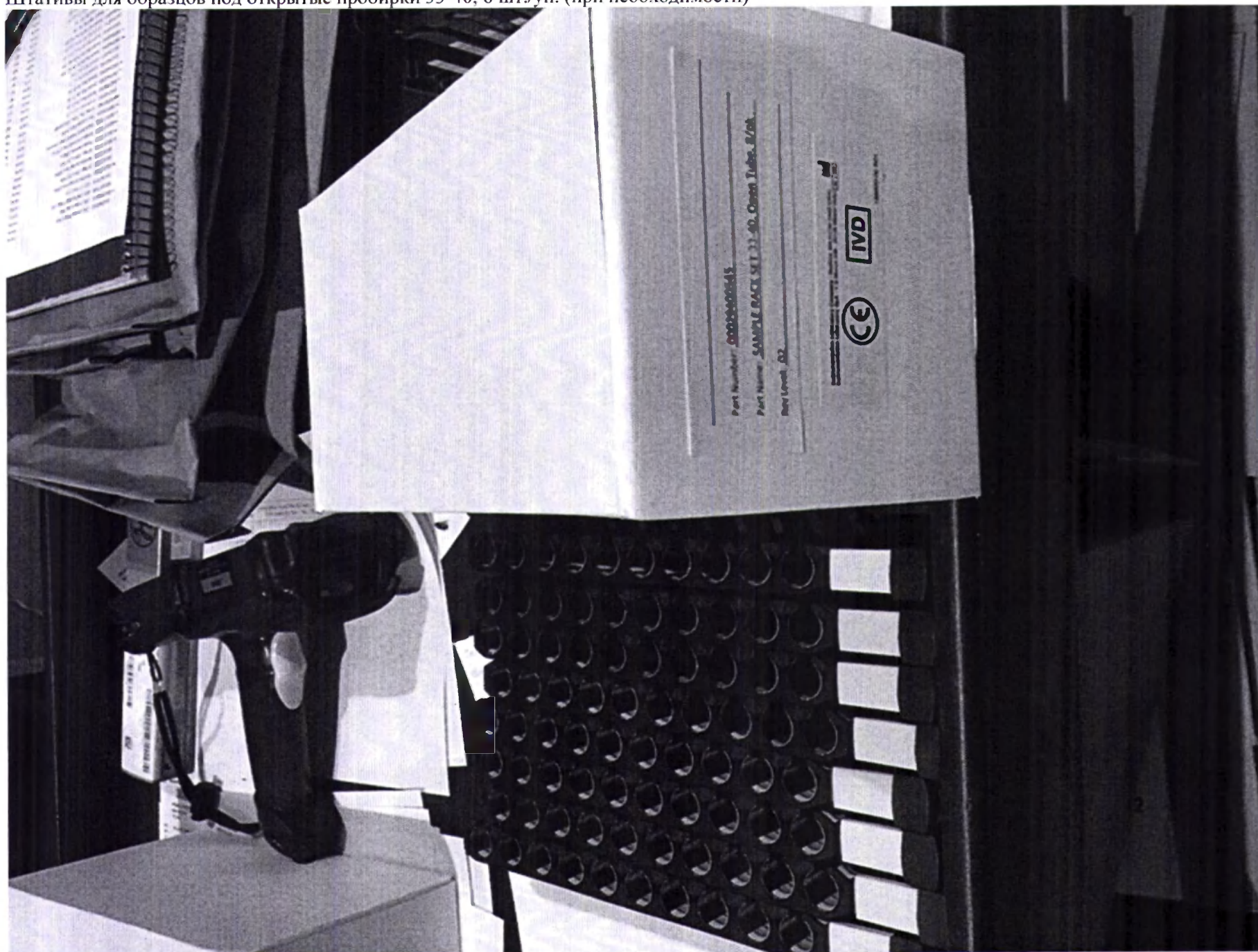
Штативы для образцов под открытые пробирки 25-32, 8 шт./уп. (при необходимости)



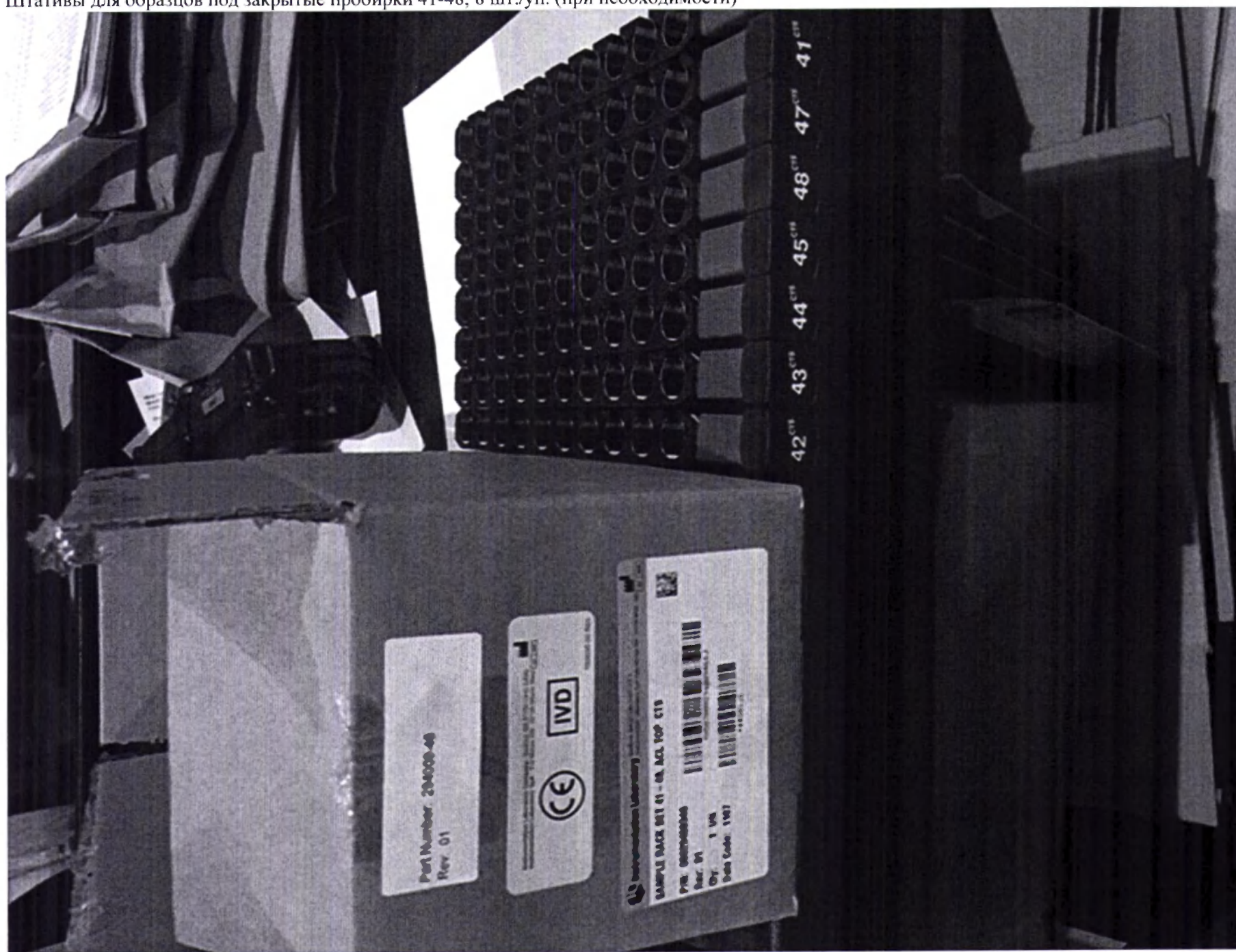
Штативы для образцов под закрытые пробирки 33-40, 8 шт./уп. (при необходимости)



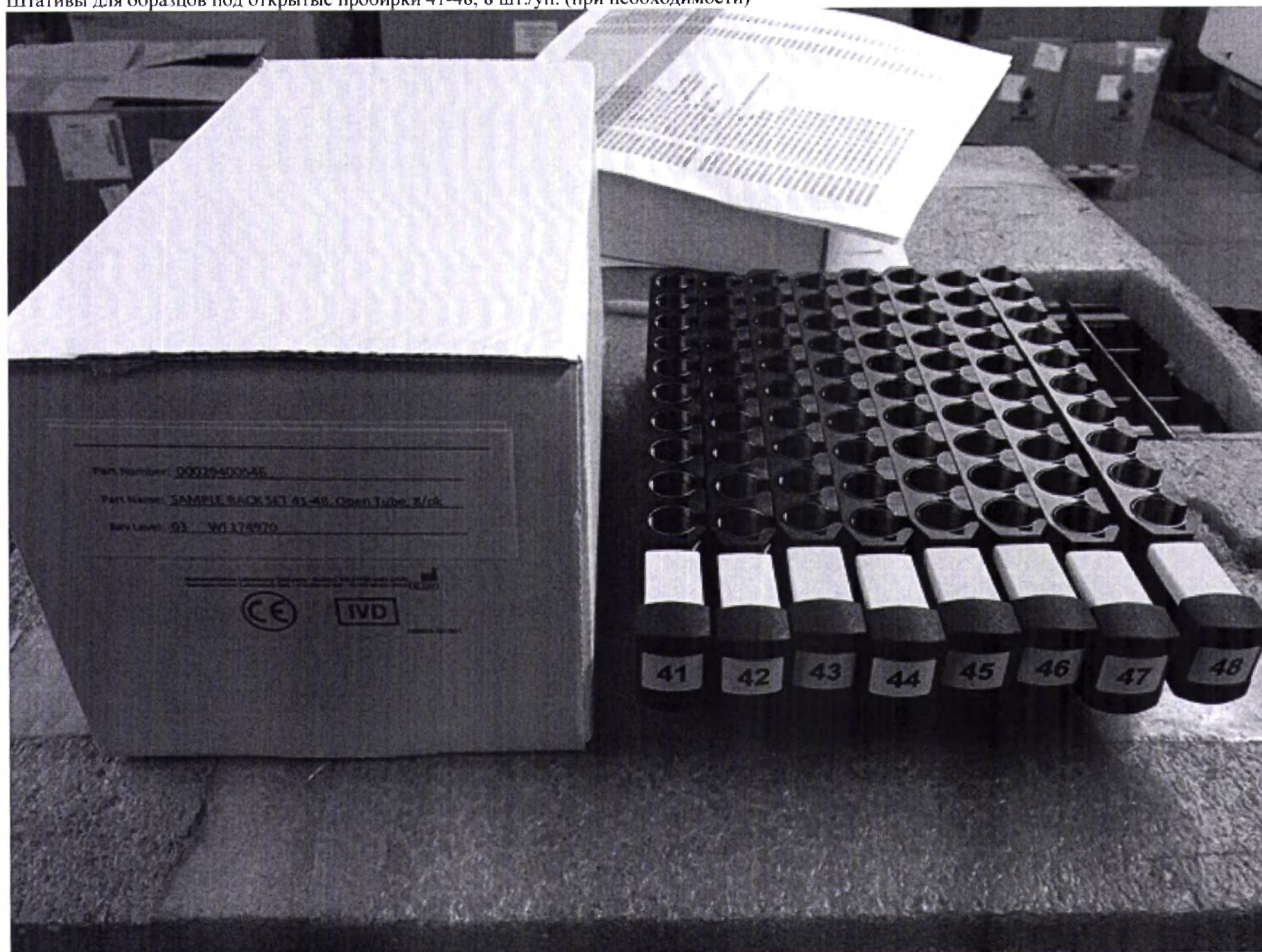
Штативы для образцов под открытые пробирки 33-40, 8 шт./уп. (при необходимости)



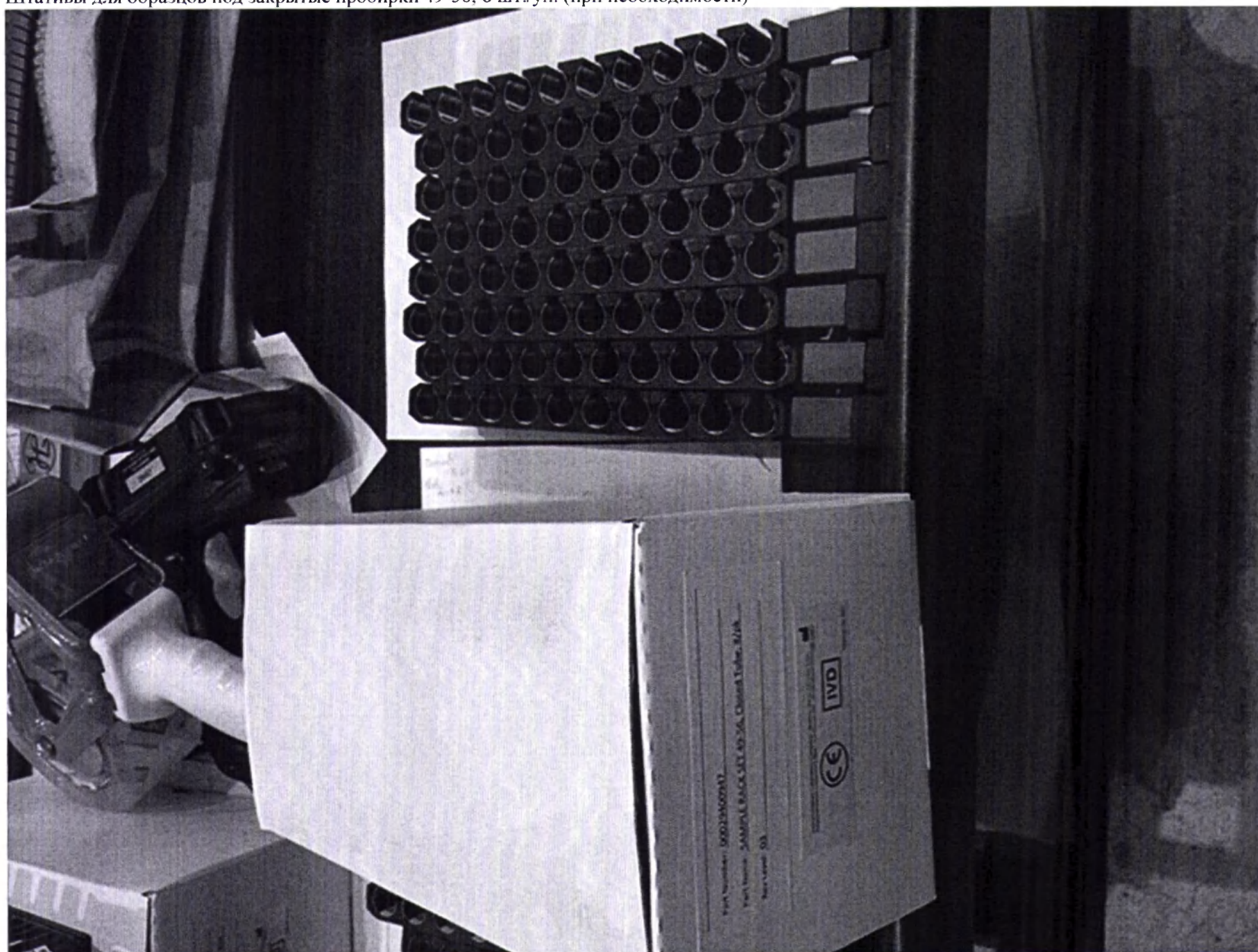
Штативы для образцов под закрытые пробирки 41-48, 8 шт./уп. (при необходимости)



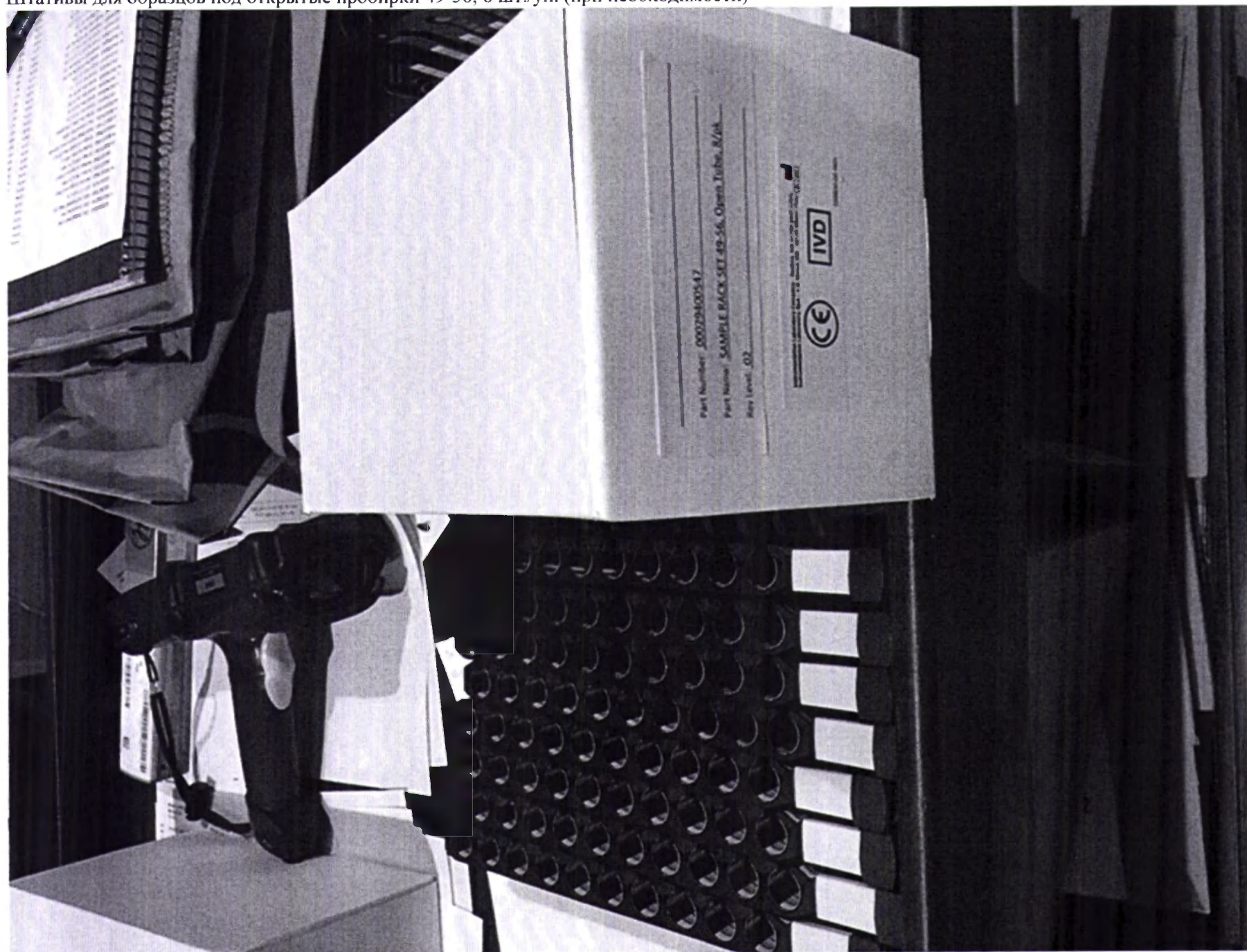
Штативы для образцов под открытые пробирки 41-48, 8 шт./уп. (при необходимости)



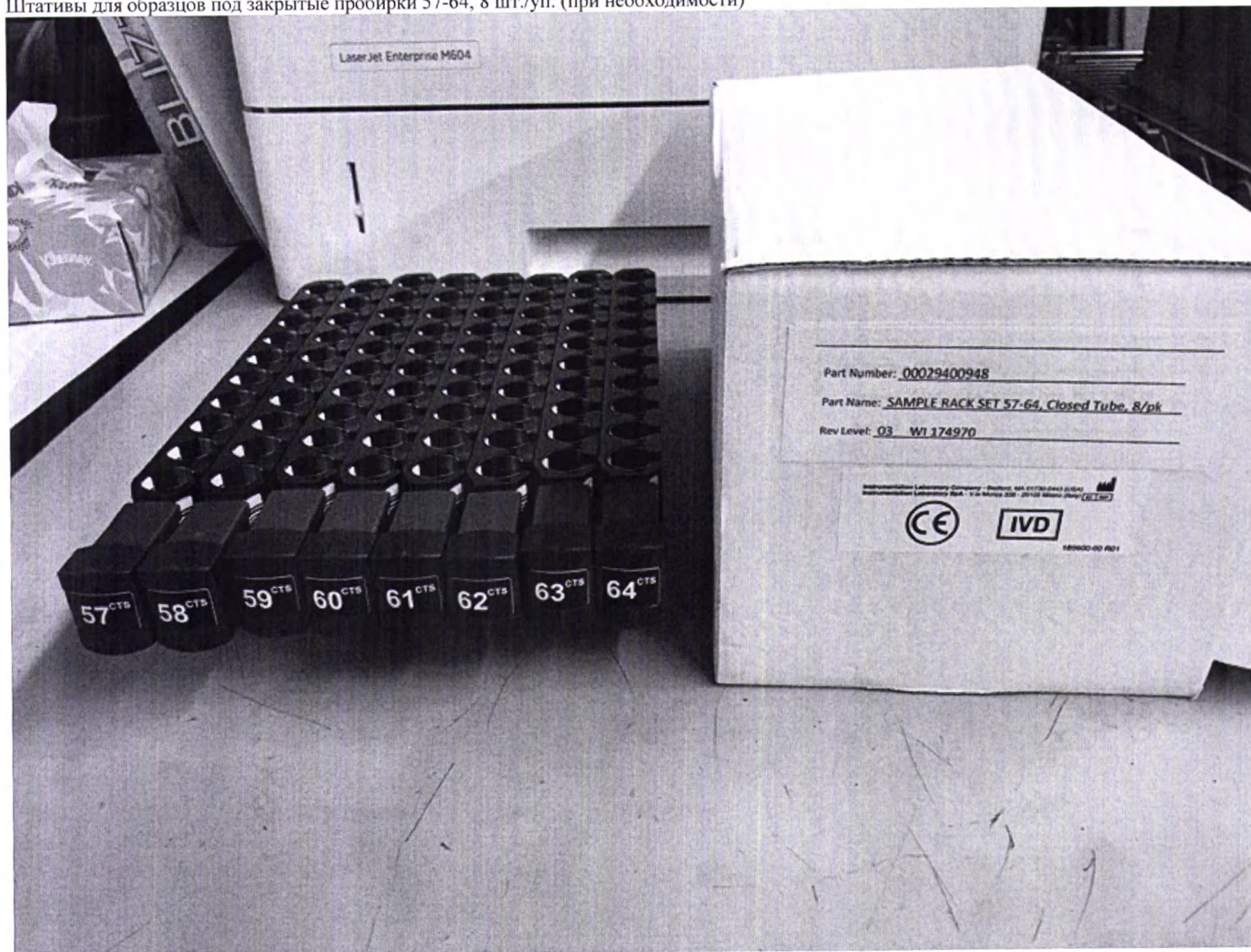
Штативы для образцов под закрытые пробирки 49-56, 8 шт./уп. (при необходимости)



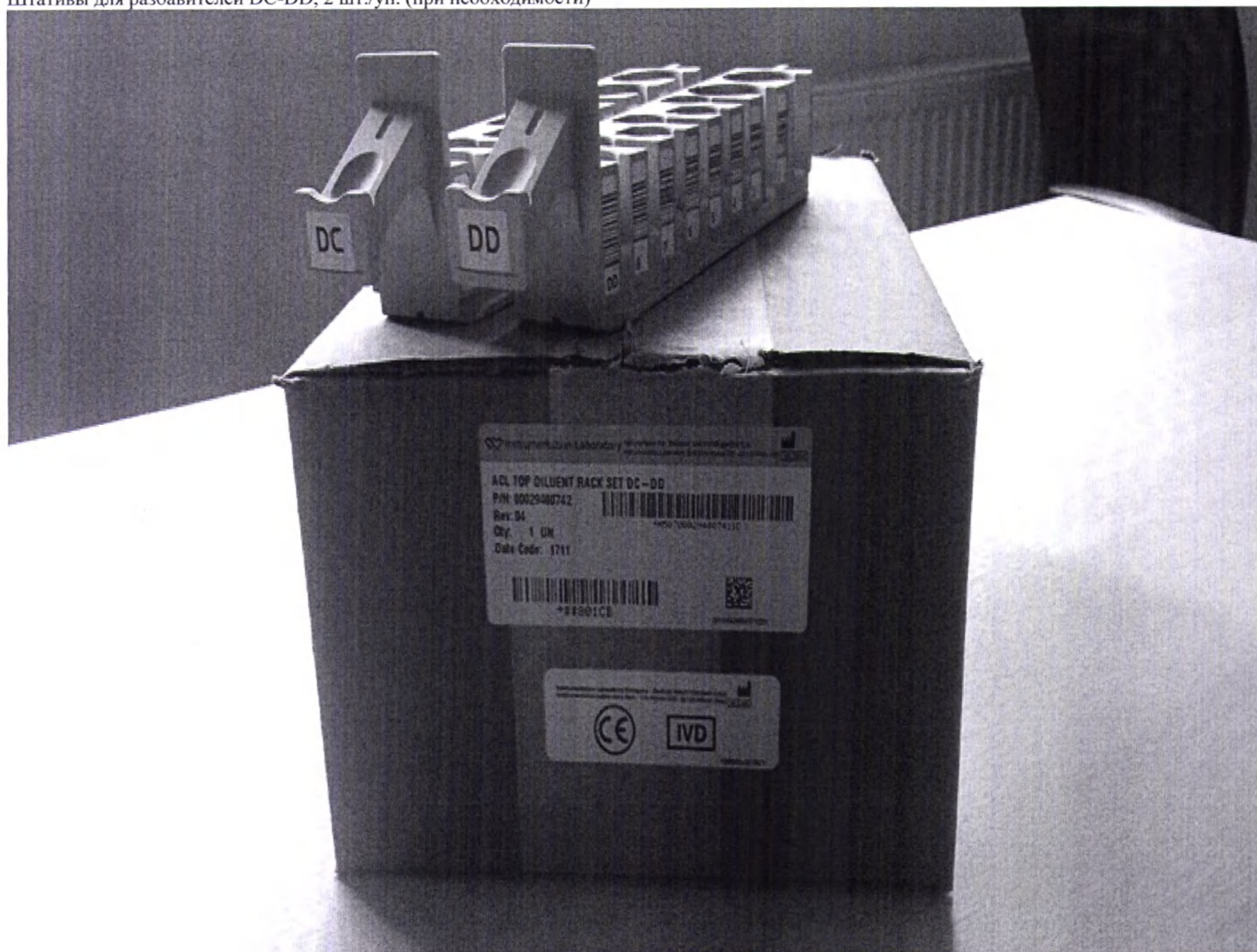
Штативы для образцов под открытые пробирки 49-56, 8 шт./уп. (при необходимости)



Штативы для образцов под закрытые пробирки 57-64, 8 шт./уп. (при необходимости)



Штативы для разбавителей DC-DD, 2 шт./уп. (при необходимости)



Штативы для реагентов RE-RH, 4 шт./уп. (при необходимости)



Договор и приложение
№ 10 к договору

Договор

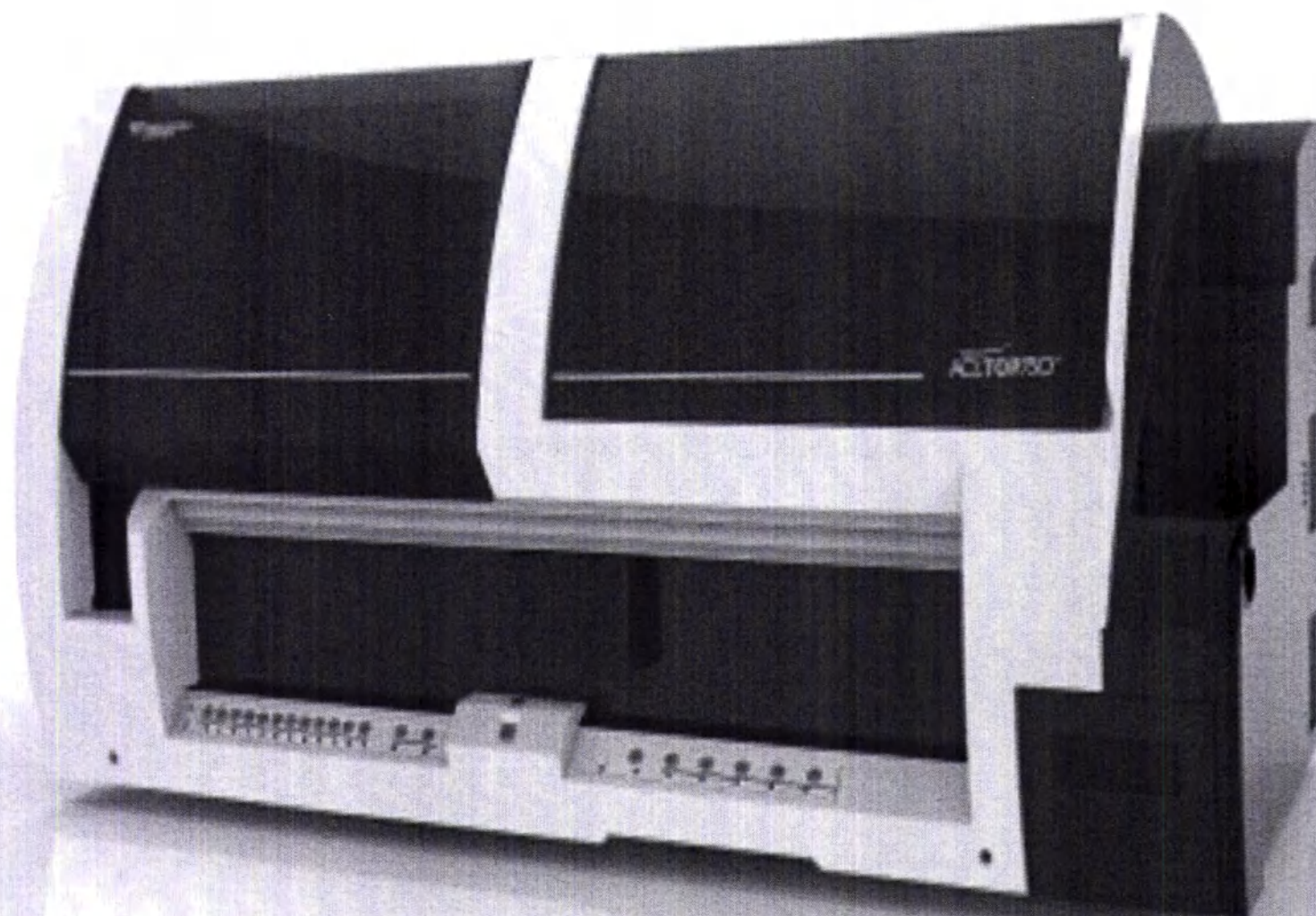
Договор

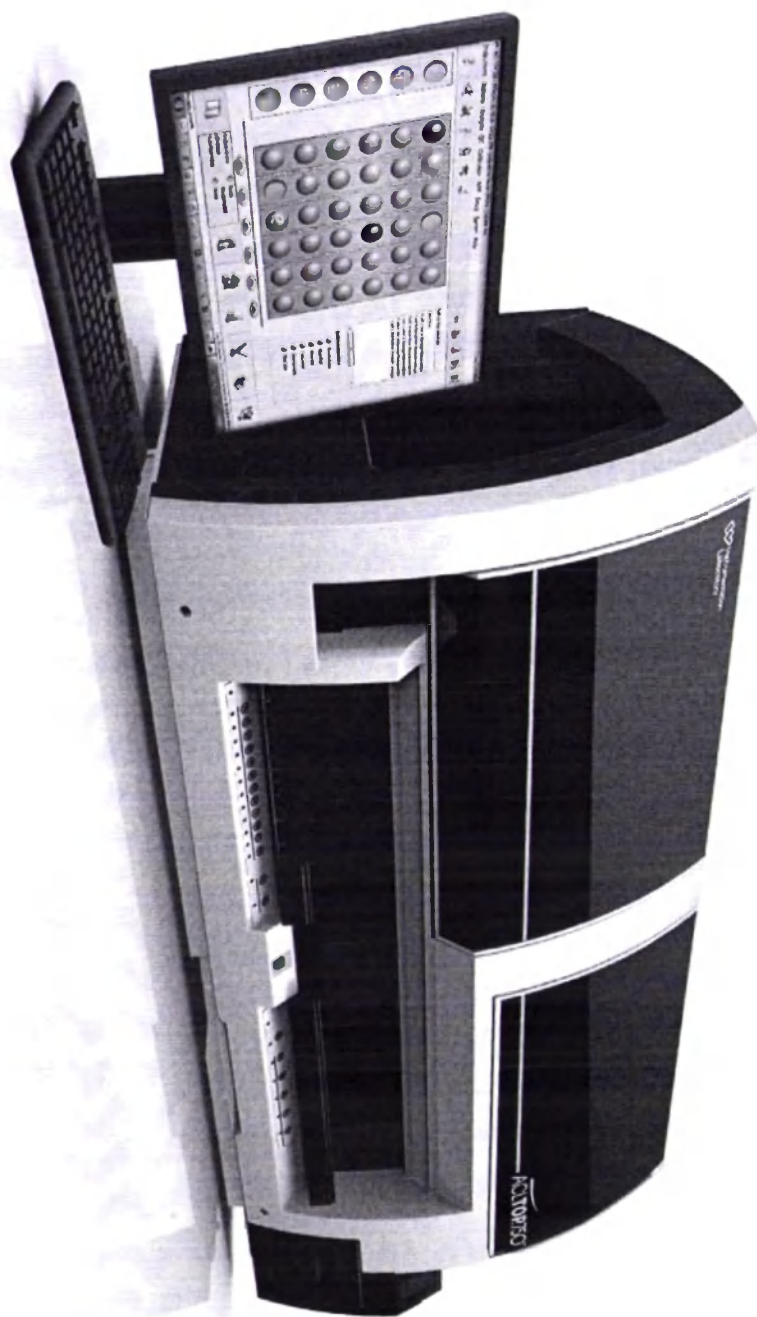


ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ МЕДИЦИНСКОГО ИЗДЕЛИЯ

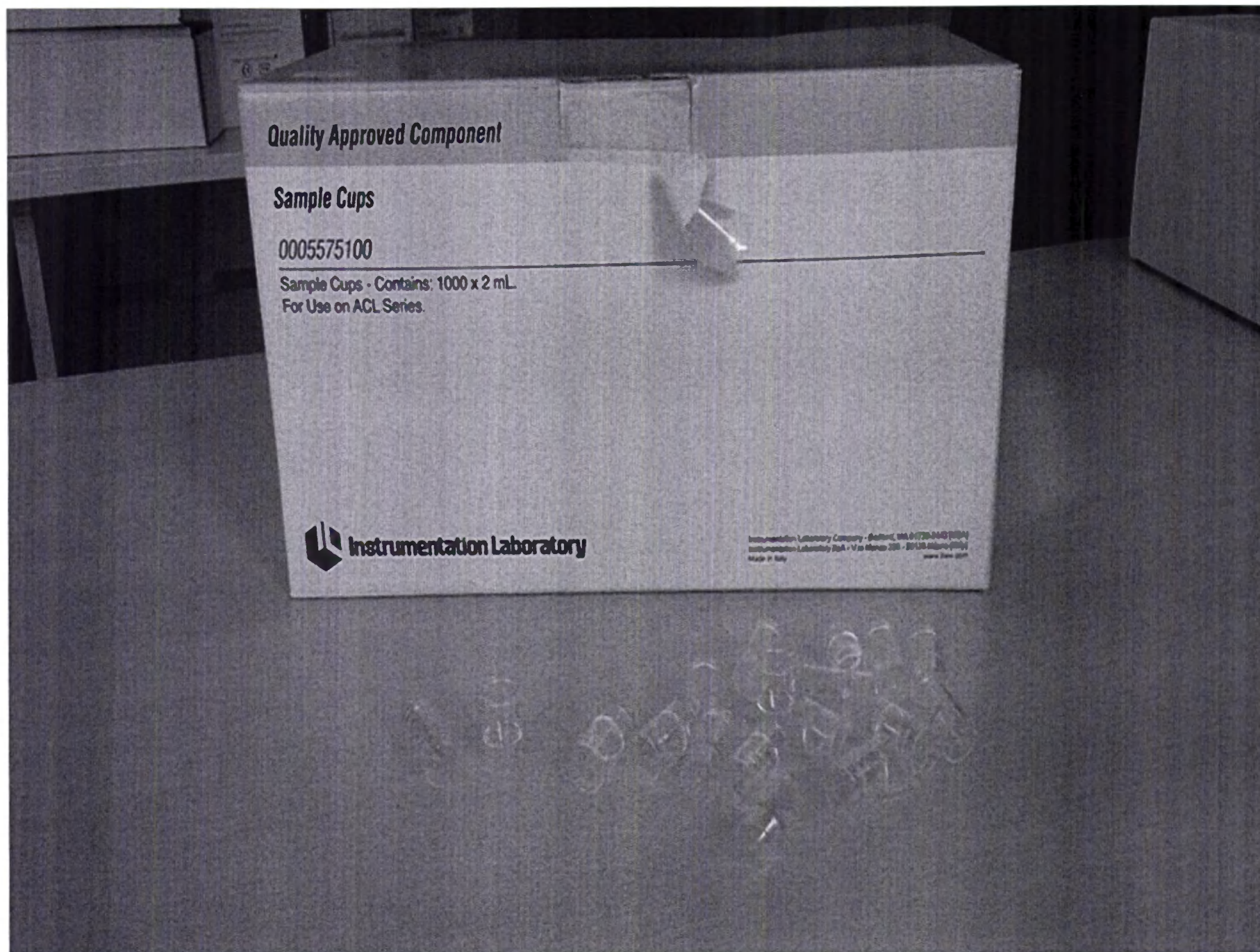
Анализатор автоматический коагулометрический для диагностики in vitro ACL TOP,
вариант исполнения ACL TOP 750

Анализатор





Чашечки для образцов 2.0 мл, 1000 шт.



Магнитные мешалки, 6 шт.

MAGNETIC STIR BARS, 6/PK

Q.ty : 1

Item N° : 0009746606

Instrumentation Laboratory Company - Bedford, MA 01730-2443 (USA)
Instrumentation Laboratory SpA - V.le Monza 338 - 20128 Milano (Italy)



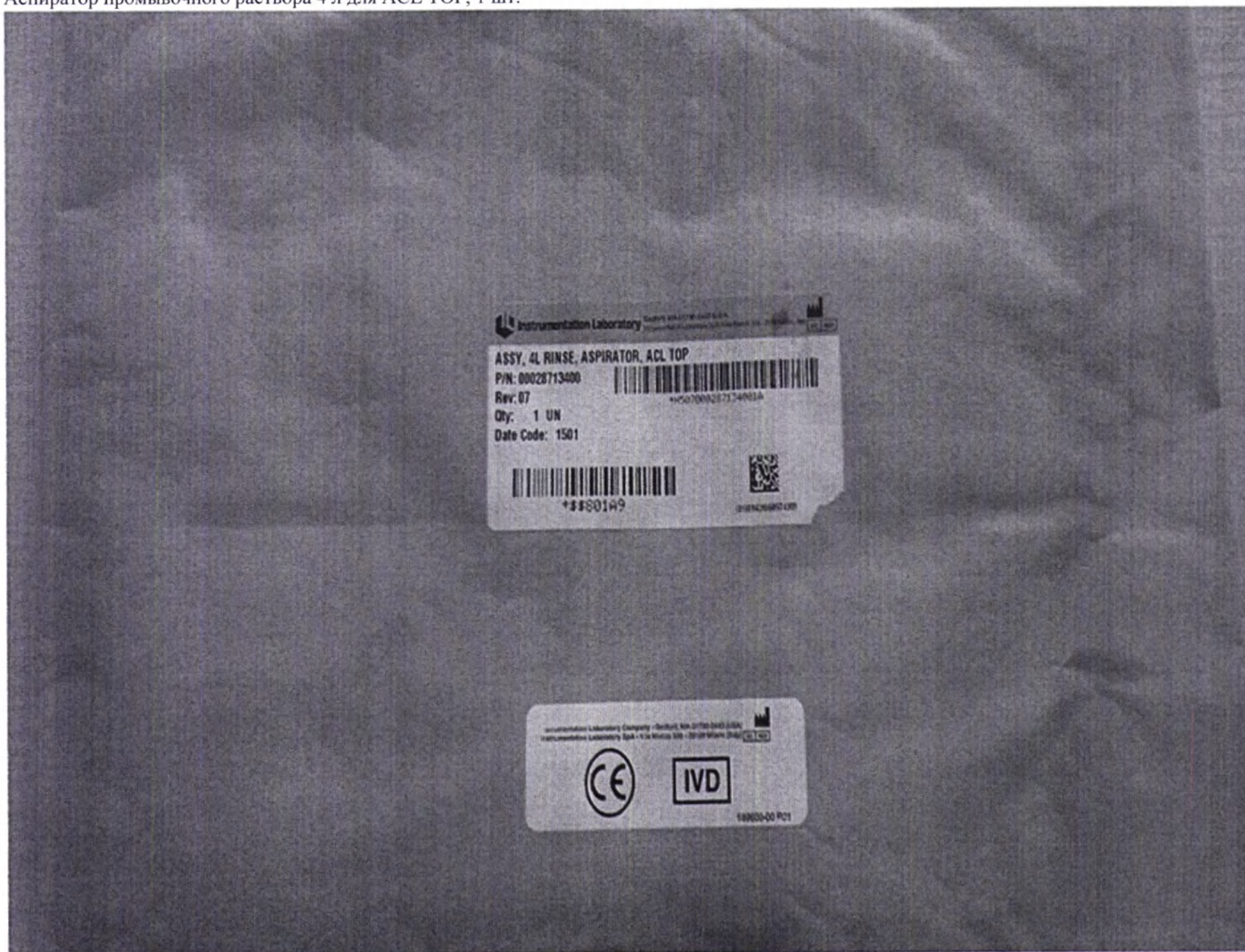
EC REP

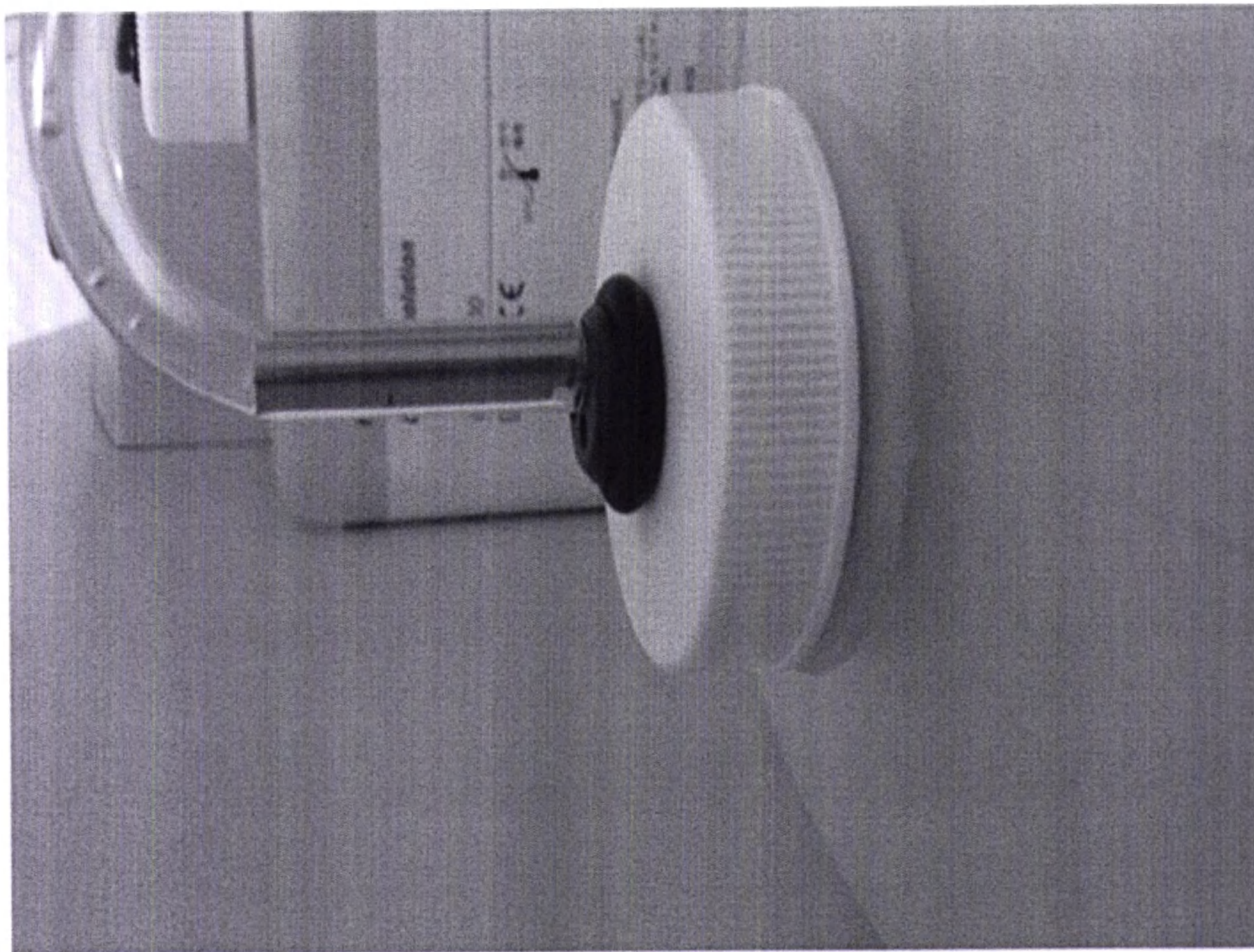
ily)



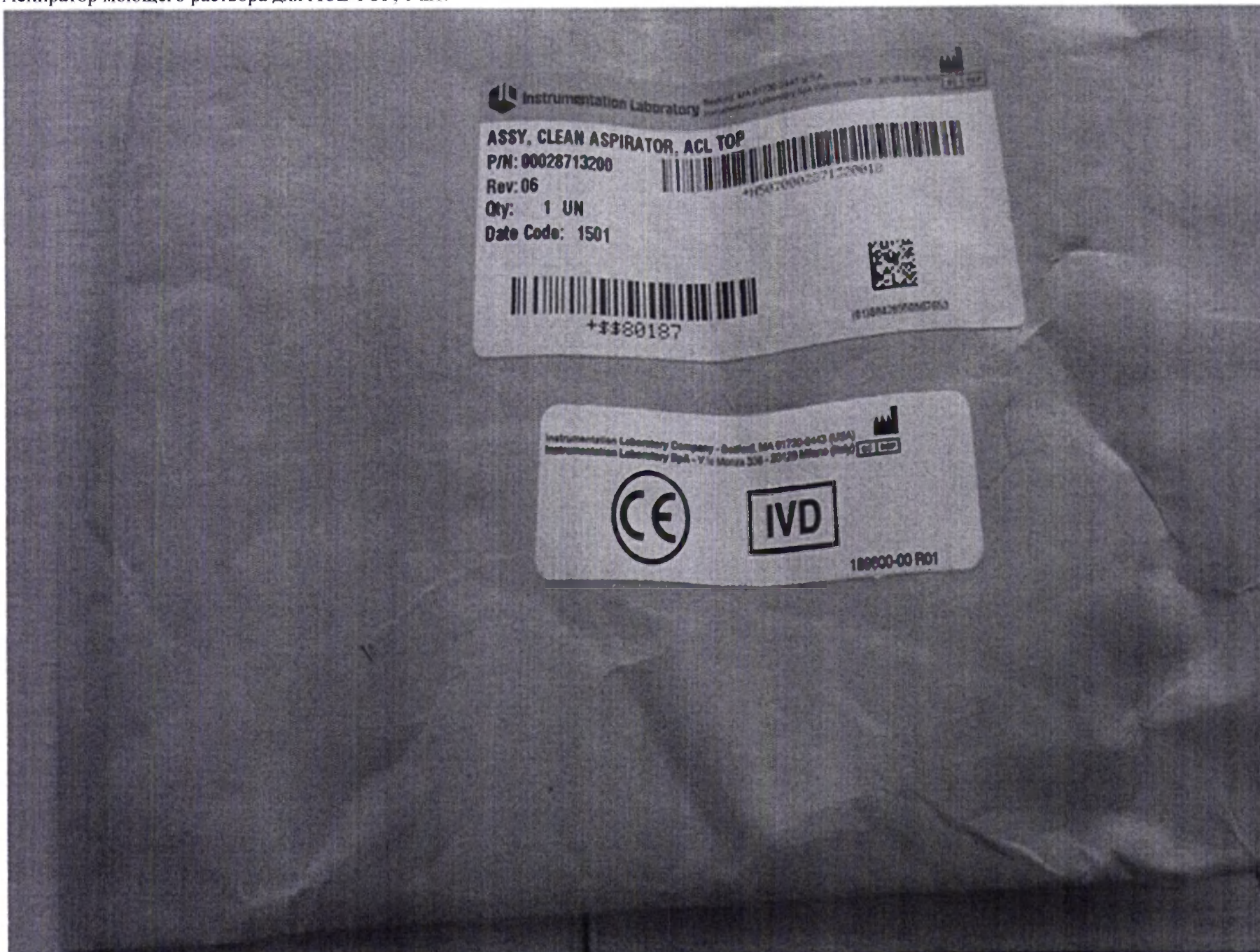
189600-00 R01

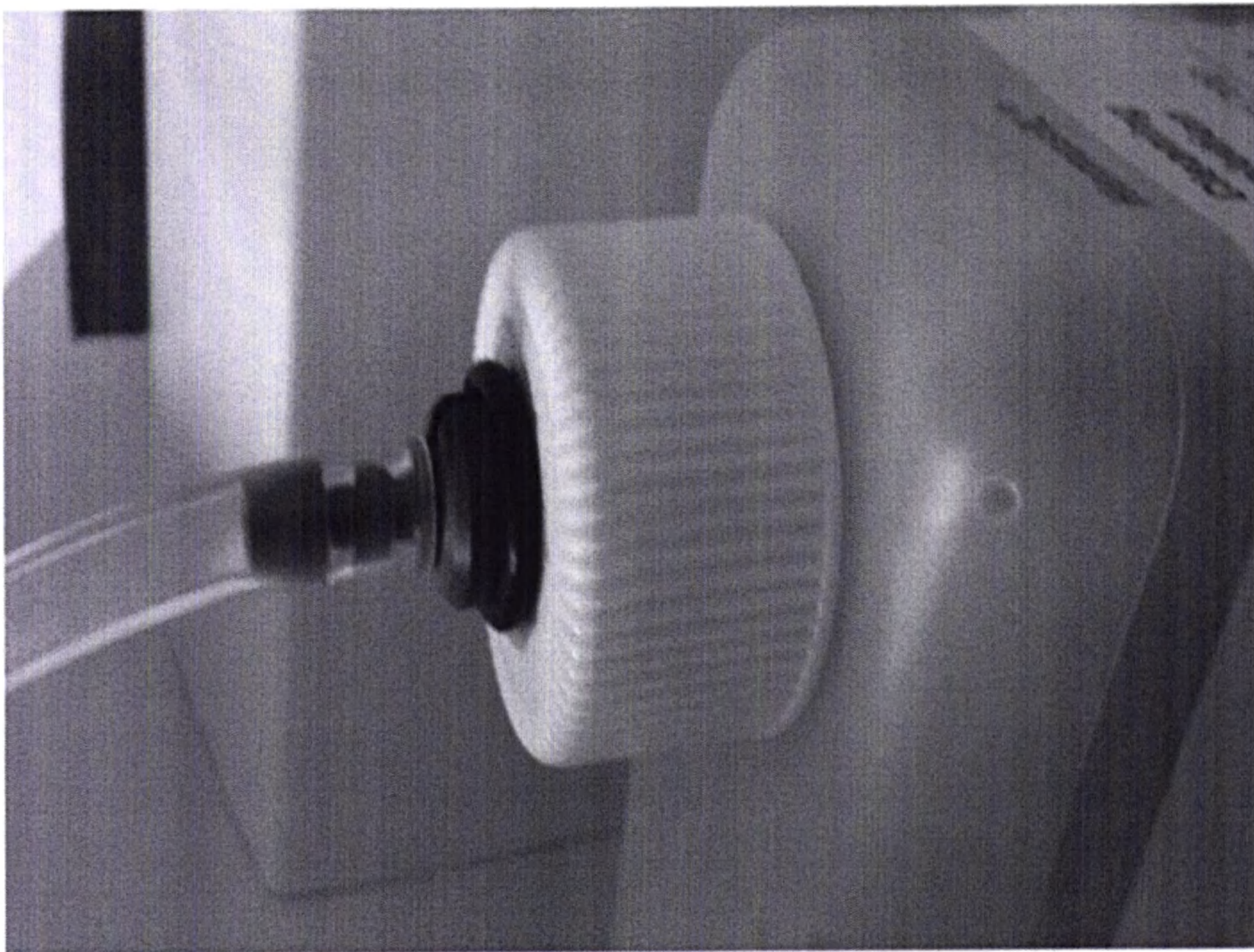
Аспиратор промывочного раствора 4 л для ACL TOP, 1 шт.



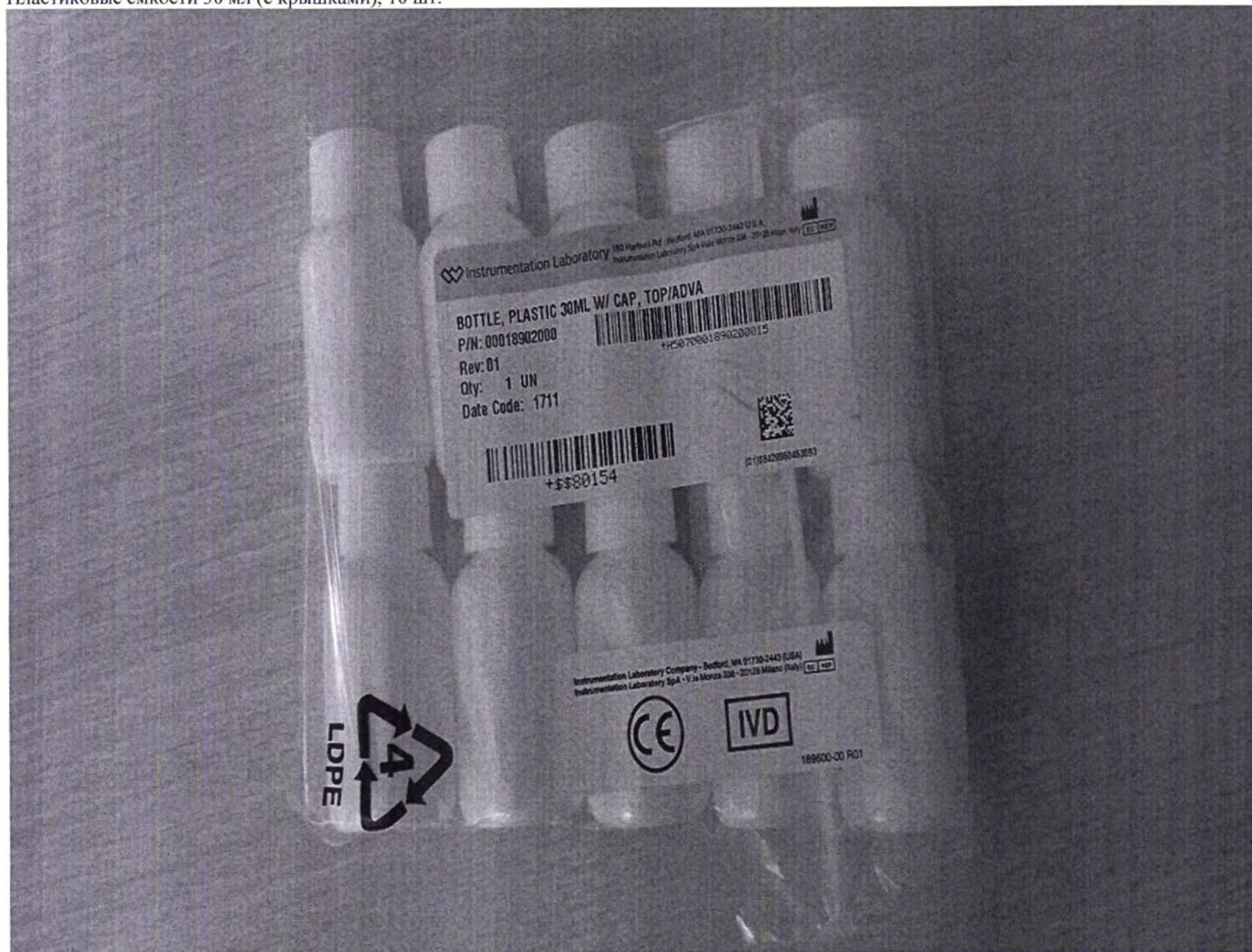


Аспиратор моющего раствора для ACL TOP, 1 шт.





Пластиковые емкости 30 мл (с крышками), 10 шт.



Предохранители на 2А, 10 шт.



 Instrumentation Laboratory

180 Hartwell Rd., Bedford, MA 01730-2443 U.S.A.

Instrumentation Laboratory SpA Viale Monza 338 - 20125 Milan, Italy



EC REP

FUSE, 2.0AMP 250 VOLT, 682

P/N: 00014871705

Rev: 03

Qty: 10 PK

Date Code: 1710



+H5070001487170590



+\$\$810QP



(01)00426950572442

Предохранители на 12.5А, 10 шт

LDPE

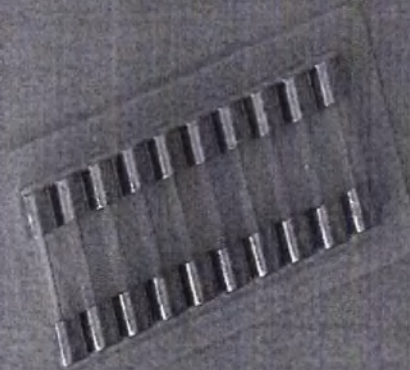
Instrumentation Laboratory 180 Hamwell Rd., Bedford, MA 01730-2443 U.S.A.
Instrumentation Laboratory S.p.A. Viale Monza 338 - 20138 Milan, Italy 

FUSE 12.5A 250V 5X20MM TLAG
P/N: 00014871713
Rev: 03
Qty: 10 PK
Date Code: 1710

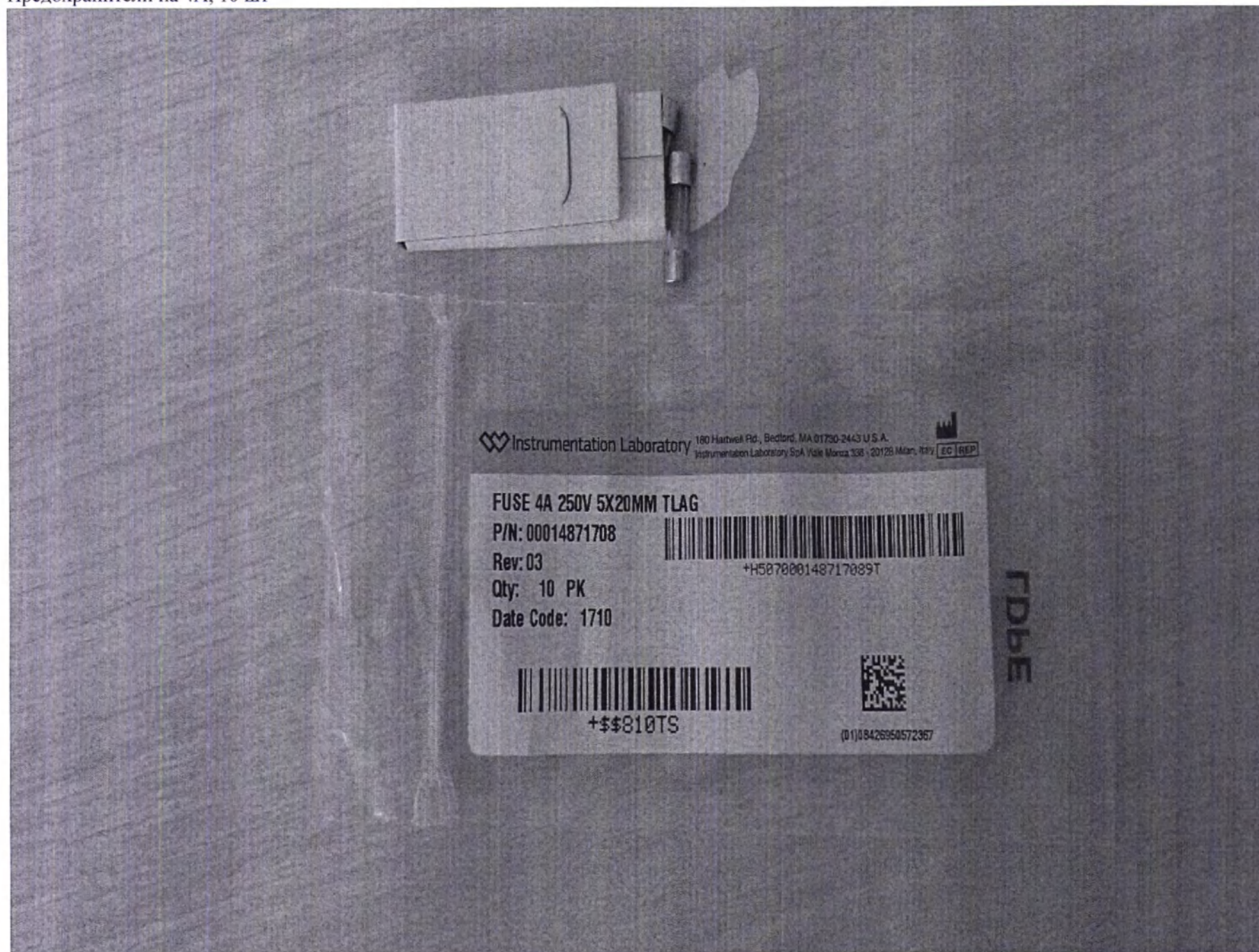

+H587000148717139P


+H5810P0


(01)00426950572862



Предохранители на 4А, 10 шт



Предохранители на 8А, 10 шт

Instrumentation Laboratory 150 Hartwell Rd., Bedford, MA 01730-2443 U.S.A.
Instrumentation Laboratory SpA Viale Monza 338 - 20128 Milan, Italy [EC REP]

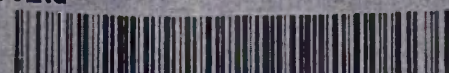
FUSE 8A 250V 5X20MM TLAG

P/N: 00014871711

Rev: 03

Qty: 10 PK

Date Code: 1709



+H507000148717119N

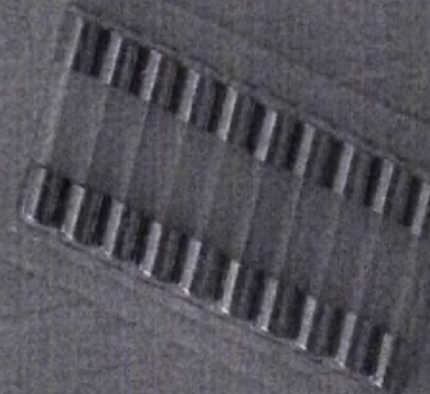


+\$810NM

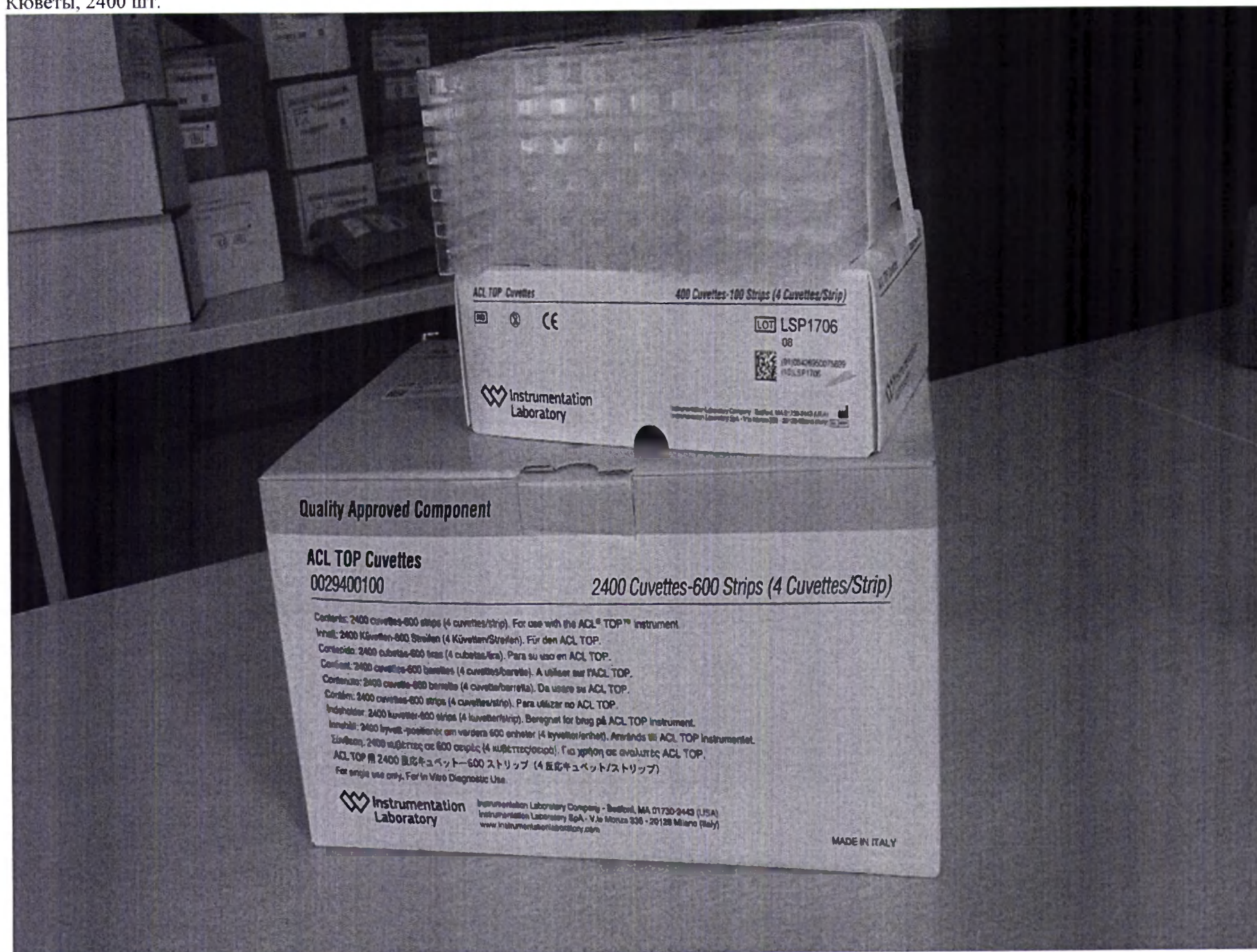


(01)08426950572000

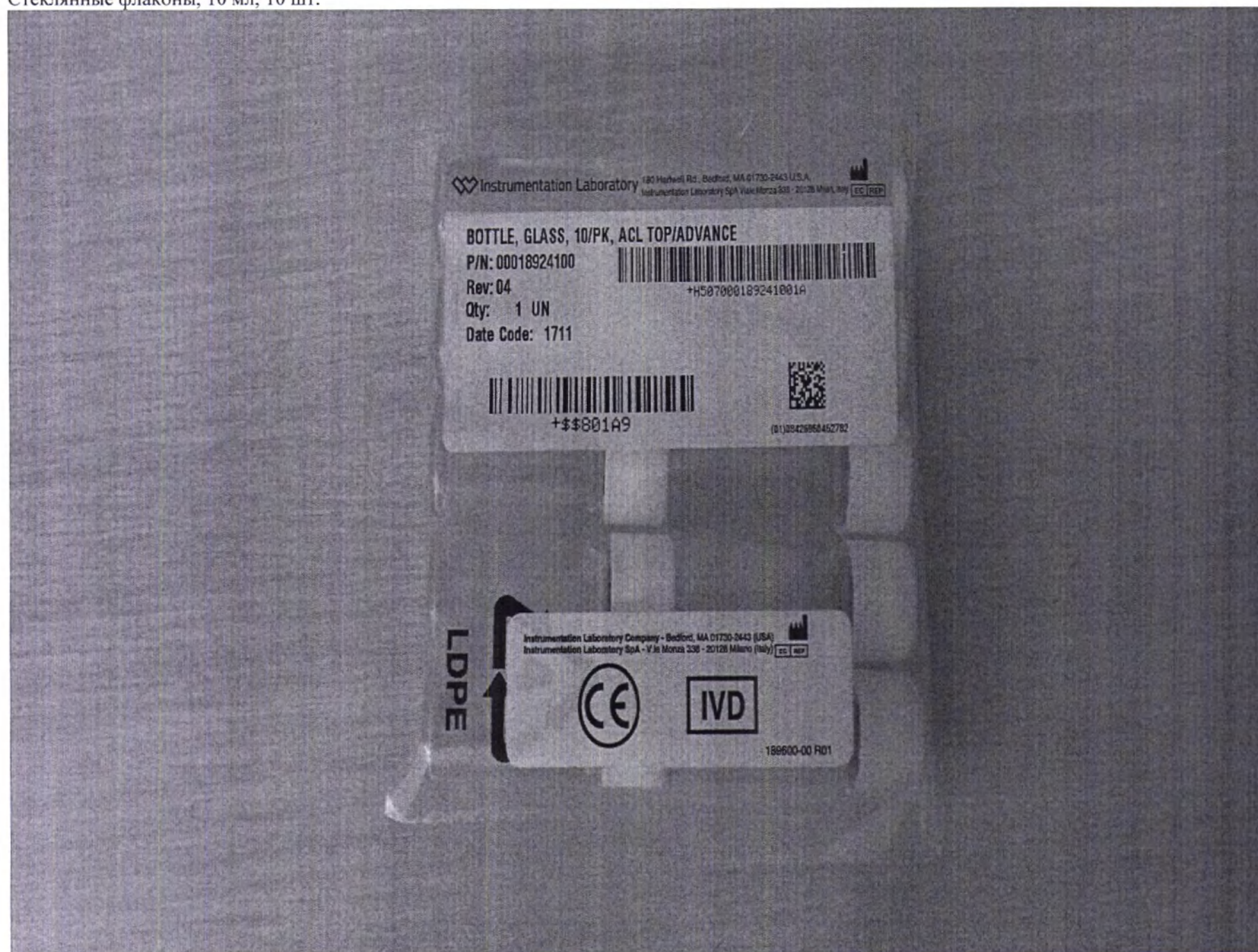
LDPE



Кюветы, 2400 шт.



Стеклянные флаконы, 10 мл, 10 шт.



Стеклянные флаконы, 4 мл, 10 шт.

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Instrumentation Laboratory SpA Viale Monza 338 - 20128 Milano (Italy)

BOTTLE KIT, 10X4 ML

P/N: 00018924104

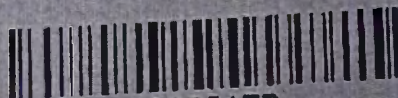
Rev: 05

Qty: 1 UN

Date Code: 1710



+H507000189241041E



+\$801ED



(01)00426950452

LDPE

Instrumentation Laboratory Company - Bedford, MA 01730-2443 (USA)
Instrumentation Laboratory SpA - Viale Monza 338 - 20128 Milano (Italy)

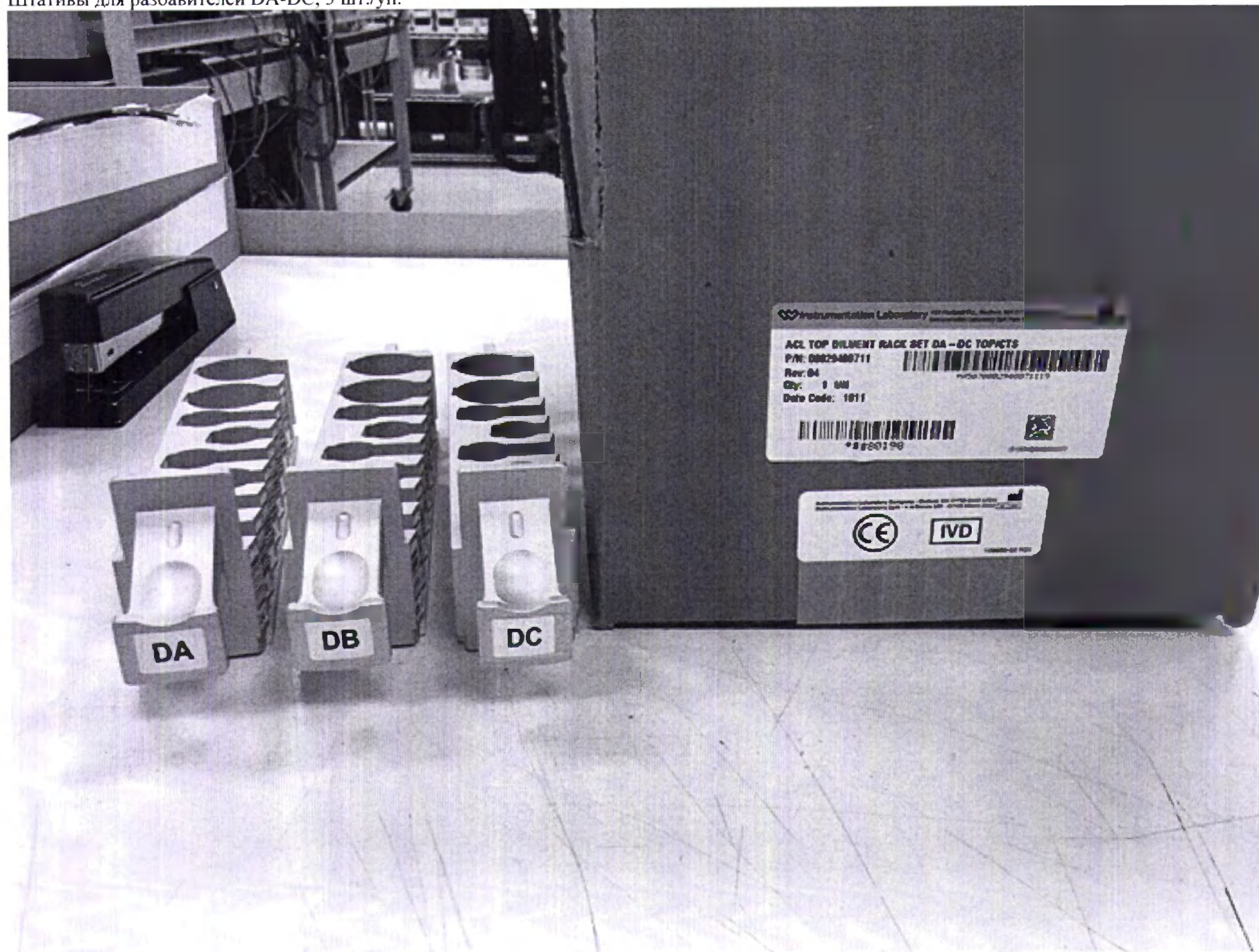


189600-00 R01

Штативы для образцов под открытые пробирки 01-12, 12 шт./уп.



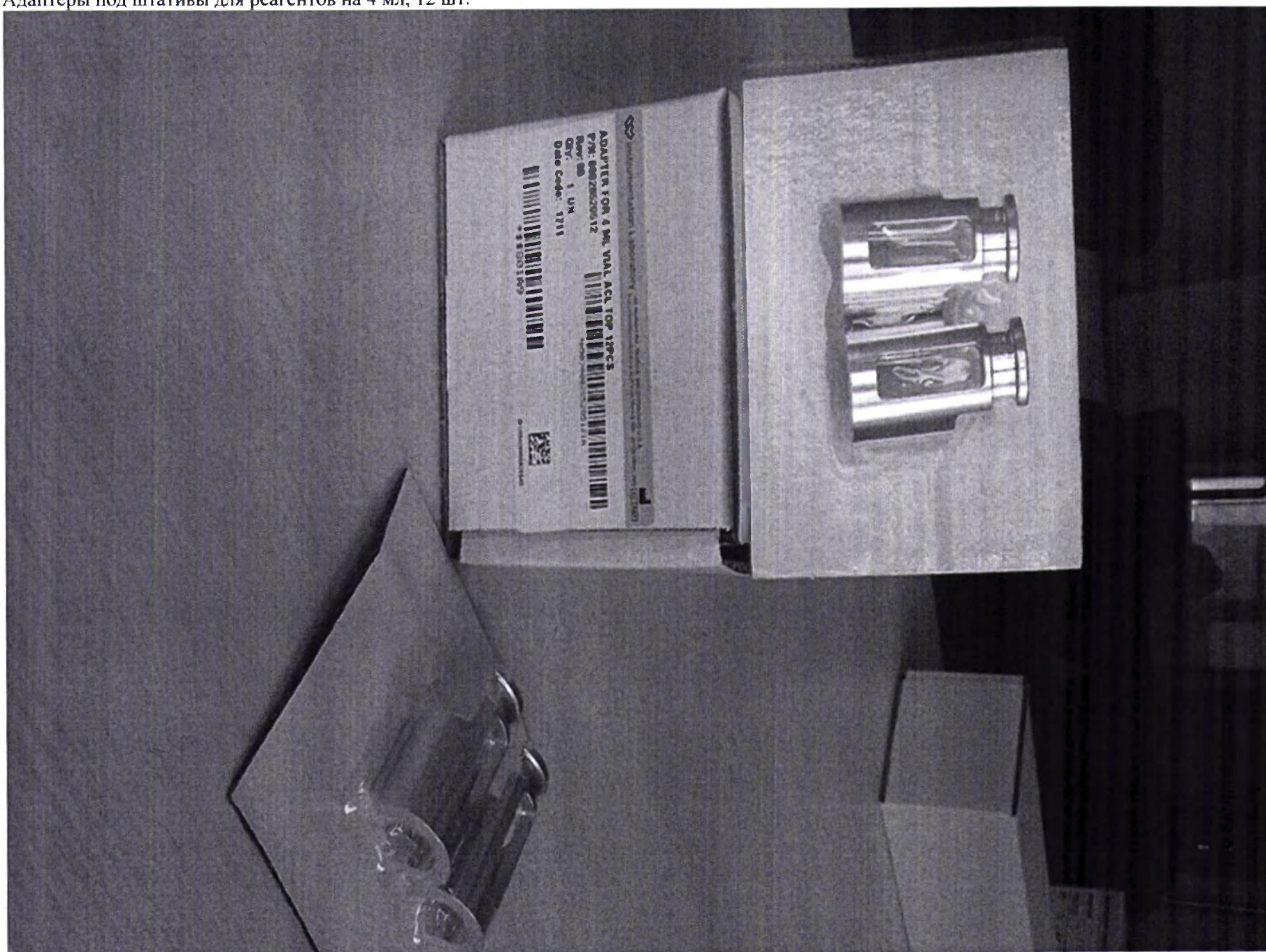
Штативы для разбавителей DA-DC, 3 шт./уп.



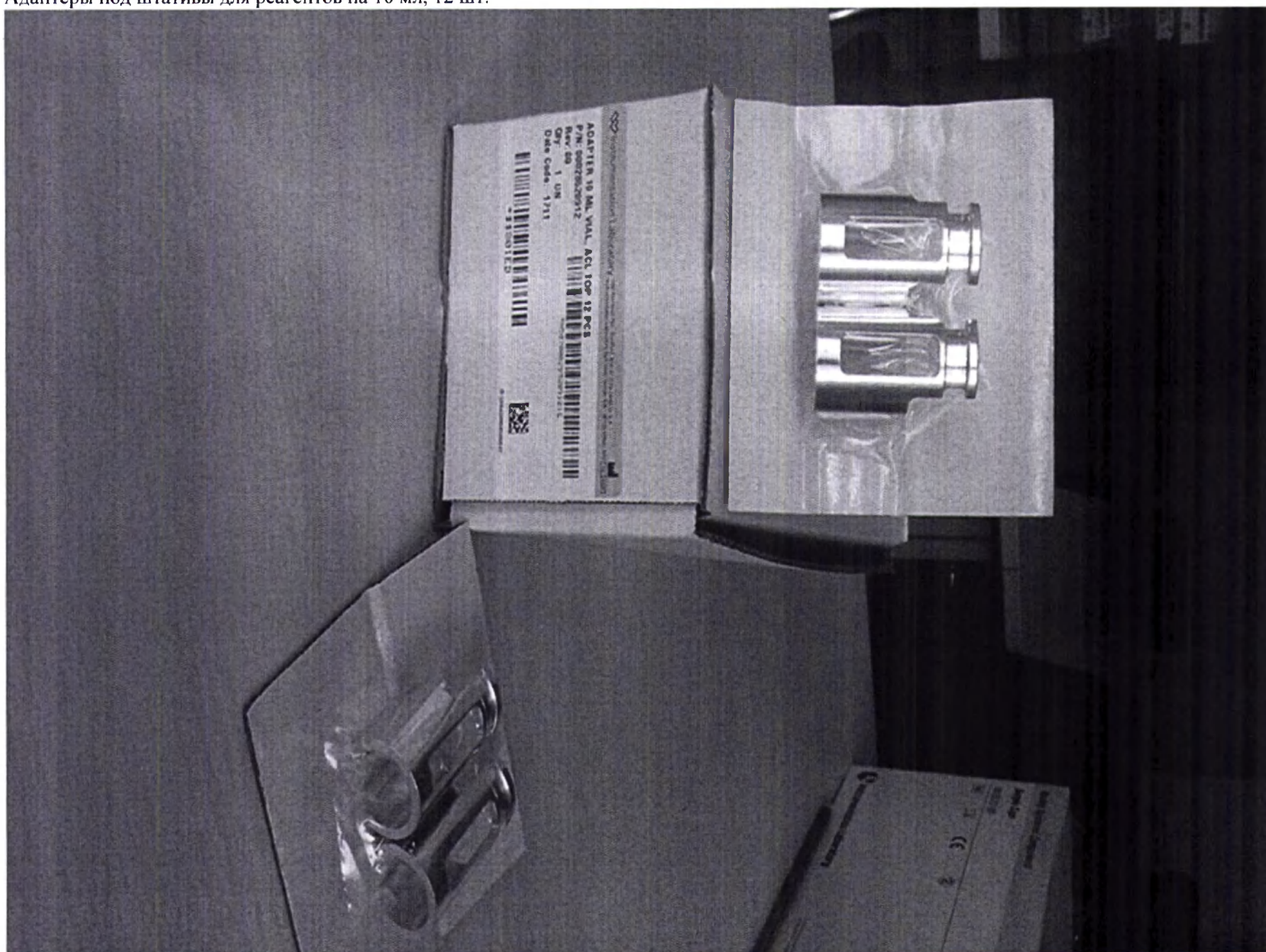
Штативы для реагентов RA-RF, 6 шт./уп.



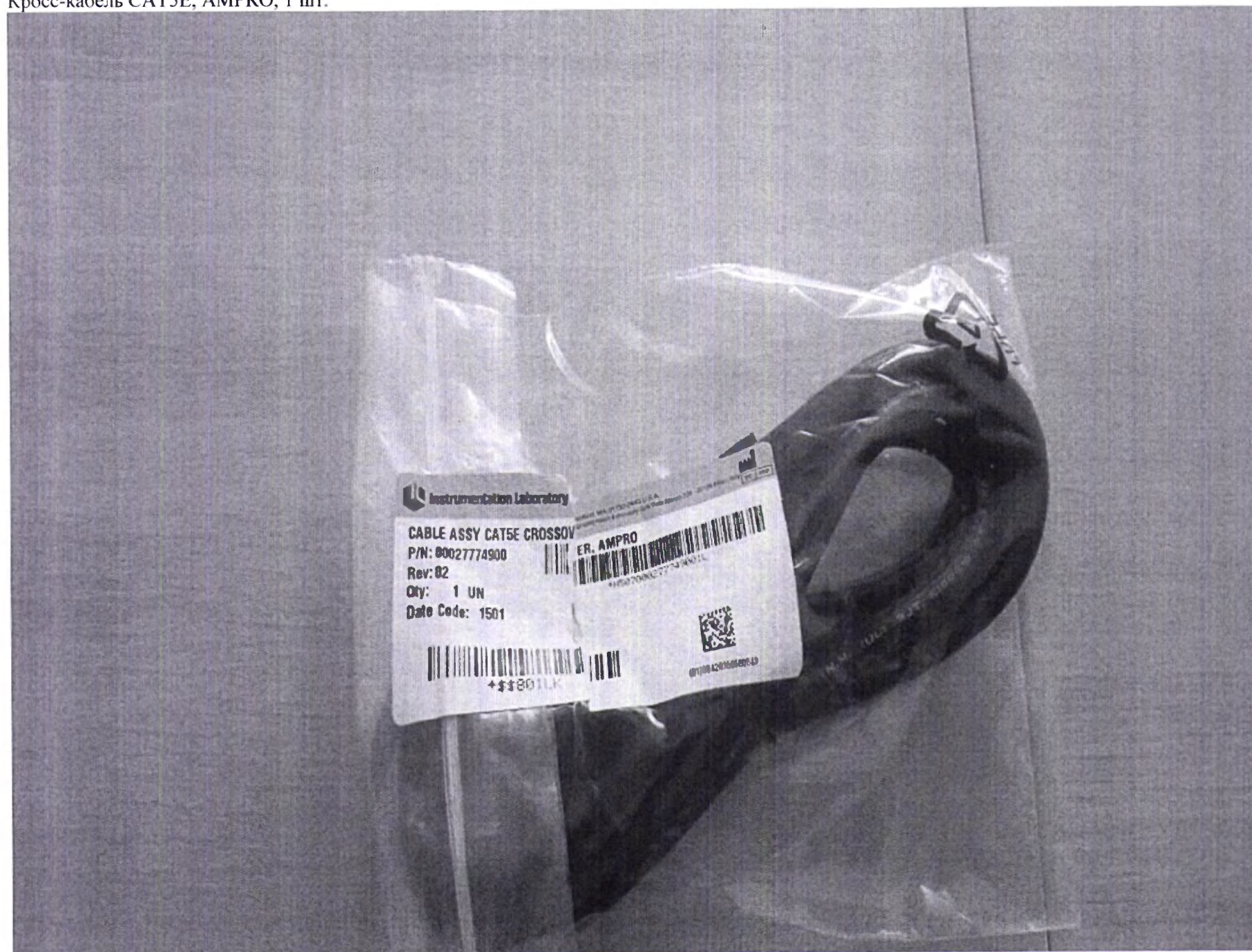
Адаптеры под штативы для реагентов на 4 мл, 12 шт.



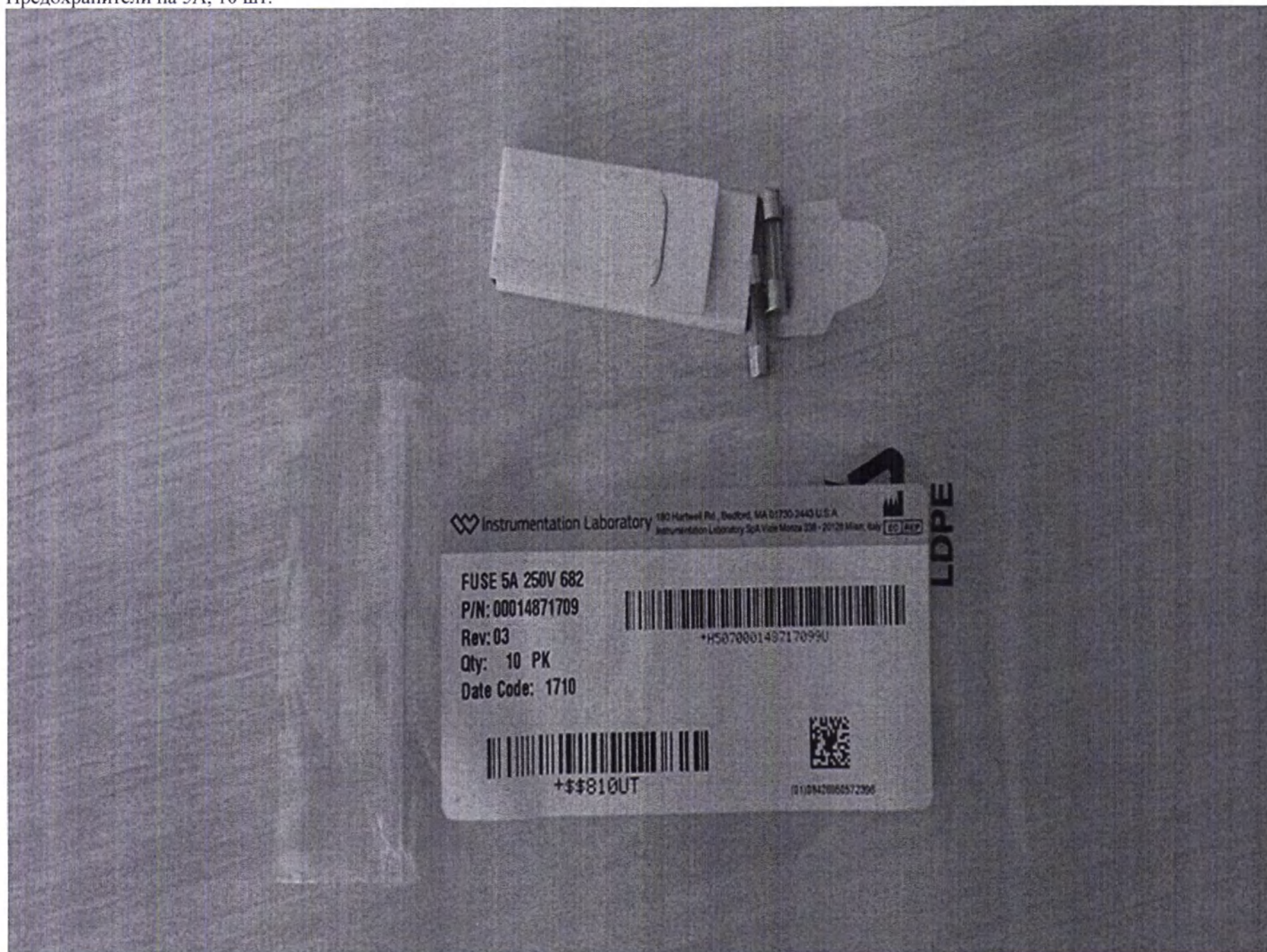
Адаптеры под штативы для реагентов на 10 мл, 12 шт.



Кросс-кабель CAT5E, AMPRO, 1 шт.



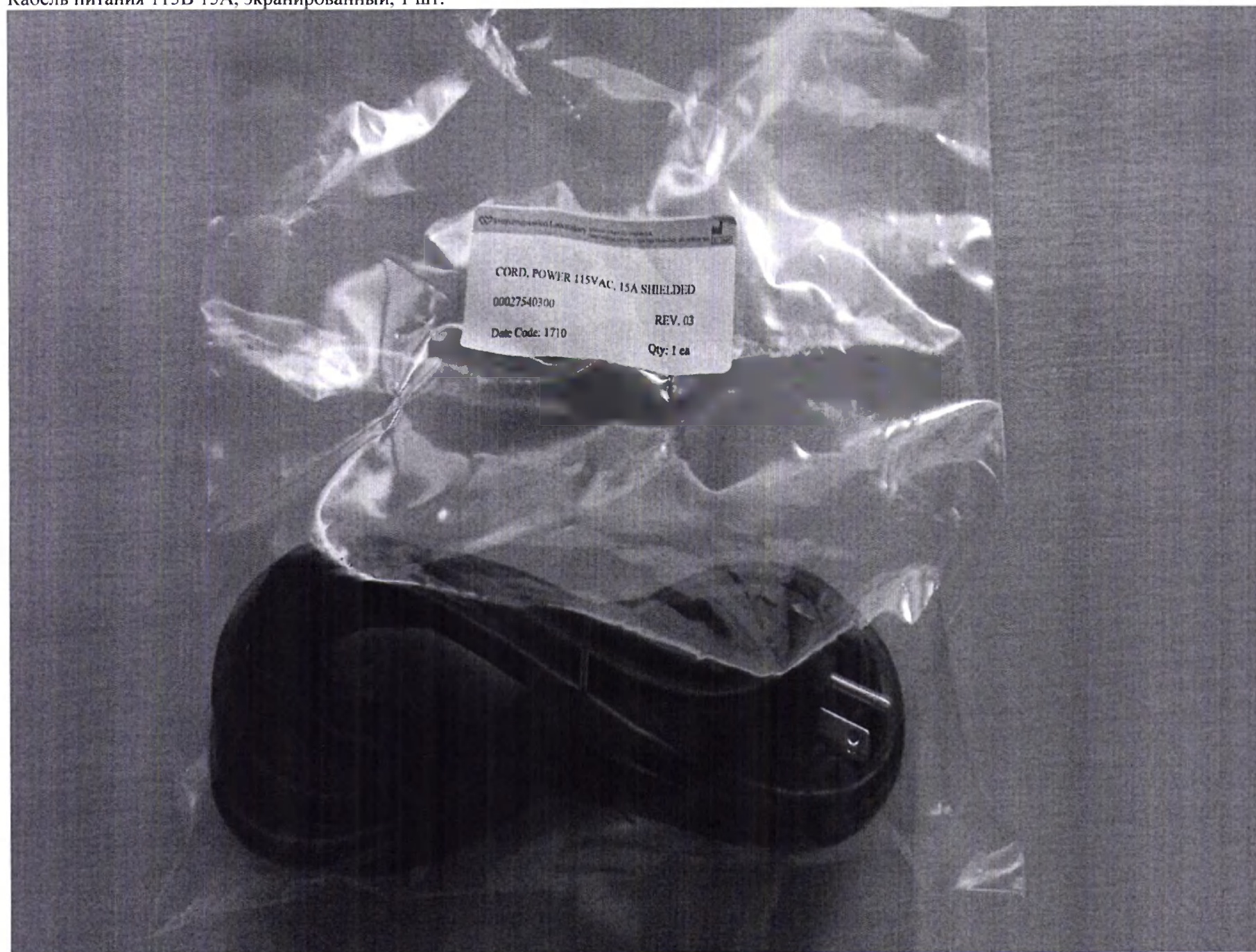
Предохранители на 5А, 10 шт.

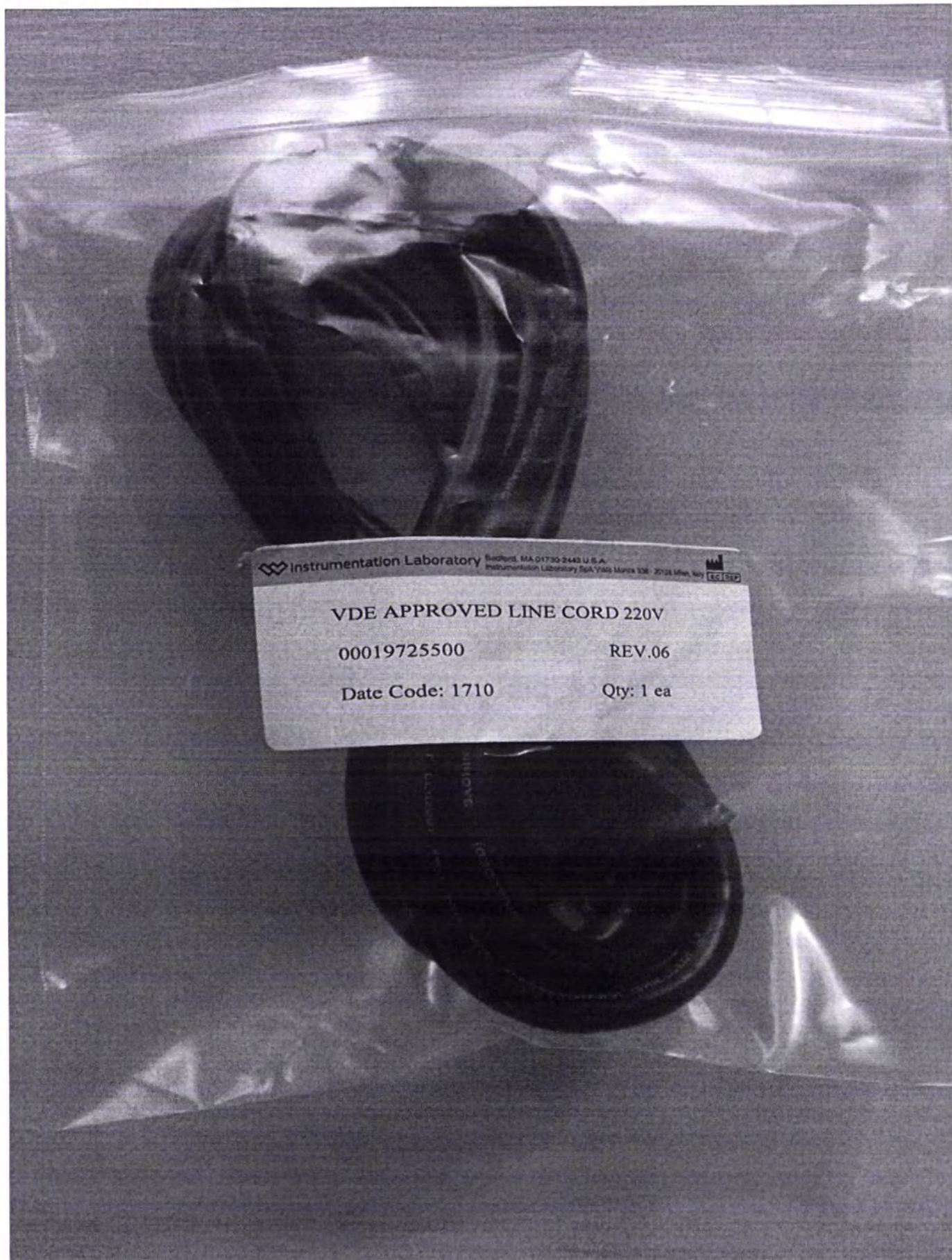


Предохранители на 1.25A, 10 шт.



Кабель питания 115В 15А, экранированный, 1 шт.





Instrumentation Laboratory Bedford, MA 01730-2443 U.S.A.
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VDE APPROVED LINE CORD 220V

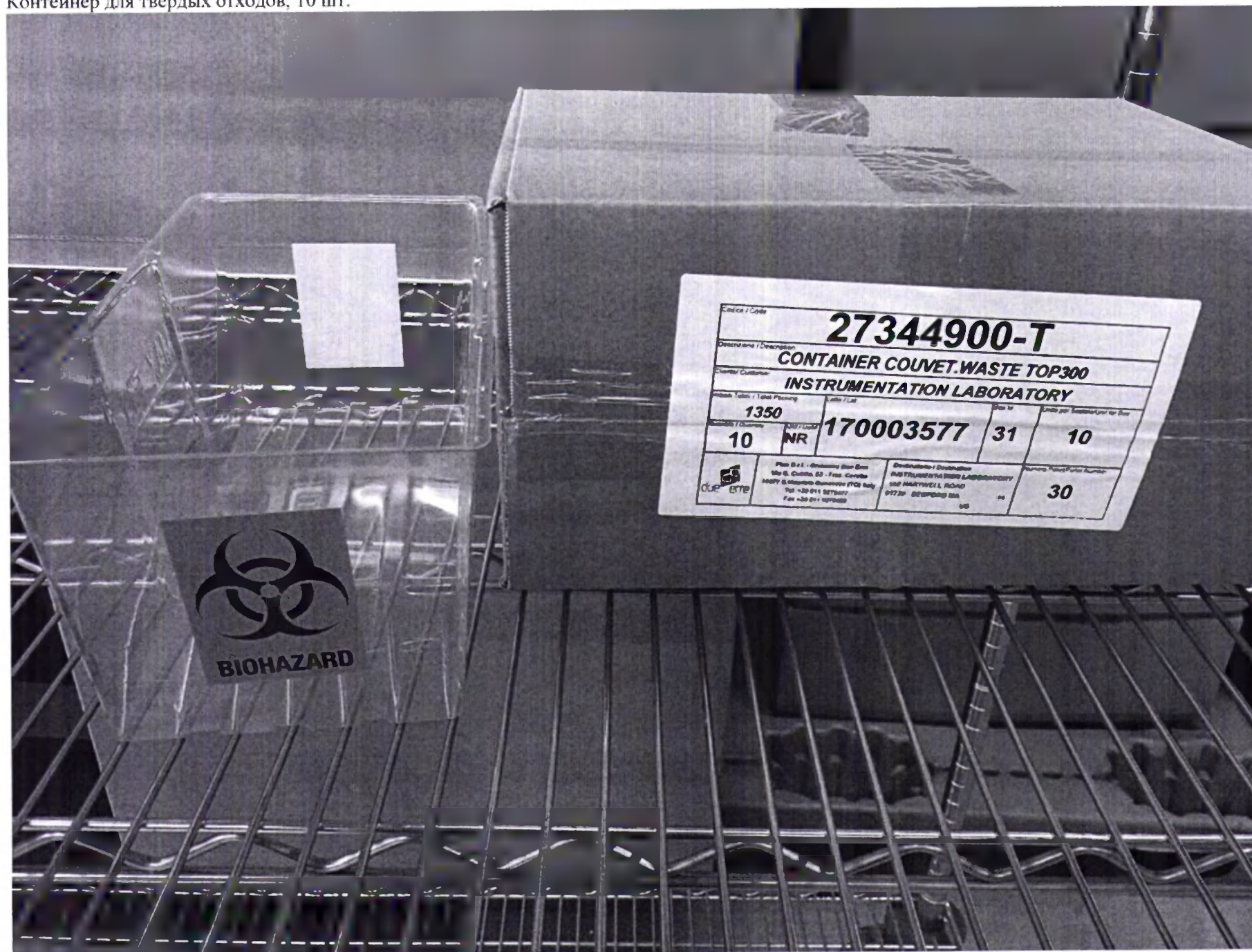
00019725500

REV.06

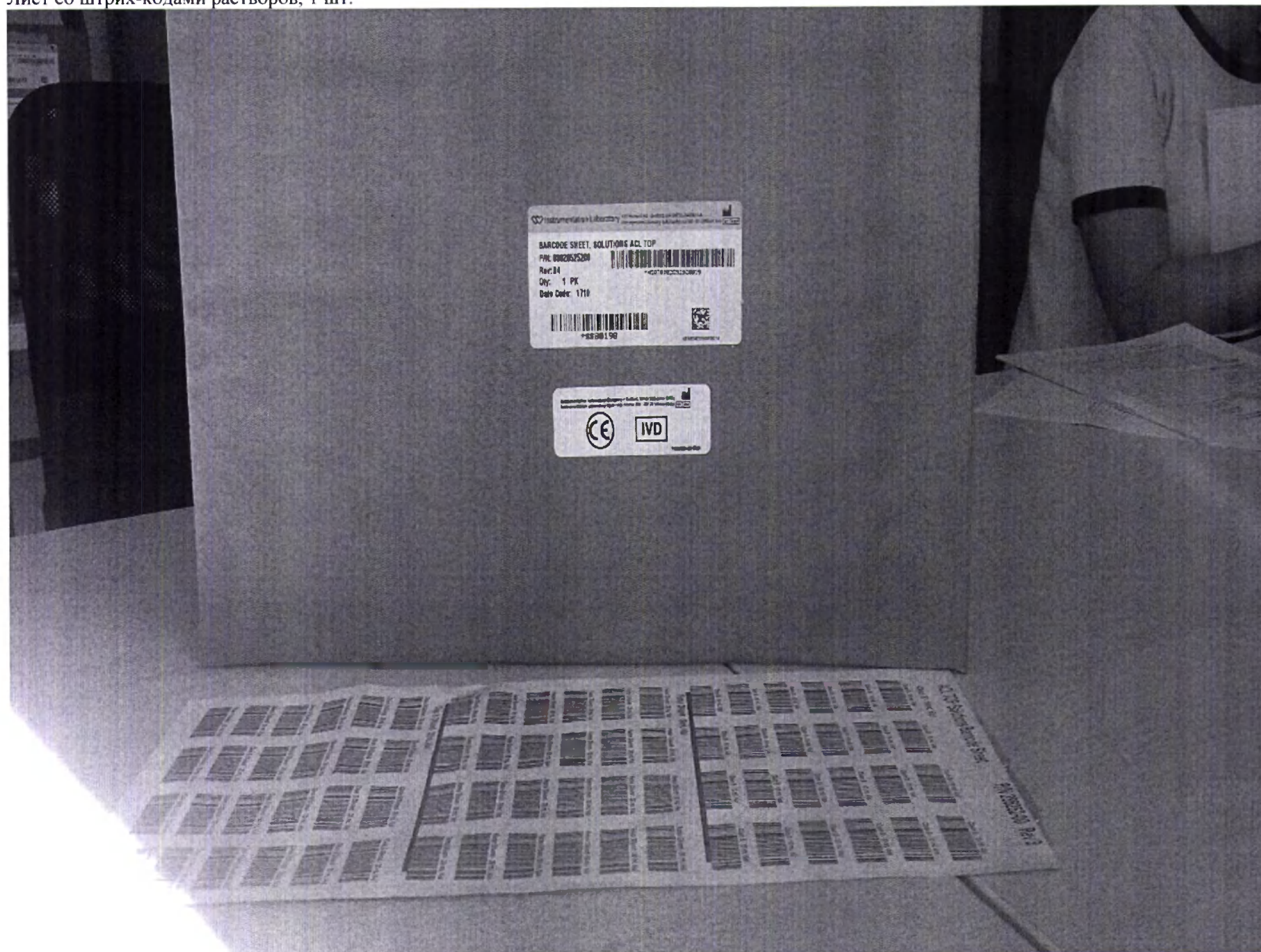
Date Code: 1710

Qty: 1 ea

Контейнер для твердых отходов, 10 шт.



Лист со штрих-кодами растворов, 1 шт.

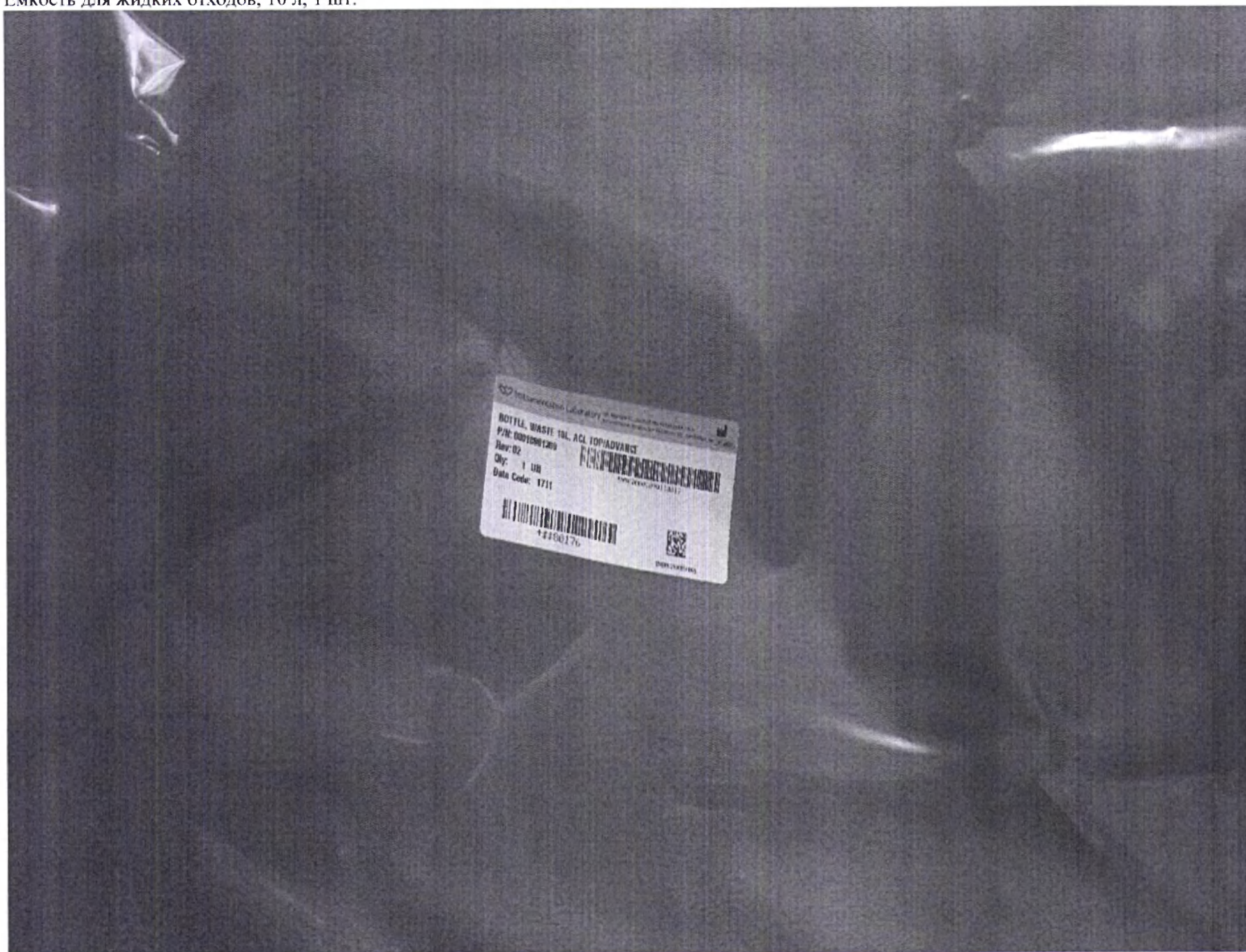


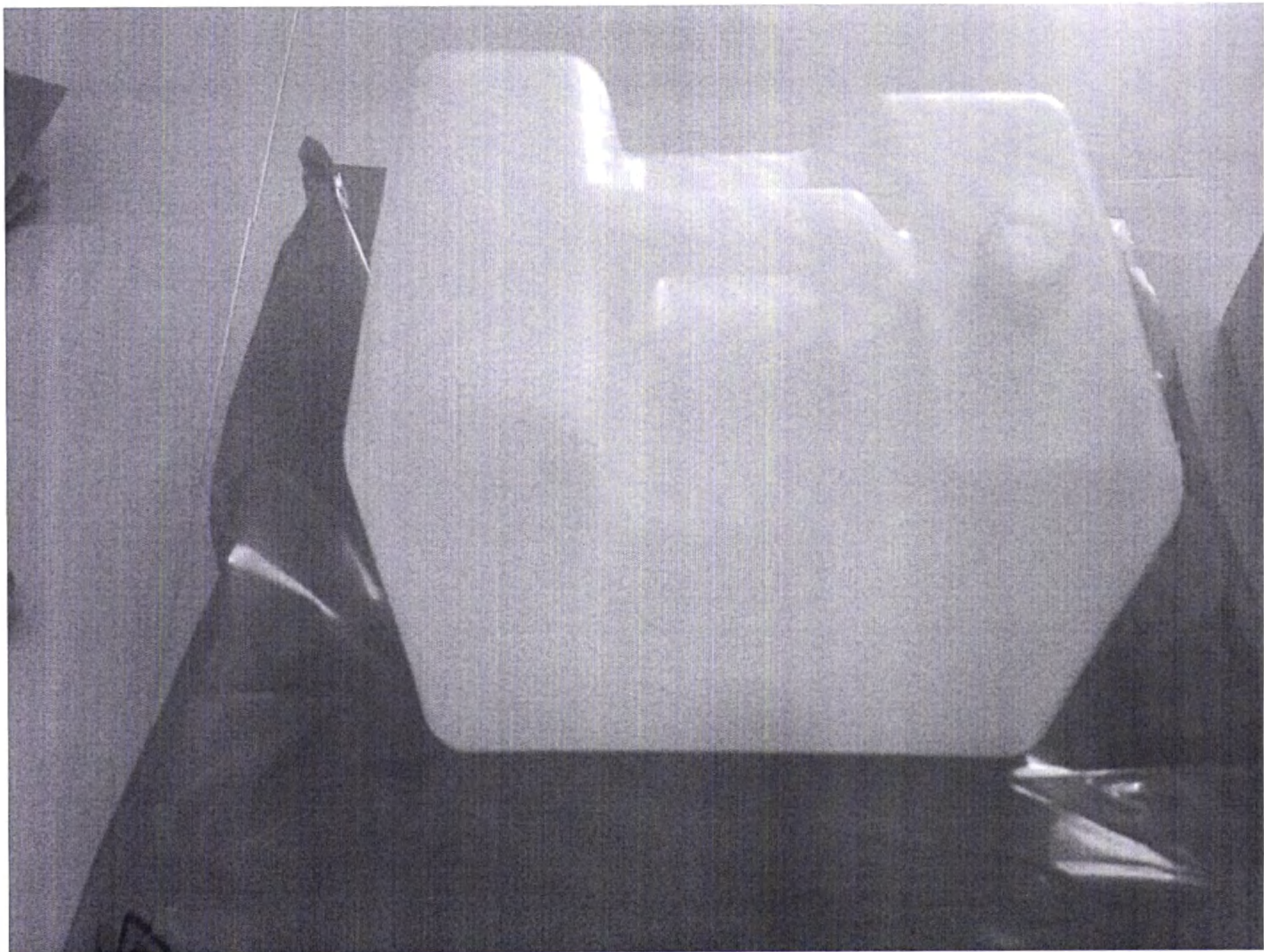
Датчик контейнера для жидких отходов, 1 шт.



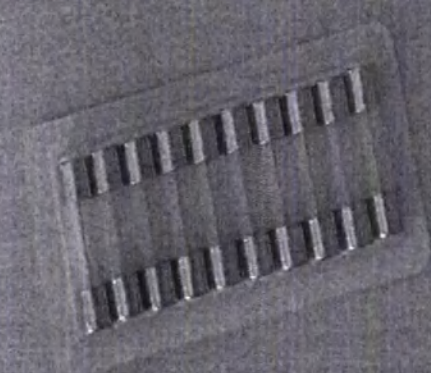
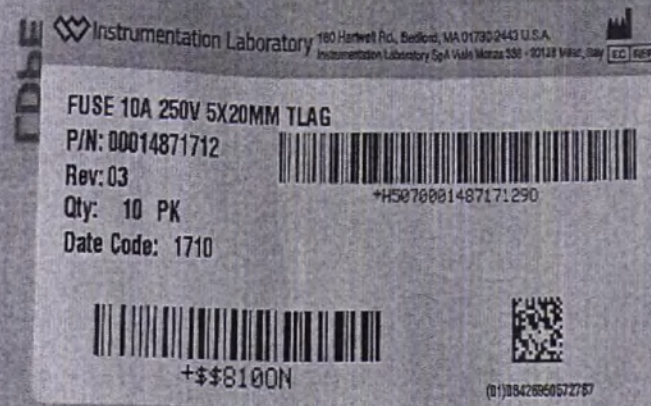


Емкость для жидких отходов, 10 л, 1 шт.

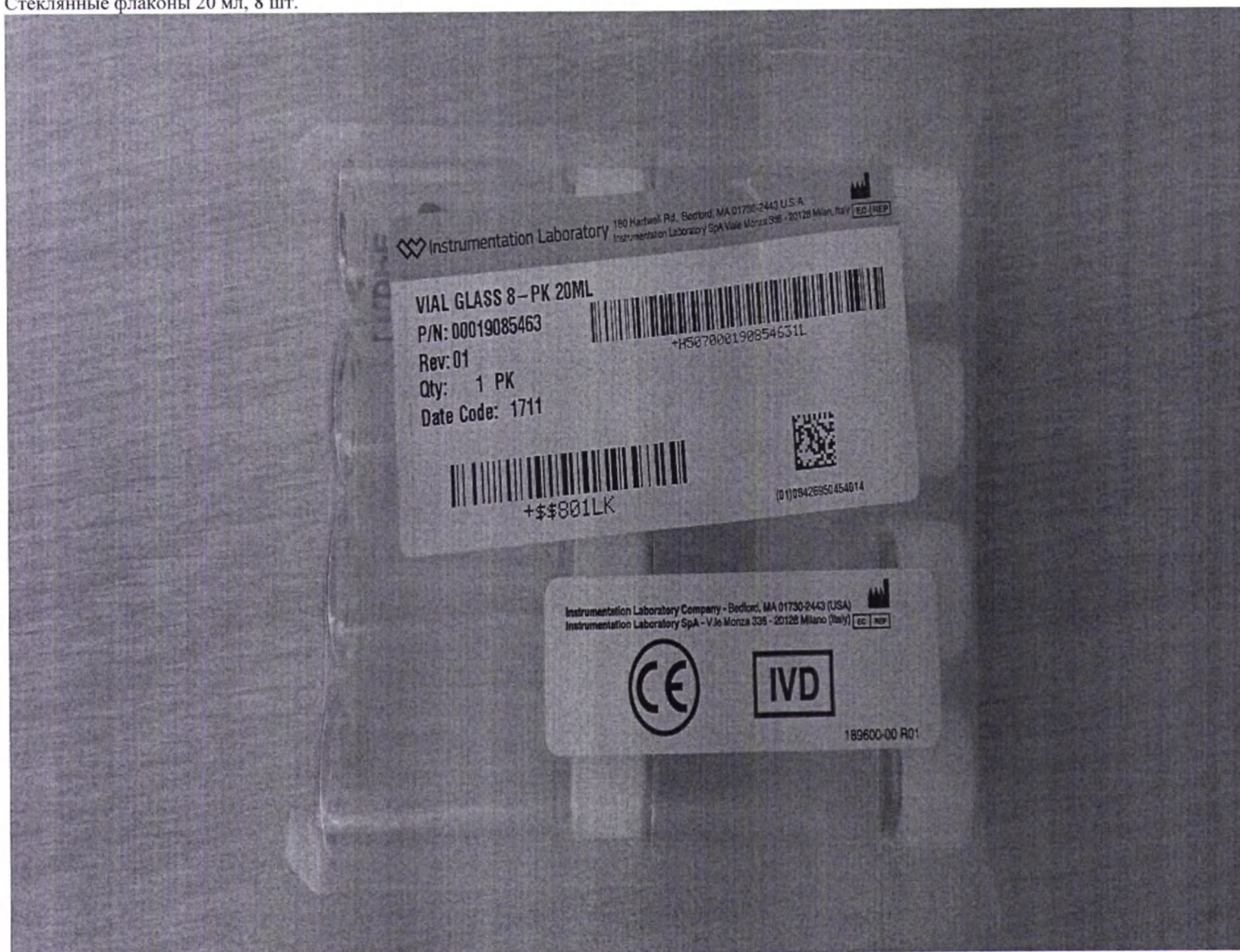




Предохранители на 10А, 10 шт.



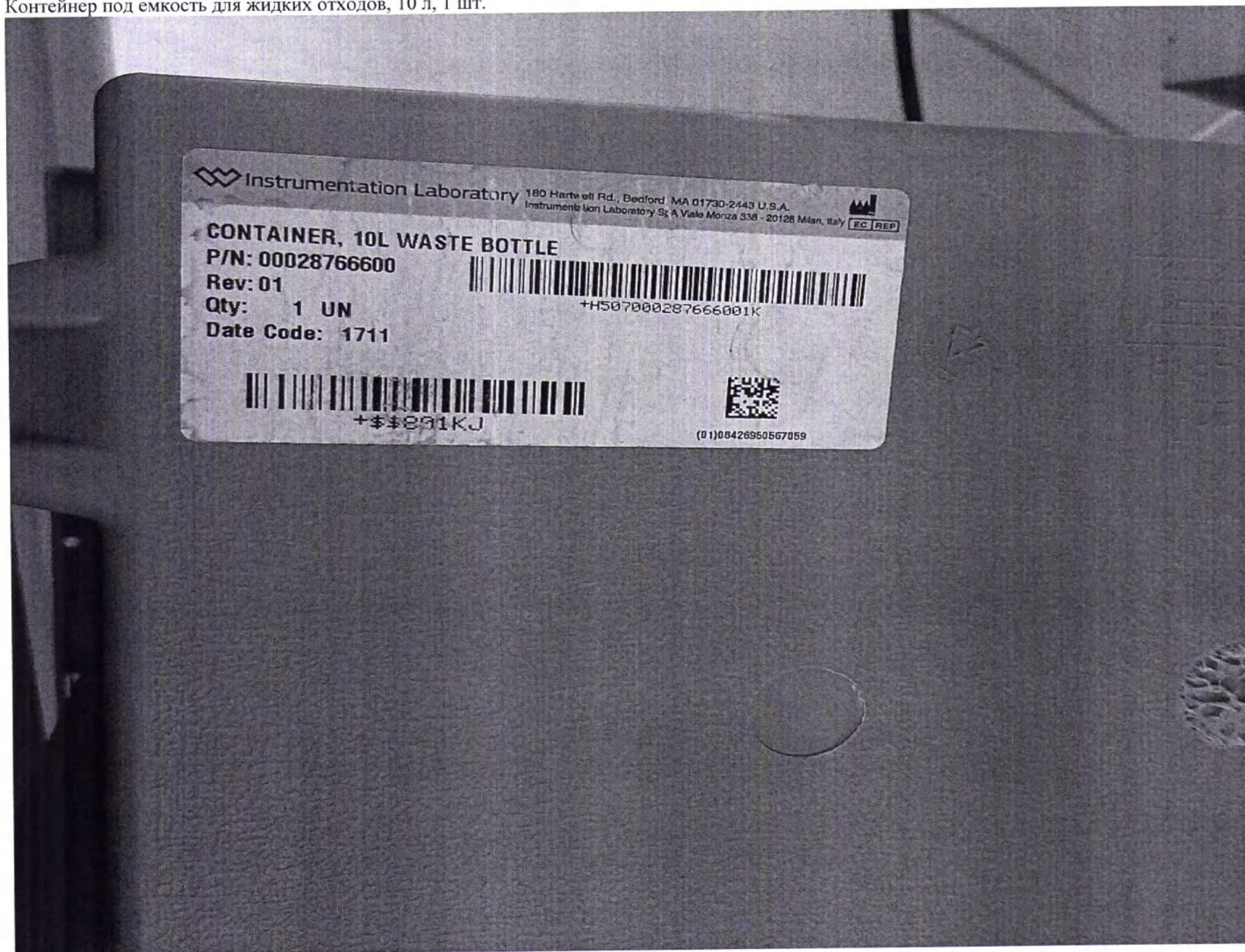
Стеклянные флаконы 20 мл, 8 шт.



Адаптеры под штативы для образцов: адаптеры для аликвотных пробирок, 5 шт.; адаптеры для педиатрических пробирок, 5 шт.



Контейнер под емкость для жидких отходов, 10 л, 1 шт.

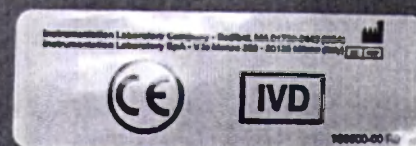
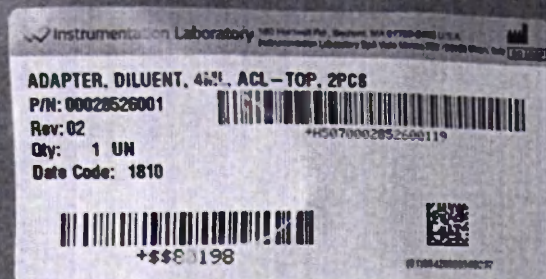
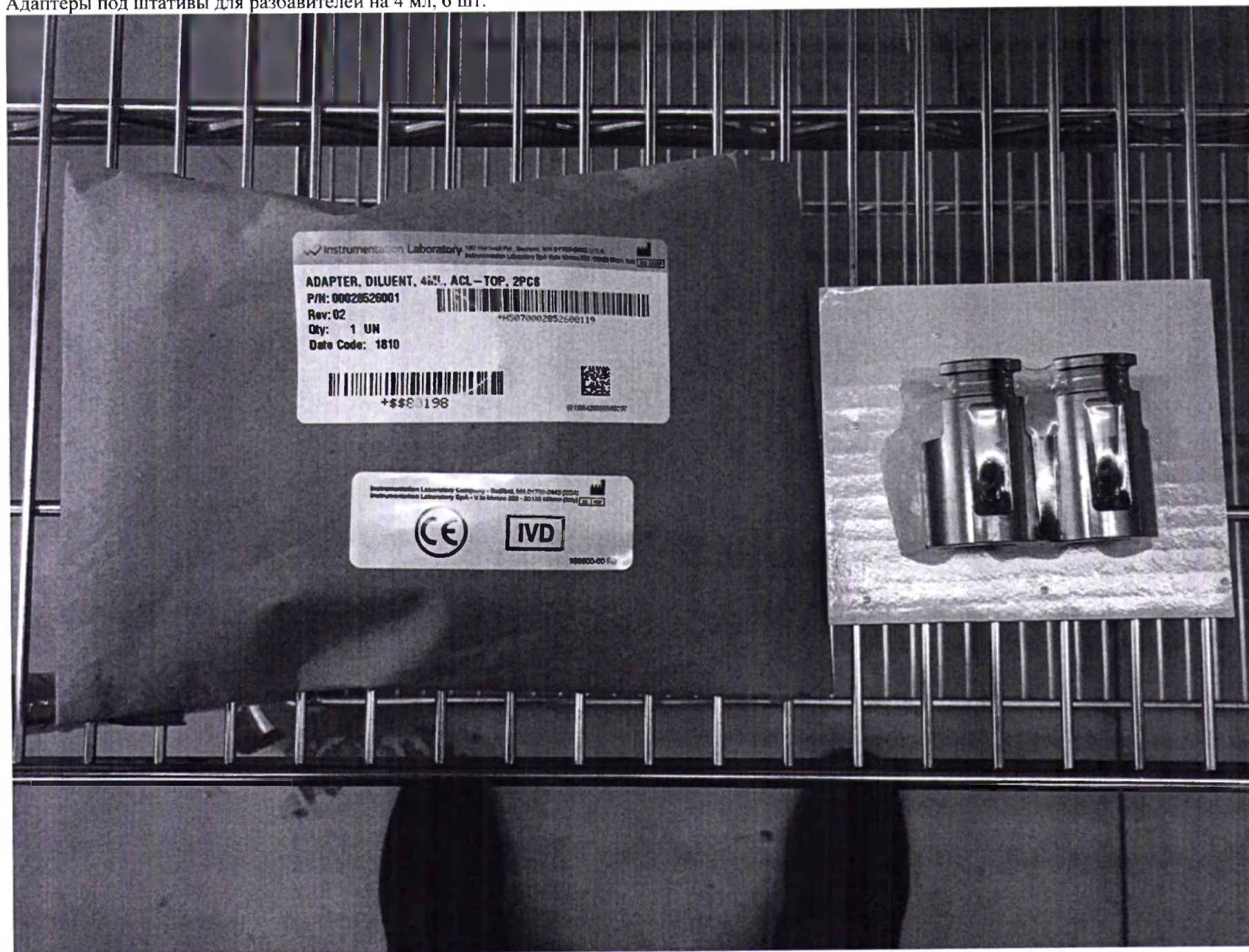




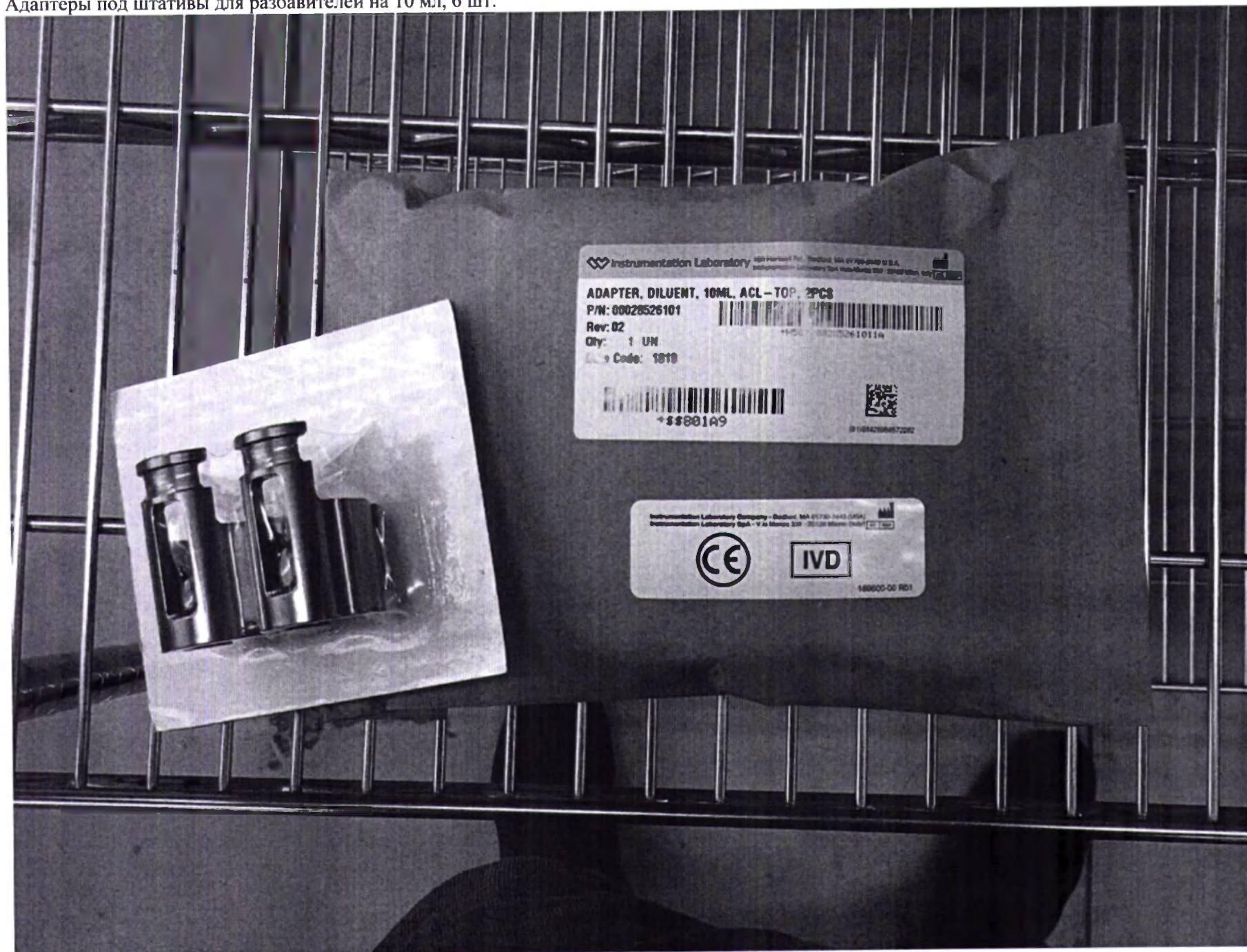
Подставка под 6 штативов для образцов, 1 шт.



Адаптеры под штативы для разбавителей на 4 мл, 6 шт.



Адаптеры под штативы для разбавителей на 10 мл, 6 шт.



Адаптеры под штативы для разбавителей на 20 мл, 6 шт.

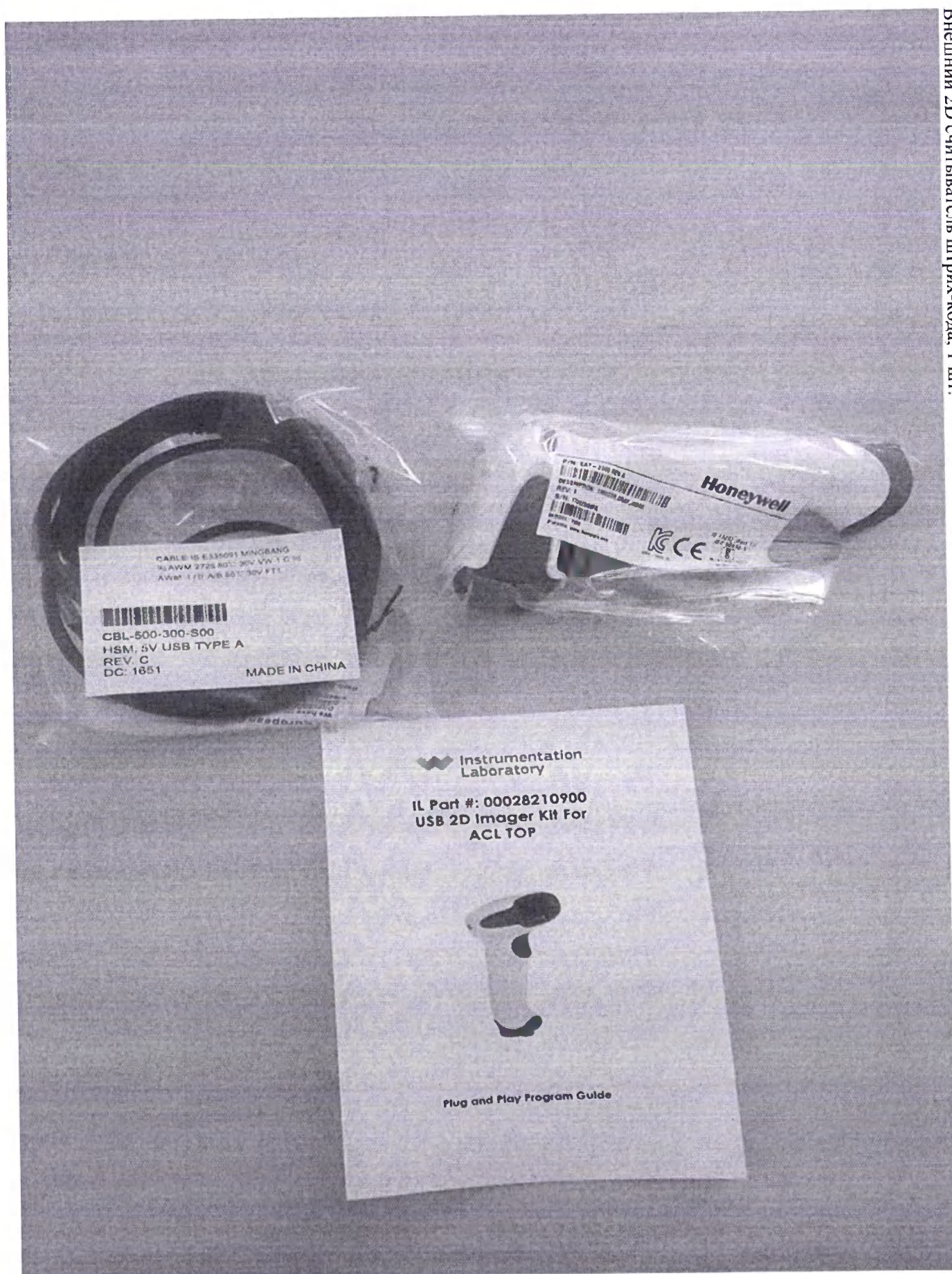


Трубки для помпы жидких отходов, 3 шт.

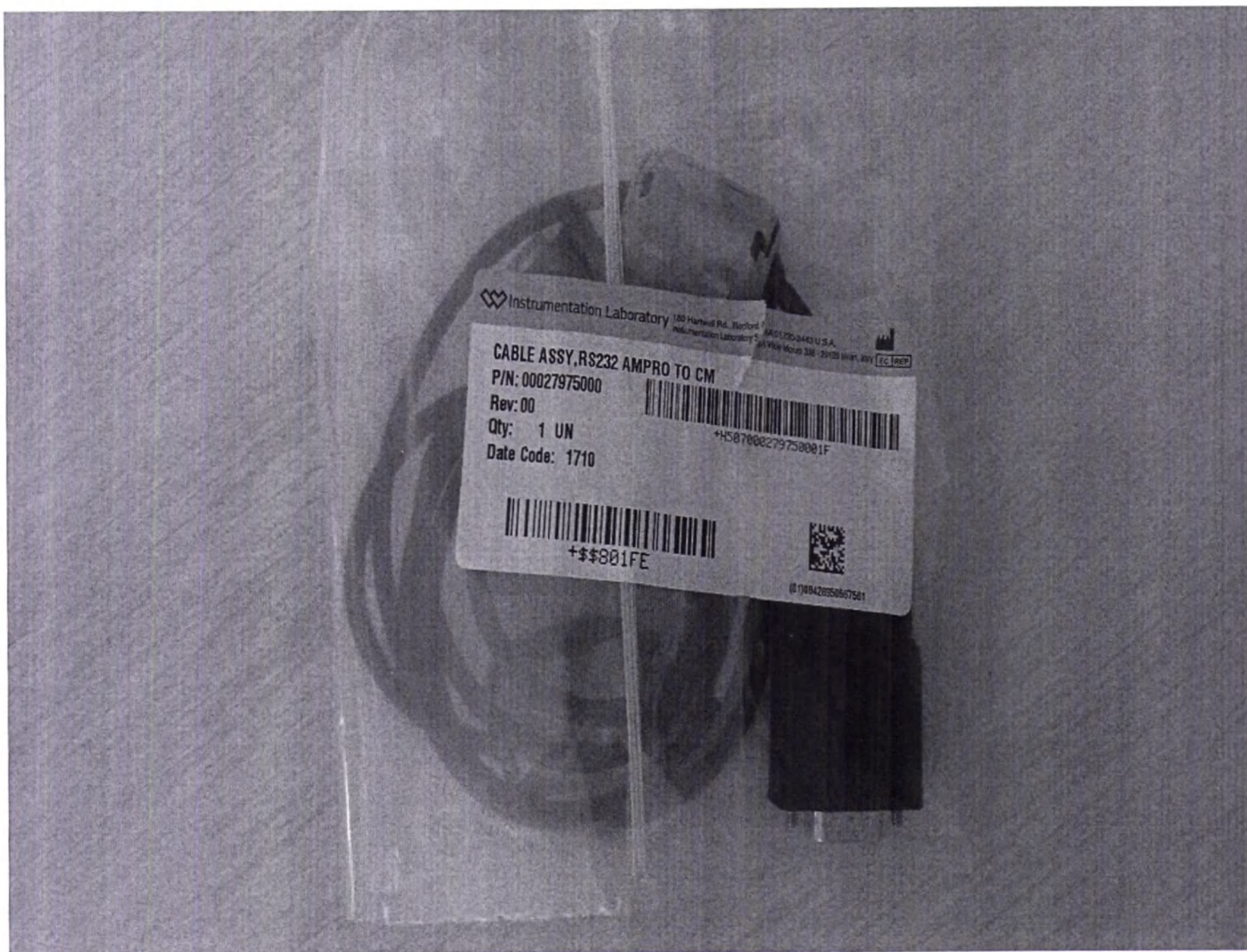


Шестигранные ключи метрические 1.5 мм - 5.0 мм, 1 уп.





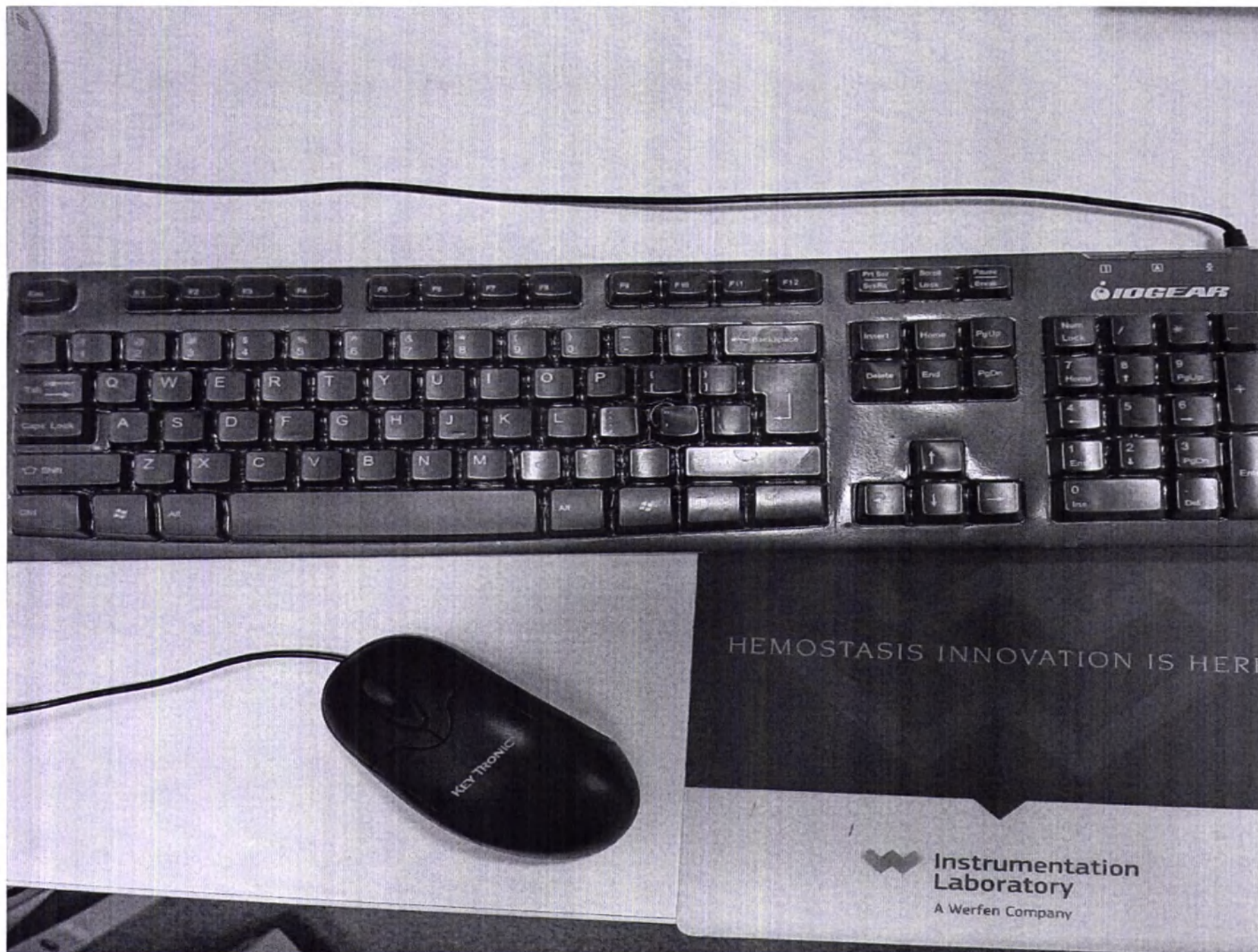
Кабель RS232, AMPRO, 1 шт.







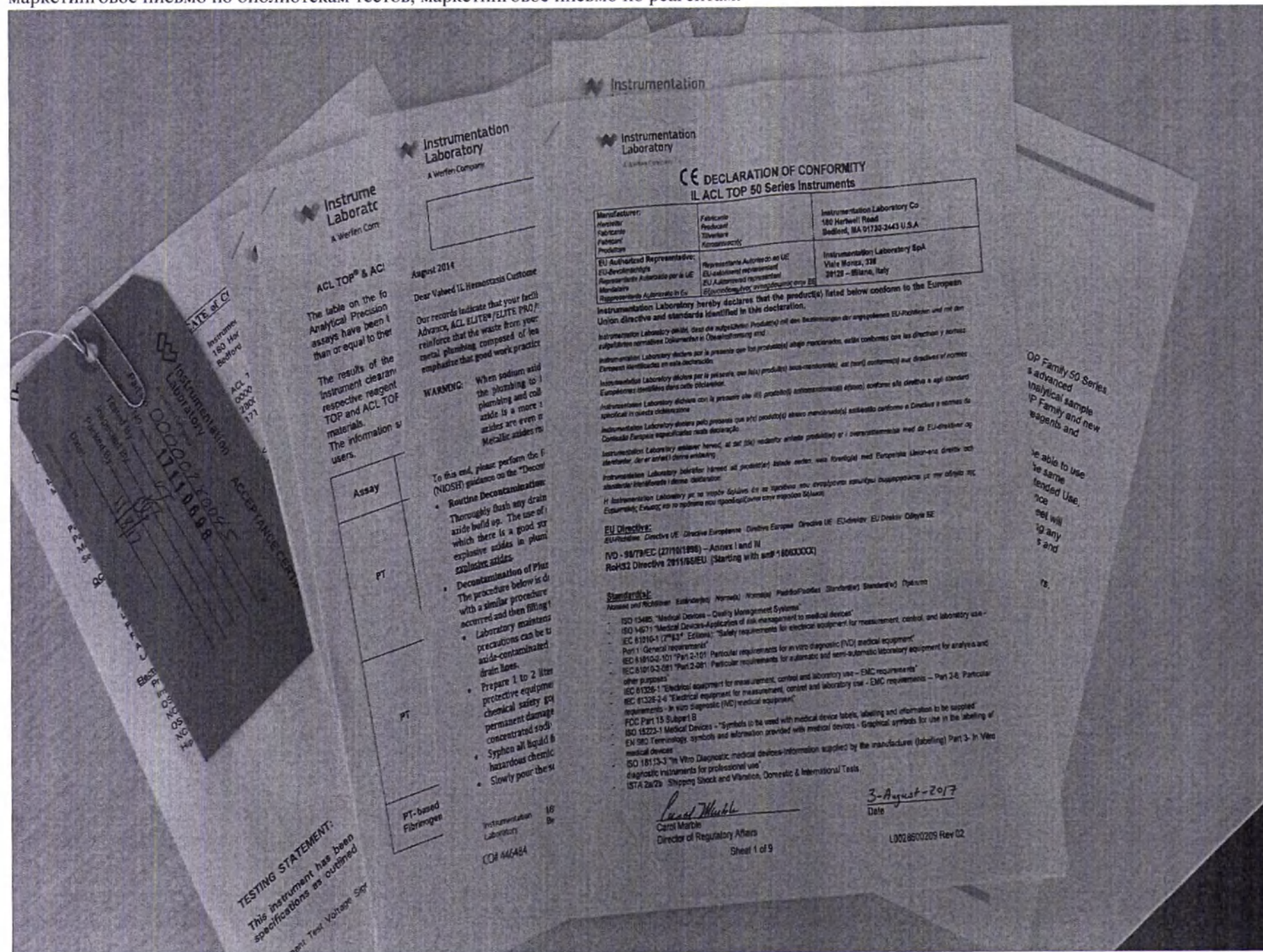




Интегрированный стол



Документация: декларация соответствия, сертификат соответствия, спецификация точности измерений, письмо-уведомление про Азид натрия, маркетинговое письмо по библиотекам тестов, маркетинговое письмо по реагентам.





Instrumentation Laboratory

A Werfen Company

February, 2016

ACL TOP Family 50 Series with Software Release V6.1.0, Parameters P-18.1.00 and User Manual (On Line Help) V6.1.0

Dear Valued ACL TOP™ Customer,

Welcome to the ACL TOP Family 50 Series of Analyzers. The ACL TOP Family 50 Series are the newest members of the ACL TOP Family; the best-in-class analyzers for the hemostasis laboratory. These high performance consolidated workstations are for routine and specialty assays: Clotting, Chromogenic and Latex-Immunoassay with pre-analytical sample integrity checks and advanced audit trail and accreditation support tools. They are part of Instrumentation Laboratory's commitment to develop and introduce products that meet the needs of today's demanding hemostasis laboratory. The ACL TOP Family 50 Series is configured with Software V6.1.0, Parameters P-18.1.00, and User Manual (On Line Help) V6.1.0 and available to select regions worldwide.

The ACL TOP Family 50 Series includes the following analyzers:

ACL TOP 350 CTS	Part Number: 00000280065
ACL TOP 550 CTS	Part Number: 00000280045
ACL TOP 750	Part Number: 00000280015
ACL TOP 750 CTS	Part Number: 00000280055
ACL TOP 750 LAS	Part Number: 00000280035

All models of the ACL TOP Family 50 Series offer:

- Same quality results
- Same comprehensive reagent portfolio
- Same powerful and intuitive software
- Same features and usability
- Same assay-specific sample checks
- Same advanced lab accreditation support tools

Software Version 6.1.0 with Parameters P-18.1.00 includes the following parameter files:

- Liquid Anti-Xa [Anti-Xa]
- Antithrombin Liquid [AT LIQ]
- APCR V with APC [APCR V+]
- APCR V without APC [APCR V-]
- APTT Syn Phospholip [APTT-SP]
- APTT SynthASII [APTT-SS]
- D-Dimer HS 500 [DDHS 500]
- D-Dimer HS [DDHS]
- D-Dimer [DD]
- Factor II-RP [FII-RP]
- Factor II- ReadiPlasTin [FIIRead]
- Factor II-RP-8 [FII-RP-8]
- Factor IX-SS [FIX-SS]
- Factor V ReadiPlasTin [FVRead]
- Factor V-RP-8 [FVRP-8]
- Factor VIII-SS [FVIII-SS]
- Factor VIII-SS with normal WVF [F8v-SS]
- Factor VII-RP [FVII-RP]
- Factor VII-RP-8 [FVII-RP-8]
- Factor VII ReadiPlasTin [FVIIRead]
- Factor V-RP [FV-RP]
- Factor X HS Plus [FX-HS+]
- Factor X -RP [FX-RP]
- FX ReadiPlasTin [FXRead]
- Factor XI-SS [FXI-SS]
- Factor XII-SS [FXII-SS]
- Factor VIII-SP [FVIII-SP]
- Factor IX-SP [FIX-SP]
- Factor XI-SP [FXI-SP]
- Factor XII-SP [FXII-SP]
- Fib RecombiPlasTin [Fib-RP]



**Instrumentation
Laboratory**

A Werfen Company

November, 2014

Dear Valued ACL TOP 50 customer,

Instrumentation Laboratory is pleased to announce the launch of the new ACL TOP Family 50 Series. The ACL TOP Family 50 Series offer low- to high- volume hemostasis laboratories advanced automation of routine to specialty assays with the added benefit of integrated pre-analytical sample integrity checks, and advanced laboratory accreditation support tools. The ACL TOP Family and new ACL TOP Family 50 Series will be able to use the same comprehensive portfolio of reagents and produce the same quality results.

Since the new ACL TOP Family 50 Series evolved from the ACL TOP Family, you will be able to use the same comprehensive portfolio of HemosIL reagents, calibrators and controls using the same assigned values as listed on the insert sheets for the ACL TOP Family. In addition, the Intended Use, Reagent Storage/Stability, Limitations/Interfering Substances, Expected Values, Performance Characteristics, and any other instrument specific claims on any HemosIL reagent insert sheet will apply to both the ACL TOP Family and the ACL TOP Family 50 Series. Therefore, when using any HemosIL reagent on the ACL TOP Family 50 Series analyzer, please use the assigned values and claims listed on the insert sheet for the ACL TOP Family.

IL is committed to delivering innovative and practical solutions to meet the needs of our customers. The features of the new ACL TOP Family 50 Series will minimize the risk of errors and enhance quality assurance leading to better patient care. Thank you for choosing IL as a partner in Hemostasis testing.

Please contact your local representative if you have any questions.

Sincerely,

Catherine Quirbach Ph.D.

Group Product Manager, Hemostasis Reagents

Instrumentation Laboratory

CO#446005

00027503098 R00

Our Passion

For Your Results

180 Hartwell Road, Bedford, MA 01730

781-861-0710

www.il.us.com



**Instrumentation
Laboratory**

A Werfen Company

**IL HEMOSTASIS SYSTEMS
URGENT SAFETY NOTIFICATION**

August 2014

Dear Valued IL Hemostasis Customer:

Our records indicate that your facility has in use one or more IL Hemostasis Systems: ACL TOP® Family, ACL Futura/ACL Advance, ACL ELITE®/ELITE PRO/8/9/10000, ACL Classic (100-7000) and ACL AcuStar. This notification is intended to reinforce that the waste from your IL Hemostasis System contains sodium azide that may potentially form explosives in metal plumbing composed of lead, brass, tin, copper or zinc or containing solder in the plumbing system and to emphasize that good work practices should be followed to mitigate the risk of explosion.

WARNING: When sodium azide preservative in reagents is disposed down the drain, it can react with the metals in the plumbing to form insoluble metallic azides, such as copper and lead azide, which settle in the plumbing and collect in traps, threads, etc. These metallic azides are highly explosive. For example, lead azide is a more sensitive primary explosive than nitroglycerine and copper azide and other metallic azides are even more explosive and are considered too sensitive to be used commercially as explosives. Metallic azides may explode if subjected to friction, heat, shock or by reaction with other chemicals.

To this end, please perform the following steps taken directly from the National Institute of Occupational Safety and Health (NIOSH) guidance on the "Decontamination Procedures for Azide Contaminated Plumbing" (1976):

- **Routine Decontamination:**

Thoroughly flush any drain used for waste disposal with copious amounts of water several times a day to prevent azide build up. The use of copper- and lead-free lines between the point of discharge of azide and the nearest pipe in which there is a good stream of water, or the use of azide-free reagents, may prevent future accumulation of explosive azides in plumbing. **NOTE: These measures will NOT decontaminate plumbing already containing explosive azides.**

- **Decontamination of Plumbing Containing Explosive Azides:**

The procedure below is designed to decontaminate a drain trap. Longer lengths of drain lines can be decontaminated with a similar procedure after plugging the drain below the point at which any azide contamination is likely to have occurred and then filling the entire length of pipe with 10% sodium hydroxide solution.

- Laboratory maintenance workers, especially plumbers, should be alerted to the azide hazard so that proper precautions can be taken. Violent explosions have resulted when plumbers have attempted to penetrate blocked azide-contaminated drainage systems with a flexible metal probe (snake) or to cut or saw azide-contaminated drain lines.
- Prepare 1 to 2 liters of 10% sodium hydroxide solution (100 g NaOH per liter of water). Wear appropriate protective equipment when preparing and handling this corrosive material including gloves, protective clothing, chemical safety goggles and face shield. Contact with eyes or skin will cause severe burns and may cause permanent damage. Carefully read and follow the manufacturer's safety instructions and instructions for diluting concentrated sodium hydroxide or sodium hydroxide solid in water.
- Syphon all liquid from the trap and drain using a soft rubber or plastic hose. Use proper precautions against any hazardous chemicals which may be present.
- Slowly pour the sodium hydroxide solution into the trap.

Instrumentation
Laboratory

180 Hartwell Road
Bedford, MA 01730

Tel 781-861-0710

www.ilus.com

CO# 446484

Page 1 of 2

L0019014800 R03



Instrumentation Laboratory

A Werfen Company

ACL TOP® & ACL TOP Family 50 Series Analytical Precision Performance Requirements

The table on the following pages reflects the current ACL TOP and ACL TOP Family 50 Series Analytical Precision Performance Requirements. The released parameters for each of the noted assays have been tested by Instrumentation Laboratory, and the imprecision data generated is less than or equal to these requirements.

The results of the internal testing have been submitted to the respective governing bodies for instrument clearance where the reagent is sold, and is also published in the insert sheets of the respective reagent products. Those published values reflect the testing performed on specific ACL TOP and ACL TOP Family 50 Series instruments using specific lots of reagent, calibrator, and control materials.

The information supplied here can serve as a guide to ACL TOP and ACL TOP Family 50 Series users.

Assay	Reagent	Result Unit	Control	Within Run Imprecision (%CV)	Total Imprecision (%CV)
PT	PT-Fib HS + PT-Fibrinogen	Seconds	HemosIL® Normal Control	≤ 2.0	≤ 3.0
			HemosIL Normal Control 1	≤ 2.0	≤ 3.0
			HemosIL Low Abnormal Control	≤ 3.0	≤ 4.0
			HemosIL Abnormal Control 2	≤ 3.0	≤ 4.0
			HemosIL High Abnormal Control	≤ 5.0	≤ 8.0
			HemosIL Abnormal Control 3	≤ 5.0	≤ 8.0
PT	RecombiPlasTin 2G ReadiPlasTin	Seconds	HemosIL® Normal Control	≤ 3.0	≤ 3.0
			HemosIL Normal Control 1	≤ 3.0	≤ 3.0
			HemosIL Low Abnormal Control	≤ 4.0	≤ 4.0
			HemosIL Abnormal Control 2	≤ 4.0	≤ 4.0
			HemosIL High Abnormal Control	≤ 5.0	≤ 8.0
			HemosIL Abnormal Control 3	≤ 5.0	≤ 8.0
PT-based Fibrinogen	PT-Fib HS + PT-Fibrinogen	mg/dL	HemosIL Normal Control	≤ 10.0	≤ 12.0
			HemosIL Normal Control 1	≤ 10.0	≤ 12.0



**Instrumentation
Laboratory**

A Werfen Company

For North America Customers Only

September 19, 2016

Dear Valued ACL TOP Family 50 Series customer,

When using any HemosIL reagent on the ACL TOP Family 50 Series analyzer, please use the assigned values and the claims listed on the insert sheet for the ACL TOP Family. Since the ACL TOP Family 50 Series evolved from the ACL TOP Family, you will be able to use the same comprehensive portfolio of HemosIL reagents, calibrators and controls. The claims for Intended Use, Reagent Storage/Stability, Limitations/Interfering Substances, Expected Values on a HemosIL reagent insert sheet will apply for both the ACL TOP Family and the ACL TOP Family 50 Series.

In addition, Instrumentation Laboratory performed additional precision and method comparison studies to achieve 510k clearance. While the HemosIL labeling is being updated, the corresponding Precision and Method Comparison data for ACL TOP 50 Series from the current 510k cleared assays are listed in this letter for your reference.

Please share this information with your laboratory staff and retain a copy of this letter for your records. Thank you for choosing IL as a partner in Hemostasis testing.

Please contact your local representative if you have any questions.

Sincerely,

Catherine Quirbach Ph.D.

Group Product Manager, Hemostasis Reagents
Instrumentation Laboratory

Part No. 00000280045
 Serial No. 17110698
 Tested By: ST
 Inspected By: ST
 Factory By: ST
 Date: 11/8/17

Instrumentation Laboratory
 ACCEPTANCE CERTIFICATE

CIFICATE of COMPLIANCE

Instrumentation Laboratory
 180 Hartwell Road
 Bedford, MA US 01730

ACL TOP 550 CTS SYSTEM
 00000280045
 2800-45 ACL TOP 550 CTS
 17110698

V = 1.7 %	0.7	PASS
V = 3.2 %	1.2	PASS
V = 1.7 %	1.2	PASS
V = 3.0 %	2.6	PASS
V = 3.0 %	1.2	PASS
V = 6.0 %	1.4	PASS
V = 2.3 %	1.1	PASS
V = 10.0 %	6.8	PASS
V = 0.200 Ohm	0.070	PASS
V = 2 MOhm	734	PASS
0.1 .. 1000.0 μ A	524.1	PASS
0.1 .. 500.0 μ A	265.3	PASS
0.1 .. 1000.0 μ A	530.4	PASS
0.1 .. 500.0 μ A	268.7	PASS
2.00 .. 10.00 mA	4.21	PASS

TESTING STATEMENT:

This instrument has been certified to meet all applicable electrical and analytical specifications as outlined in Instrumentation Laboratory's final test and QC procedures.

Instrument Test Voltage Signature: JNUON

Date: 11/03/2017

QC Signature: SYI

Date: 11/07/2017

CO # 464252

Sheet 1 of 1

Part No. 00028786200 Rev 18

CE DECLARATION OF CONFORMITY **IL ACL TOP 50 Series Instruments**

Manufacturer: Hersteller Fabricante Fabricant Produttore	Fabricante Producent Tilvarekøber Κατασκευαστής	Instrumentation Laboratory Co 180 Hartwell Road Bedford, MA 01730-2443 U.S.A
EU Authorized Representative: EU-Bevollmächtigte Representante Autorizado por la UE Mendataire Rappresentante Autorizzato in Eu	Representante Autorizado na UE EU-authorized representative EU Auktoriseret representant Εξουσιοδοτημένος αντιπρόσωπος στην ΕΕ	Instrumentation Laboratory SpA Viale Monza, 338 20128 - Milano, Italy

Instrumentation Laboratory hereby declares that the product(s) listed below conform to the European Union directive and standards identified in this declaration.

Instrumentation Laboratory erklärt, dass die aufgeführten Produkt(e) mit den Bestimmungen der angegebenen EU-Richtlinien und mit den aufgeführten normativen Dokumenten in Übereinstimmung sind.

Instrumentation Laboratory declara por la presente que los producto(s) abajo mencionados, están conformes con las directivas y normas Europeas identificadas en esta declaración.

Instrumentation Laboratory déclare par la présente, que le(s) produit(s) sous-mentionné(s), est (sont) conforme(s) aux directives et normes Européennes identifiées dans cette déclaration.

Instrumentation Laboratory dichiara con la presente che il(ri) prodotto(i) sotto menzionato(i) è(sono) conformi alla direttiva e agli standard specificati in questa dichiarazione.

Instrumentation Laboratory declara pela presente que o(s) produto(s) abaixo mencionado(s) está(ão) conforme a Directiva e normas da Comissão Europeia especificadas nesta declaração.

Instrumentation Laboratory erklærer herved, at det (de) nedenfor anførte produkt(er) er i overensstemmelse med de EU-direktiver og standarder, der er anført i denne erklæring.

Instrumentation Laboratory bekräftar härmed ett produkt(er) listade nedan, vara förenliga med Europeiska Union-ens direktiv och standarder identifierade i denna deklaration.

H Instrumentation Laboratory με το παρόν δηλώνει ότι τα προϊόντα που αναφέρονται κατωτέρω συμμορφούνται με την οδηγία της Ευρωπαϊκής Ένωσης και τα πρότυπα που προσδιορίζονται στην παρούσα δήλωση.

EU Directive:

EU-Richtlinie Directive UE Directive Européenne Directive Europea Directiva UE EU-direktiv EU Direktiv Οδηγία ΕΕ

IVD - 98/79/EC (27/10/1998) – Annex I and III

RoHS2 Directive 2011/65/EU (Starting with sn# 1606XXXX)

Standard(s):

Normen und Richtlinien Estándar(es) Norme(s) Norma(e) Padrão/Padrões Standard(er) Standard(er) Πρότυπο

- ISO 13485, "Medical Devices – Quality Management Systems"
- ISO 14971 "Medical Devices-Application of risk management to medical devices"
- IEC 61010-1 (2nd & 3rd Editions) "Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements"
- IEC 61010-2-101 "Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment"
- IEC 61010-2-081 "Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes"
- IEC 61326-1 "Electrical equipment for measurement, control and laboratory use – EMC requirements"
- IEC 61326-2-6 "Electrical equipment for measurement, control and laboratory use - EMC requirements – Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment"
- FCC Part 15 Subpart B
- ISO 15223-1 Medical Devices – "Symbols to be used with medical device labels, labelling and information to be supplied"
- EN 980 Terminology, symbols and information provided with medical devices - Graphical symbols for use in the labelling of medical devices
- ISO 18113-3 "In Vitro Diagnostic medical devices-Information supplied by the manufacturer (labelling) Part 3- In Vitro diagnostic instruments for professional use"
- ISTA 2a/2b Shipping Shock and Vibration, Domestic & International Tests.

Carol Marble
Carol Marble
Director of Regulatory Affairs

Sheet 1 of 9

3-August-2017
Date

L0028600209 Rev 02

SYRINGE TIP, 250UL 2/PK ACL TOP
 P/N: 00028911601
 Rev: 02
 Qty: 1 UM
 Date Code: 1602

Instrumentation Laboratory
 191 Harvard Rd., Boston, MA 02130-2443 U.S.A.
 Instrumentation Laboratory SpA Via Vercelli 20 20134 Milano, Italy

+*507000269116011D
 +*801DC

Трубка пробозаборника, 1 шт. (при необходимости)



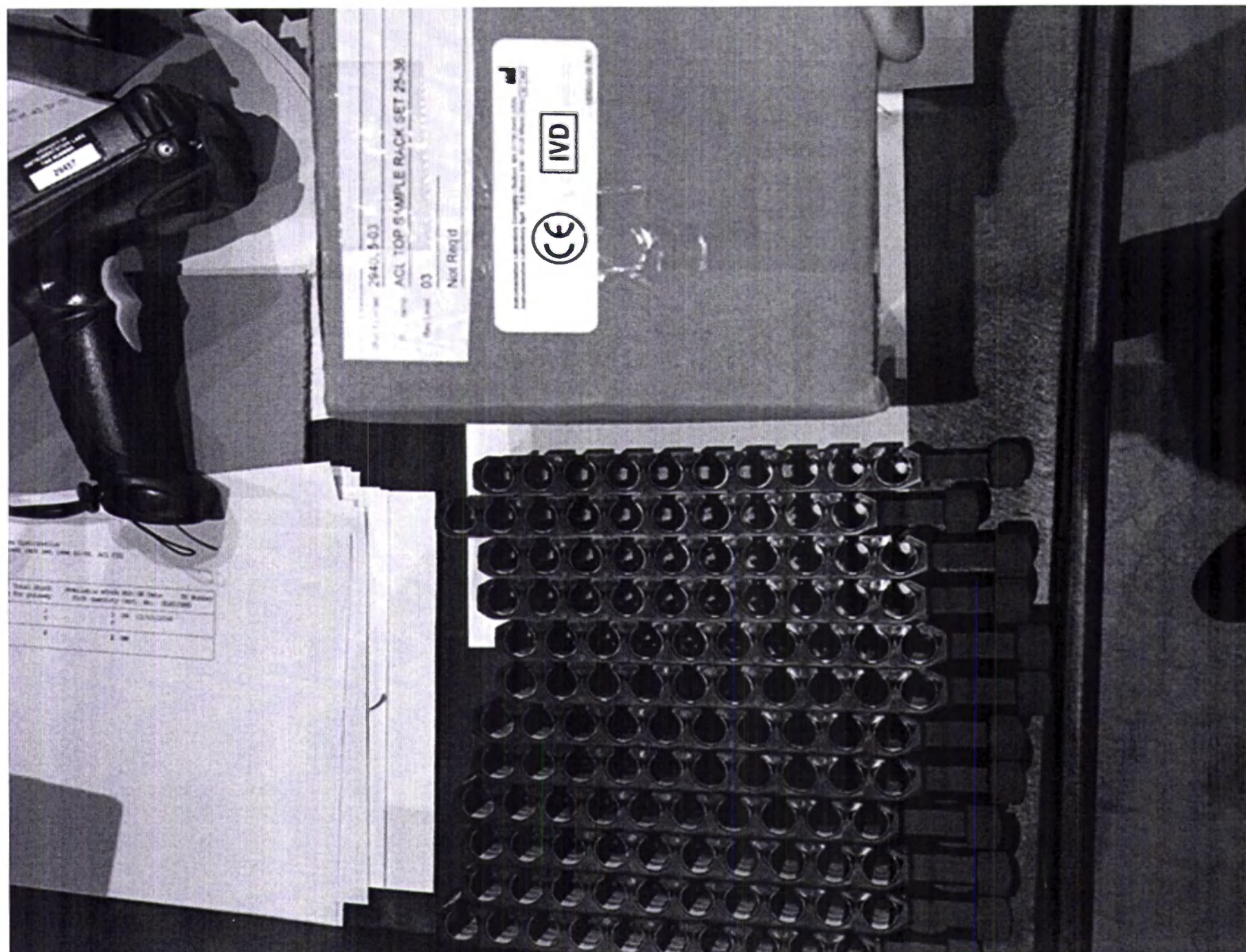
Штативы для реагентов RG-RM, 6 шт./уп. (при необходимости)



Штативы для разбавителей DD-DF, 3 шт./уп. (при необходимости)



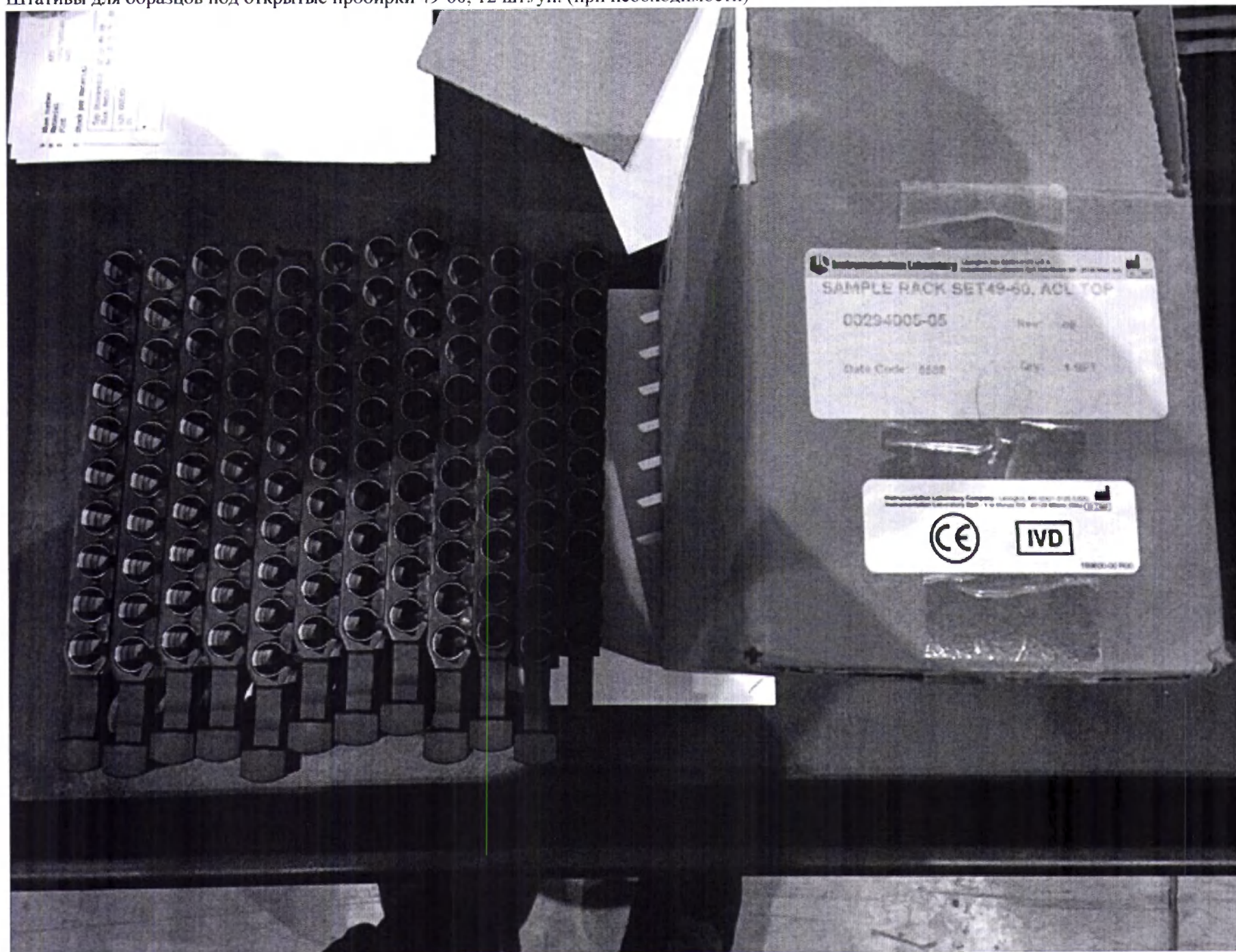
Штативы для образцов под открытые пробирки 25-36, 12 шт./уп. (при необходимости)



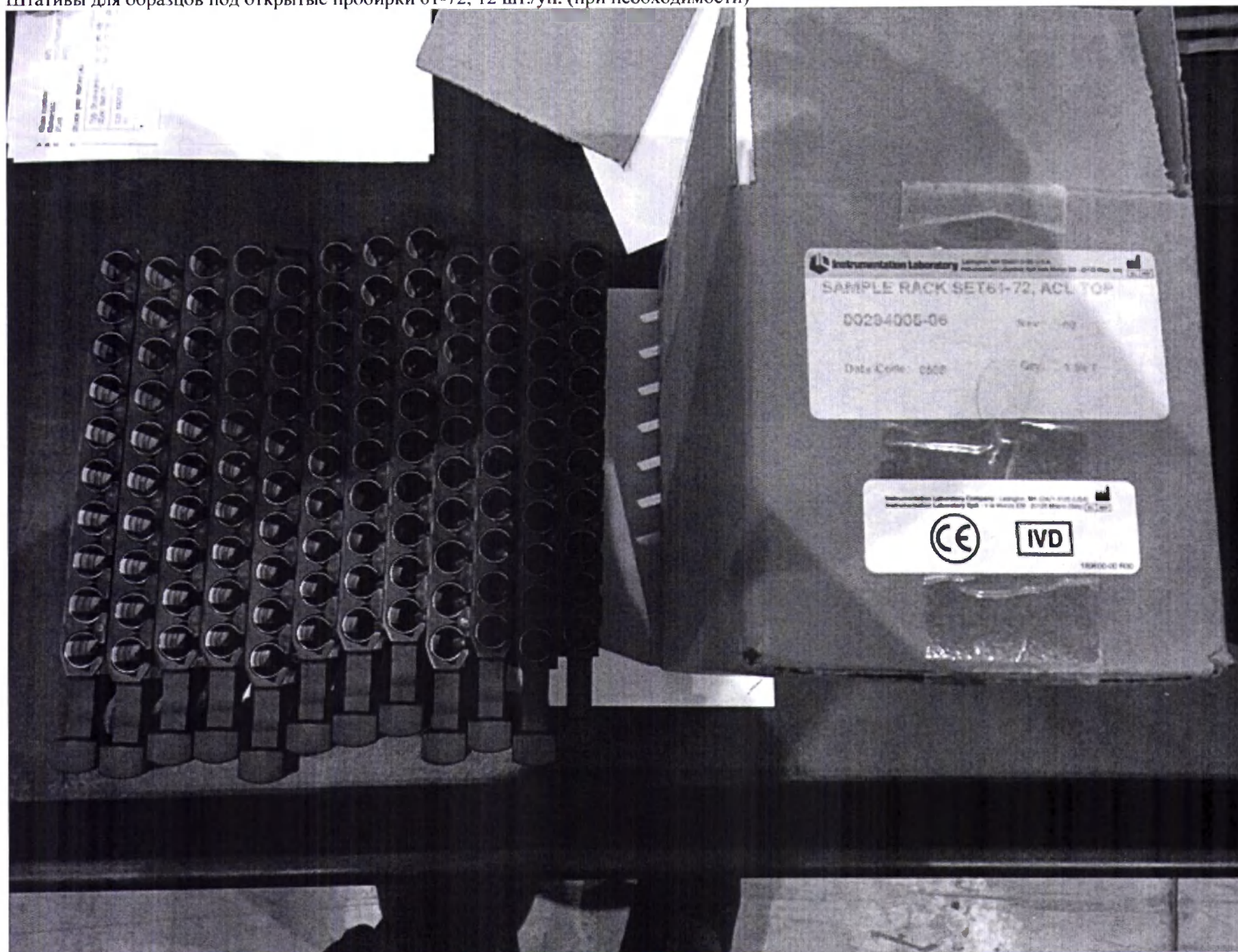
Штативы для образцов под открытые пробирки 37-48, 12 шт./уп. (при необходимости)



Штативы для образцов под открытые пробирки 49-60, 12 шт./уп. (при необходимости)



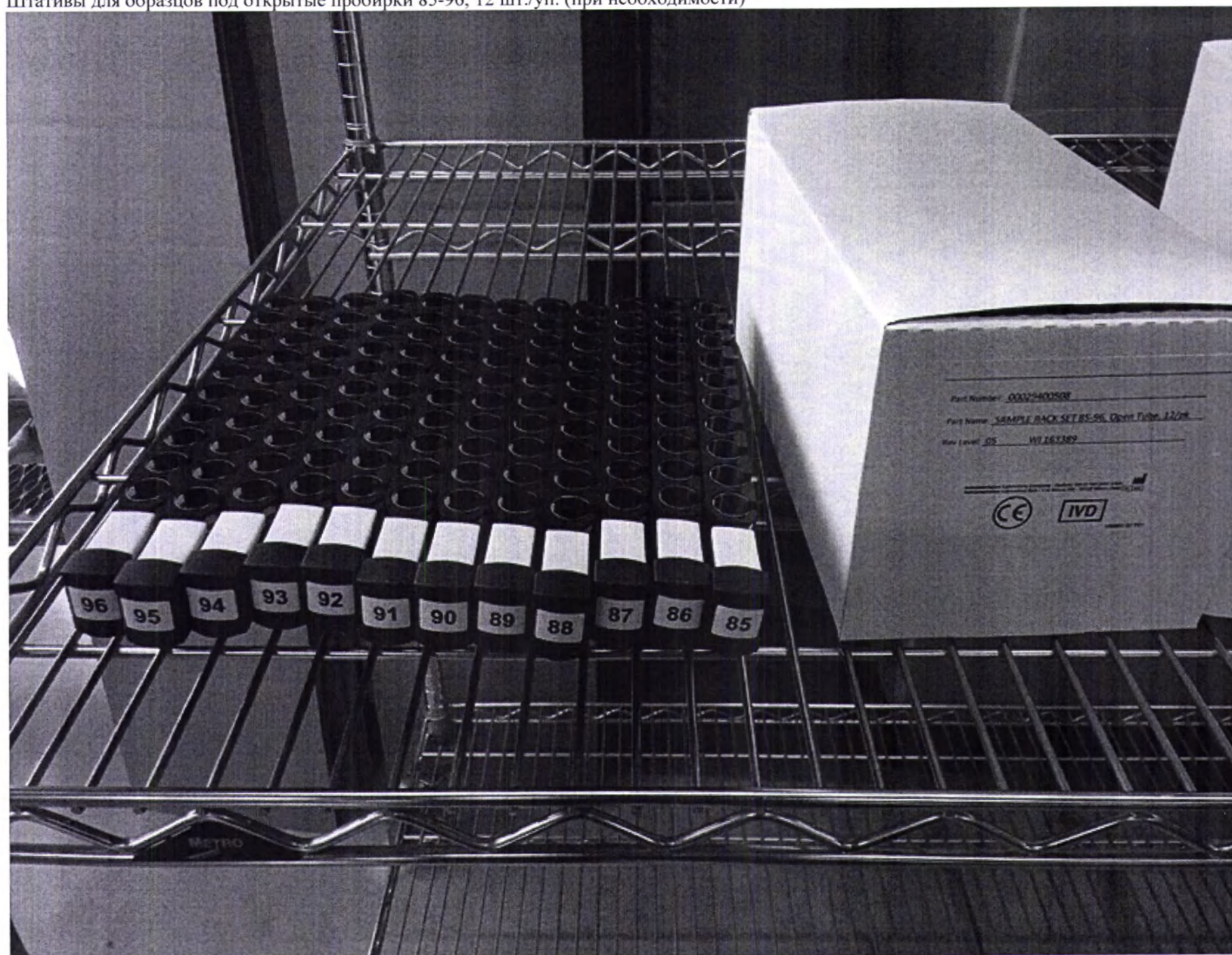
Штативы для образцов под открытые пробирки 61-72, 12 шт./уп. (при необходимости)



Штативы для образцов под открытые пробирки 73-84, 12 шт./уп. (при необходимости)



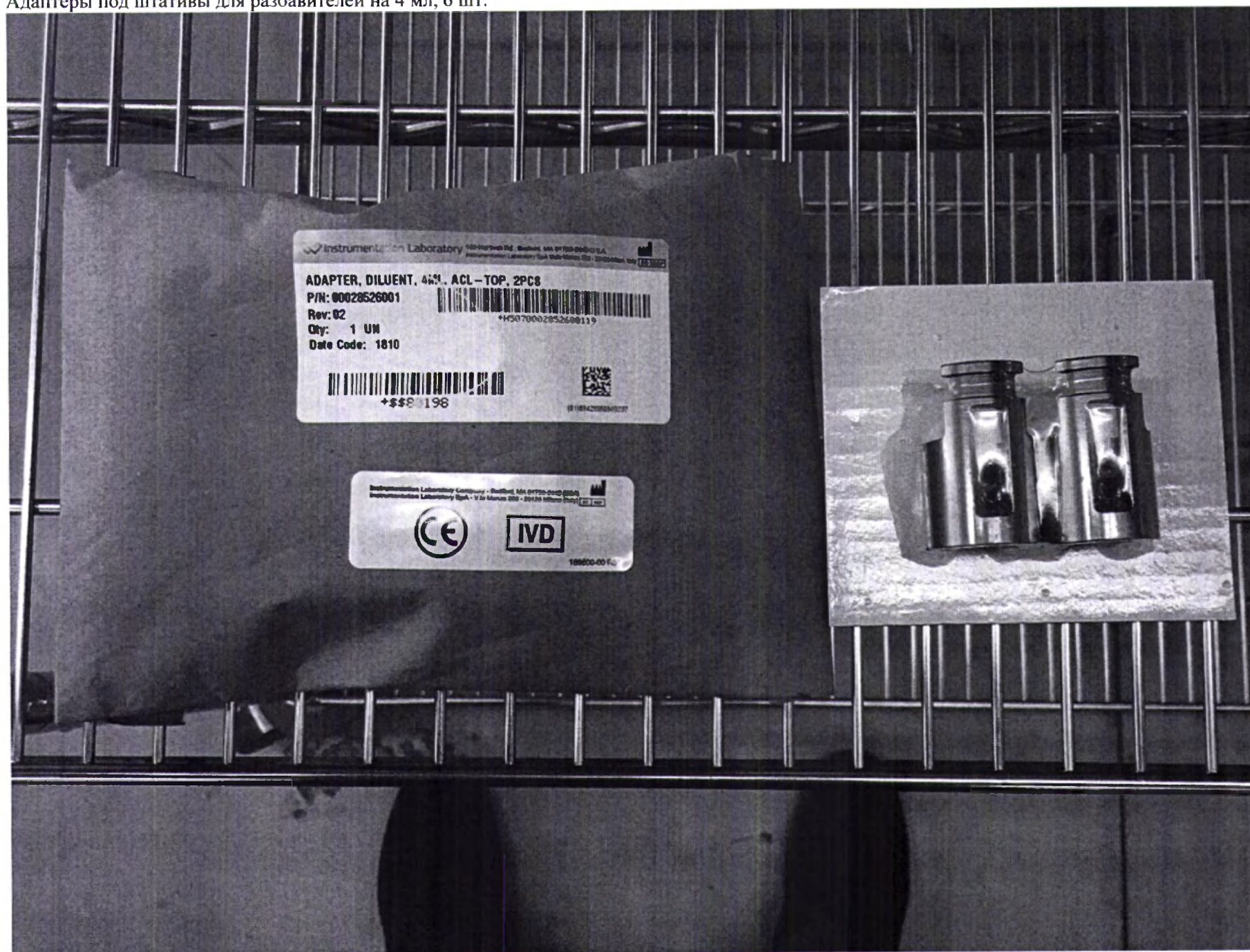
Штативы для образцов под открытые пробирки 85-96, 12 шт./уп. (при необходимости)



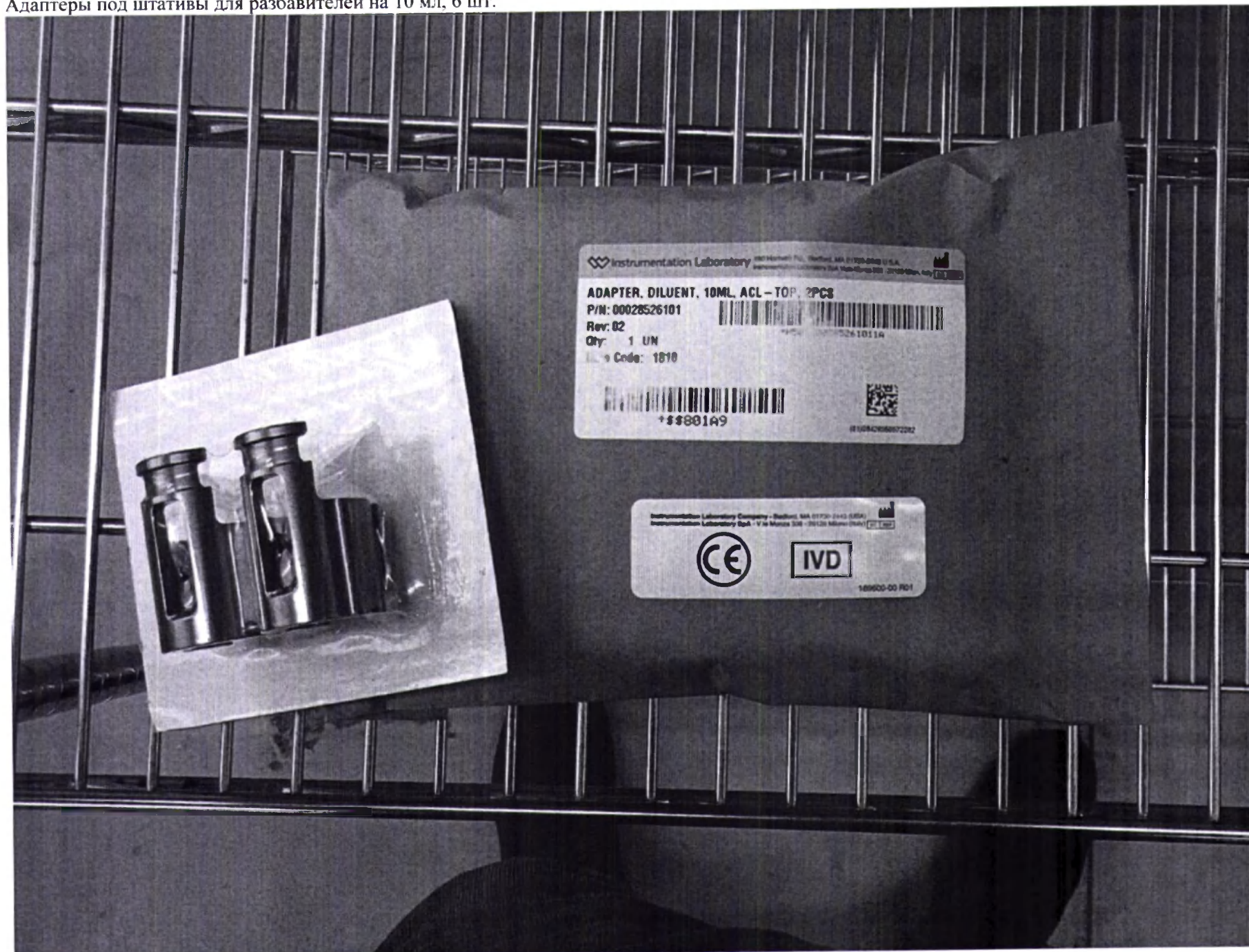
Подставка под 6 штативов для образцов, 1 шт.



Адаптеры под штативы для разбавителей на 4 мл, 6 шт.



Адаптеры под штативы для разбавителей на 10 мл, 6 шт.



Адаптеры под штативы для разбавителей на 20 мл, 6 шт.

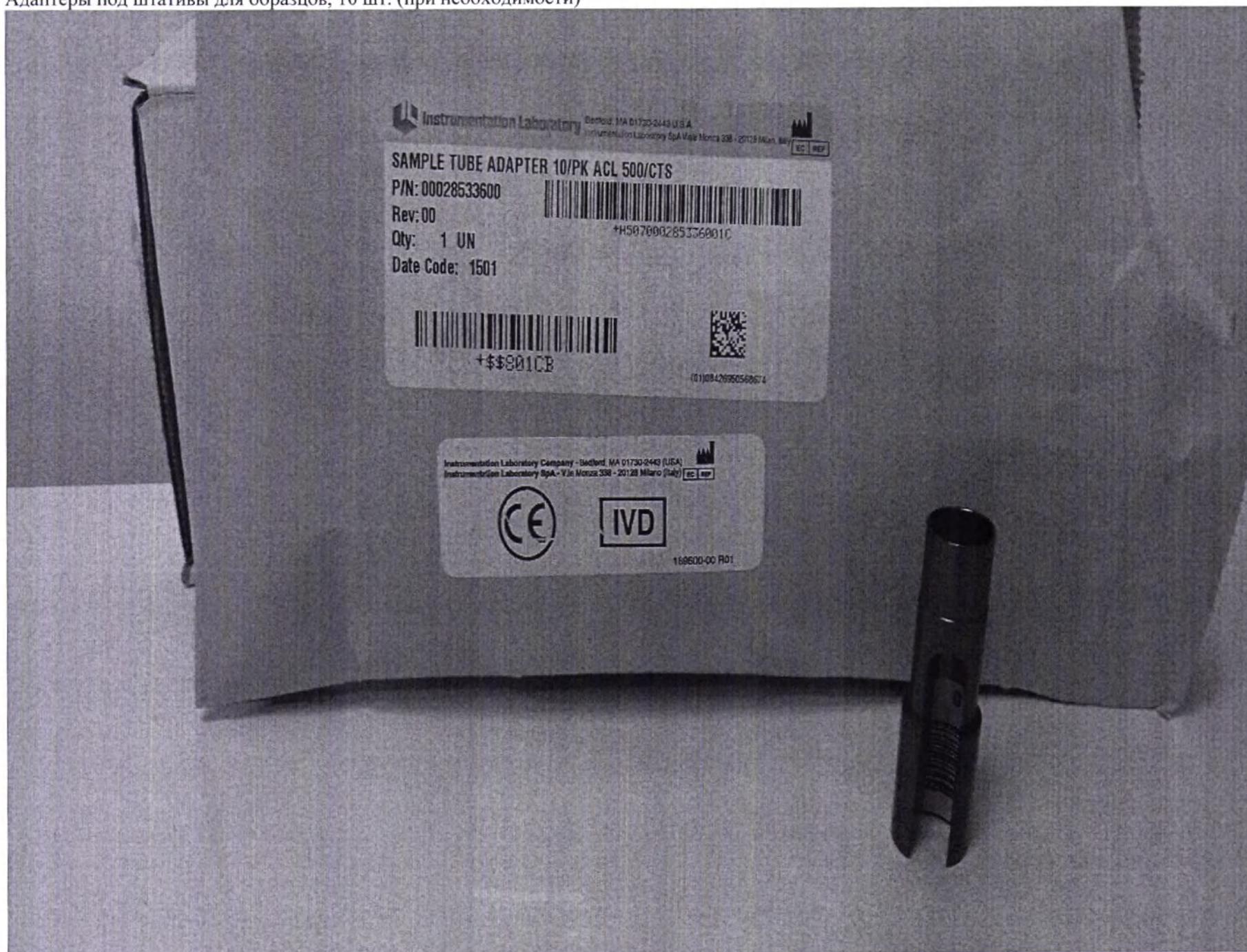


Адаптеры для аликвотных пробирок, 10 шт. (при необходимости)



The photograph shows an open shipping box containing several pediatric tubes, each individually packaged in a clear LDPE (Low Density Polyethylene) bag. The bags are labeled "LDPE" and "14". The tubes are black and silver, with a handwritten "14" on each. The box is lined with white foam packing peanuts. Two labels are affixed to the inside of the box lid. The larger label is white with black text and includes a barcode, a QR code, and the following information: "Pediatric Tubes Adapter 10/PK", "PIN: 00020533500", "Rev: 00", "Qty: 1 UN", "Date Code: 1001", and "M0000-00 R01". The smaller label is white with black text and includes a CE mark, the text "IVD", and the text "Pediatric Tubes Adapter 10/PK".

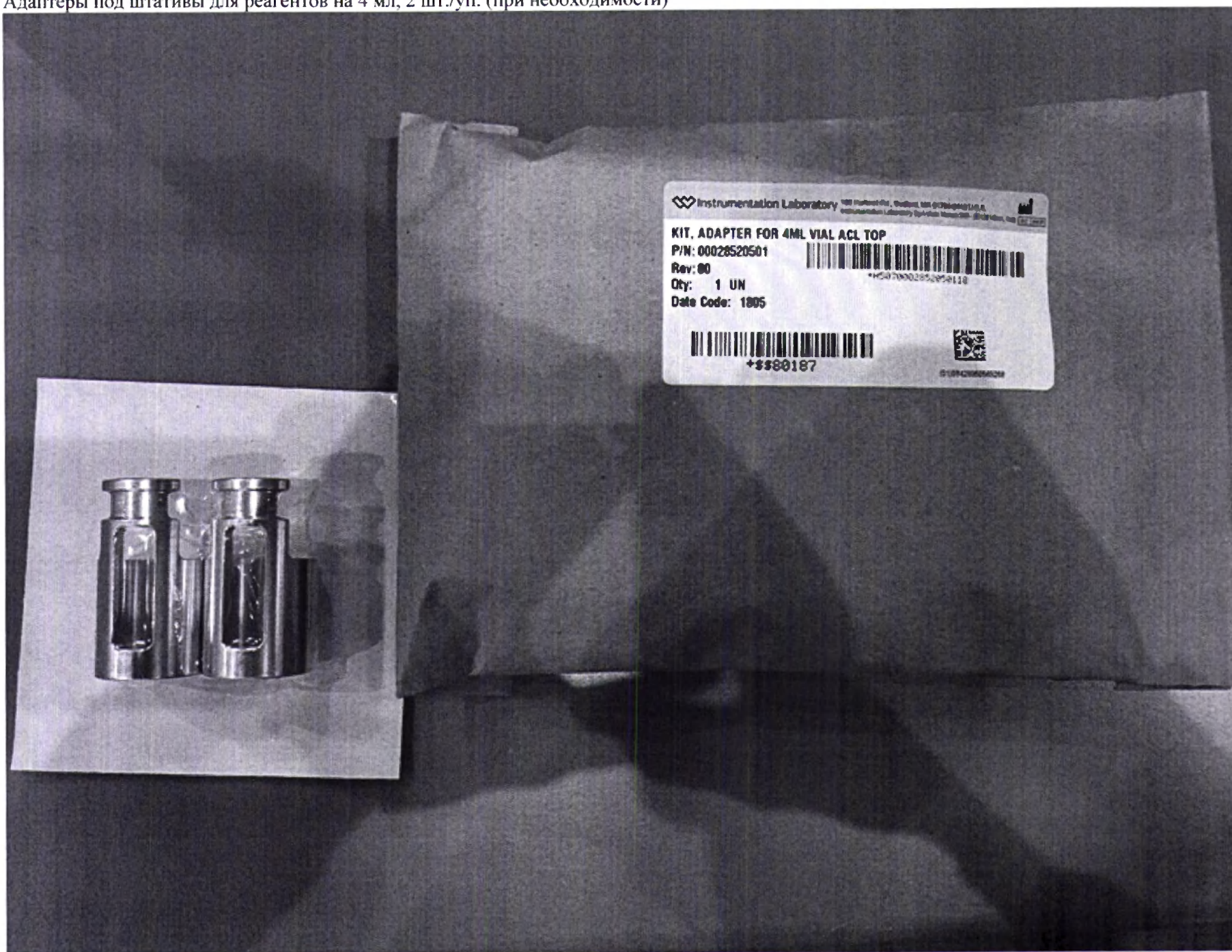
Адаптеры под штативы для образцов, 10 шт. (при необходимости)



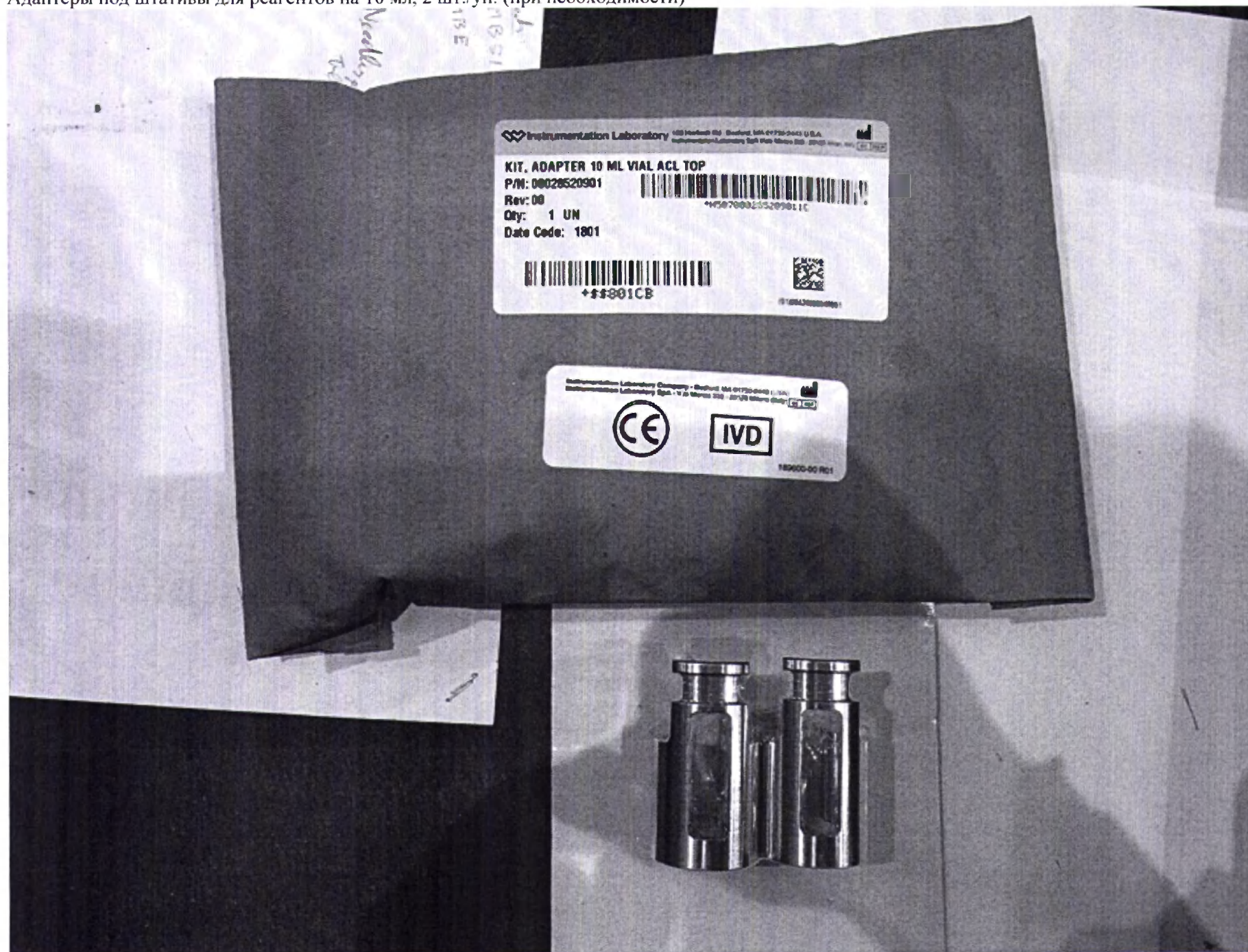
Адаптеры для микропробирок, 10 шт. (при необходимости)



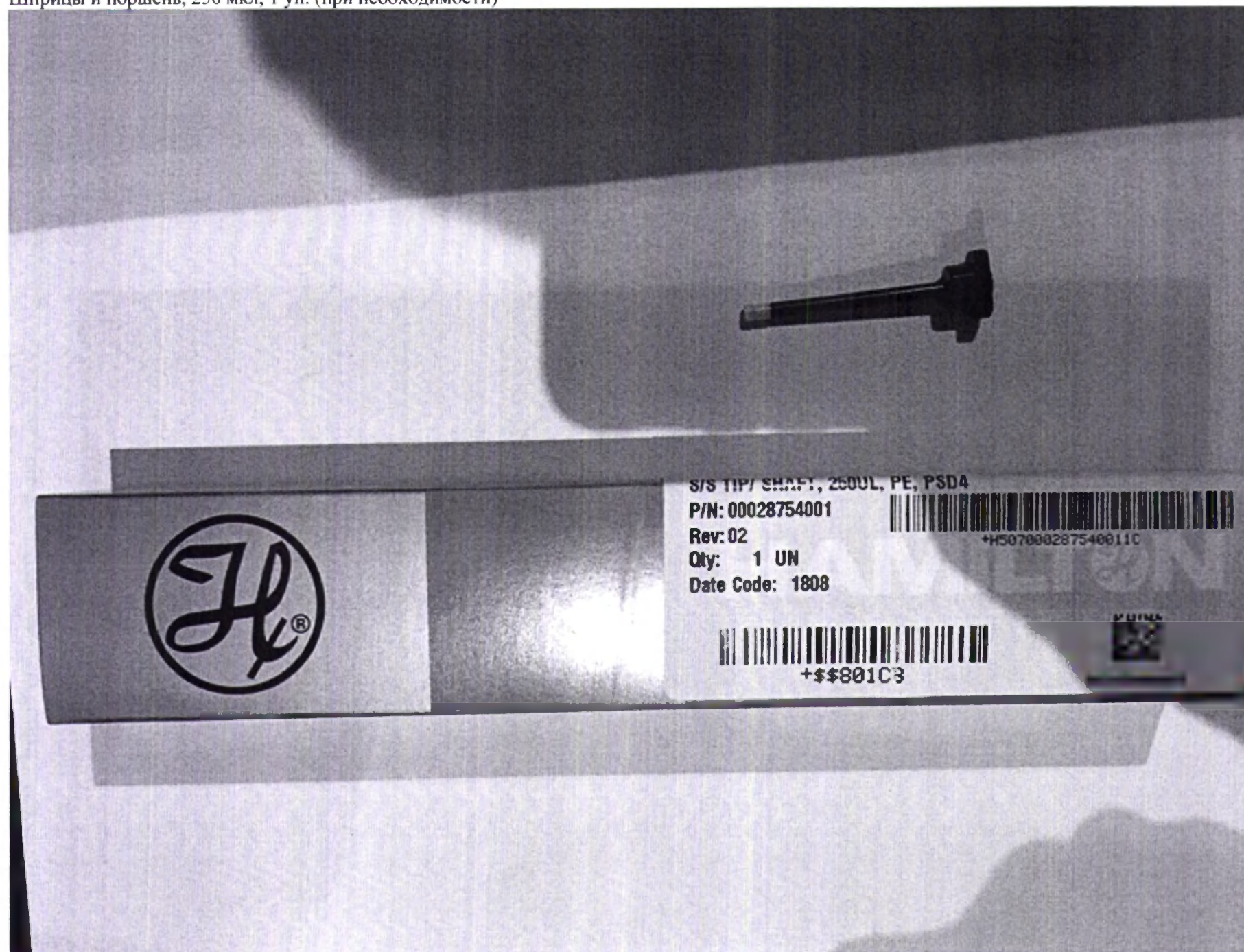
Адаптеры под штативы для реагентов на 4 мл, 2 шт./уп. (при необходимости)



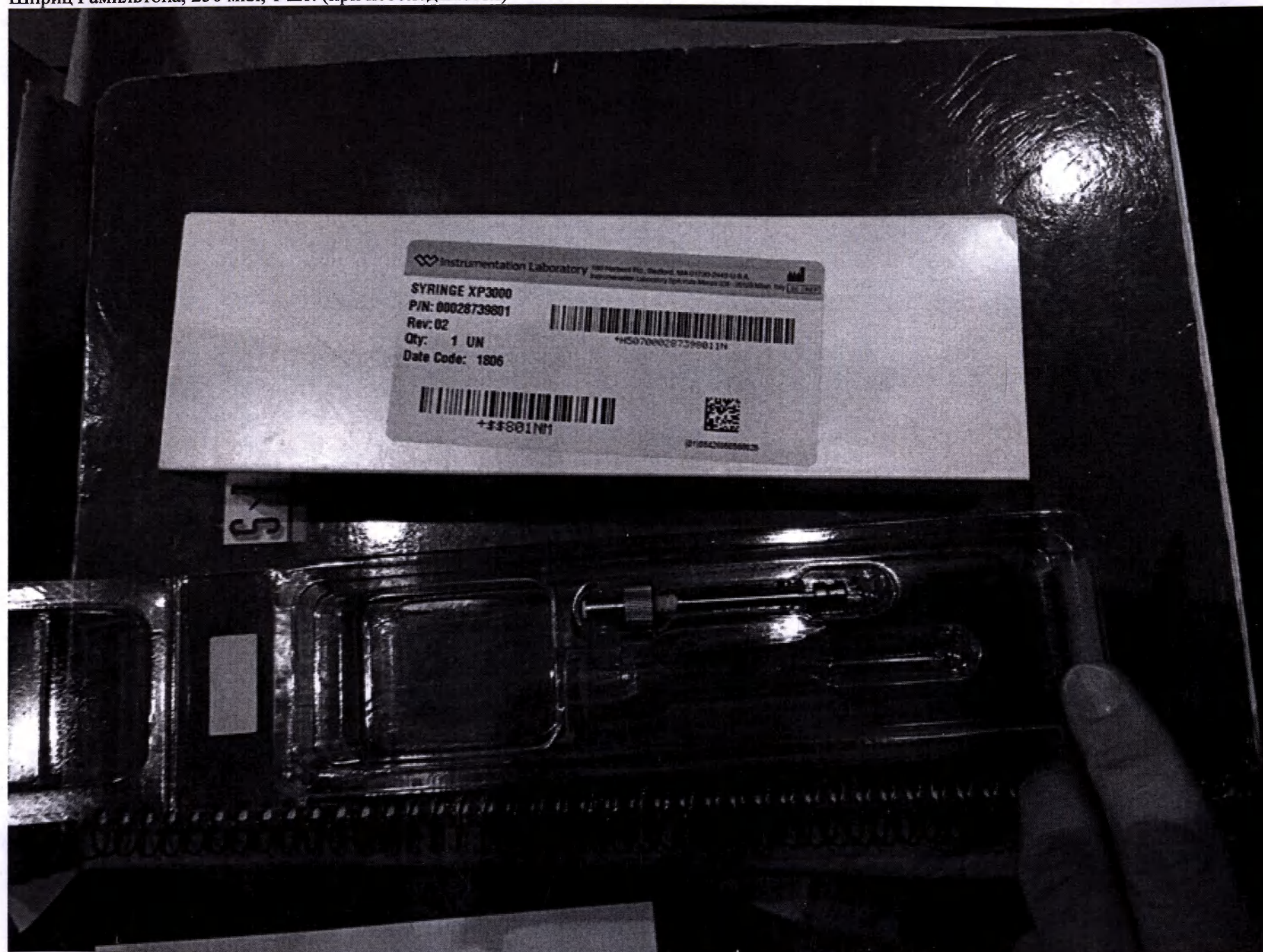
Адаптеры под штативы для реагентов на 10 мл, 2 шт./уп. (при необходимости)



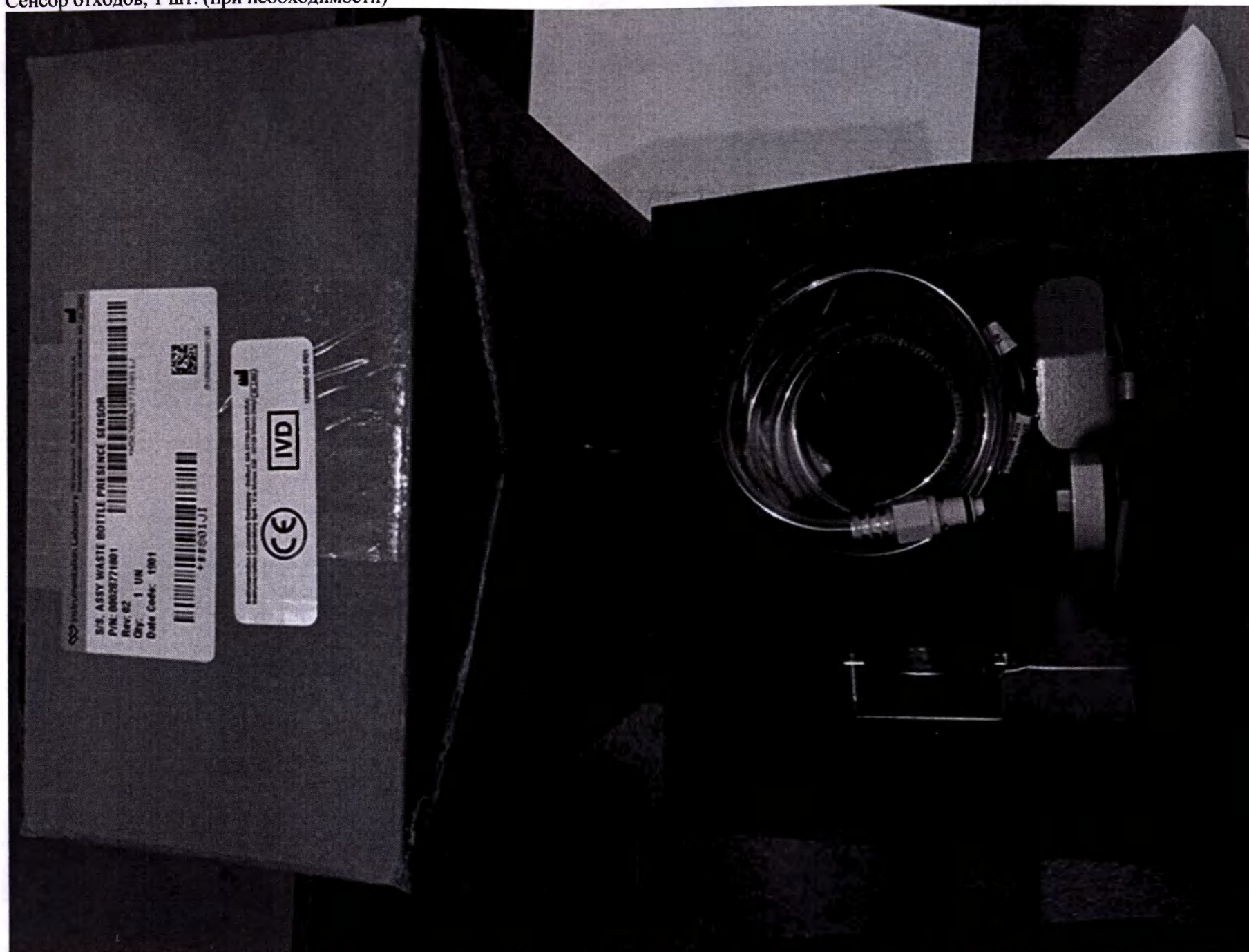
Шприцы и поршень, 250 мкл, 1 уп. (при необходимости)

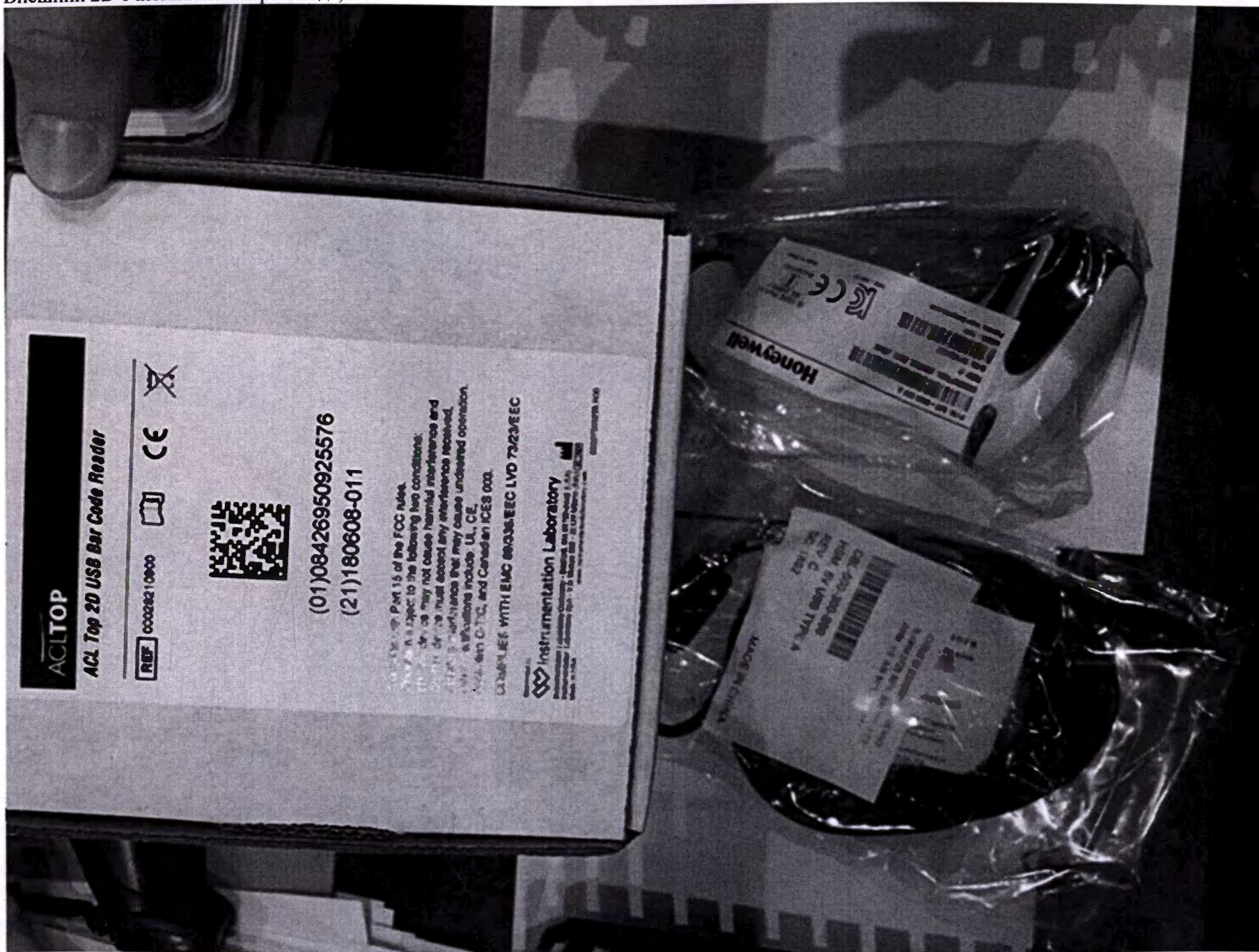


Шприц Гамильтона, 250 мкл, 1 шт. (при необходимости)



Сенсор отходов, 1 шт. (при необходимости)





ACLTOP

ACL Top 2D USB Bar Code Reader

REF 00000010000



CE



(01)08426950925576

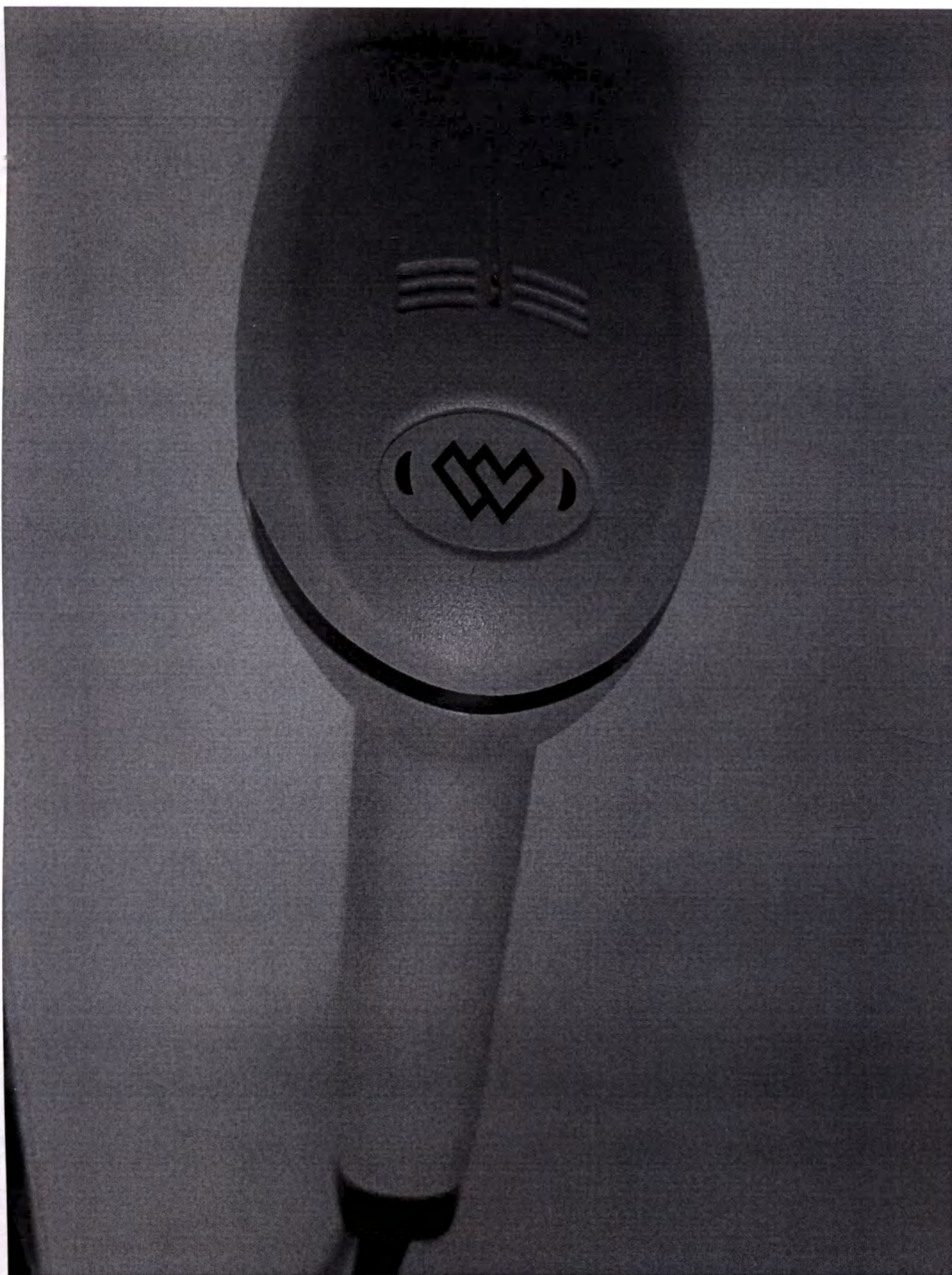
(21)180808-011

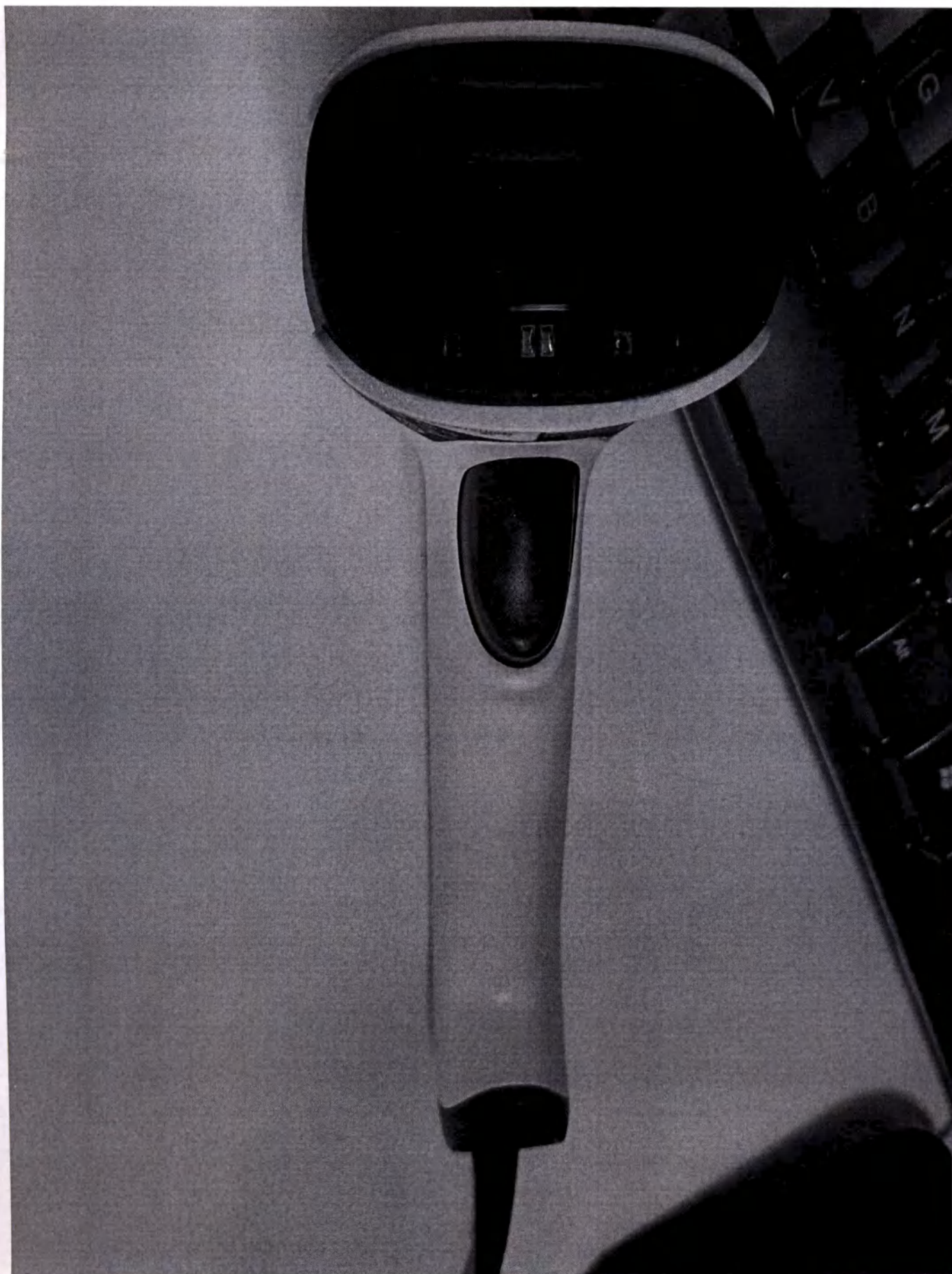
PLEASE READ Part 15 of the FCC rules.
This device is subject to the following two conditions:
1. It must not cause harmful interference and
2. It must accept any interference received, including interference that may cause undesired operation.
This device complies with the following requirements:
FCC Part 15, Class B, and Canadian ICES 003.

DECLARATION WITH EMC 80335 EEC LVD 7023 EEC

Instrumentation Laboratory
10000 W. 100th Ave., Suite 100, Golden, CO 80641, USA
Tel: 303.440.1000 Fax: 303.440.1001
www.instrumentationlab.com

000000000000





Syringe Drive Motor

Шприц РЕ PSD4, 250 мл, 1 шт. (при необходимости)

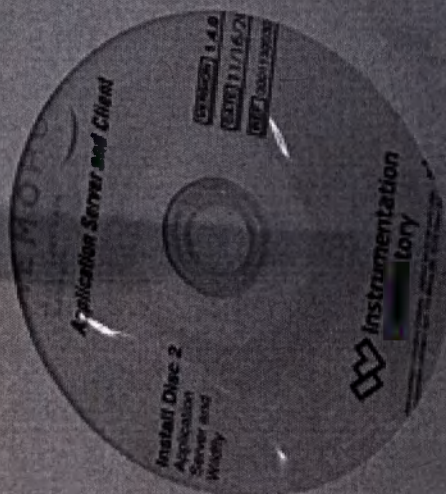
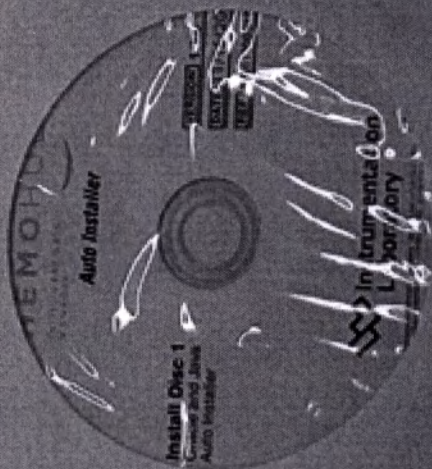
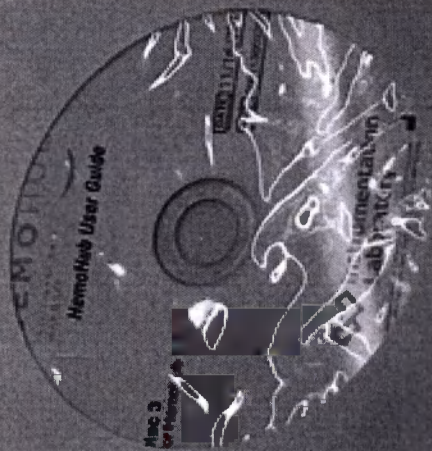
Syringe

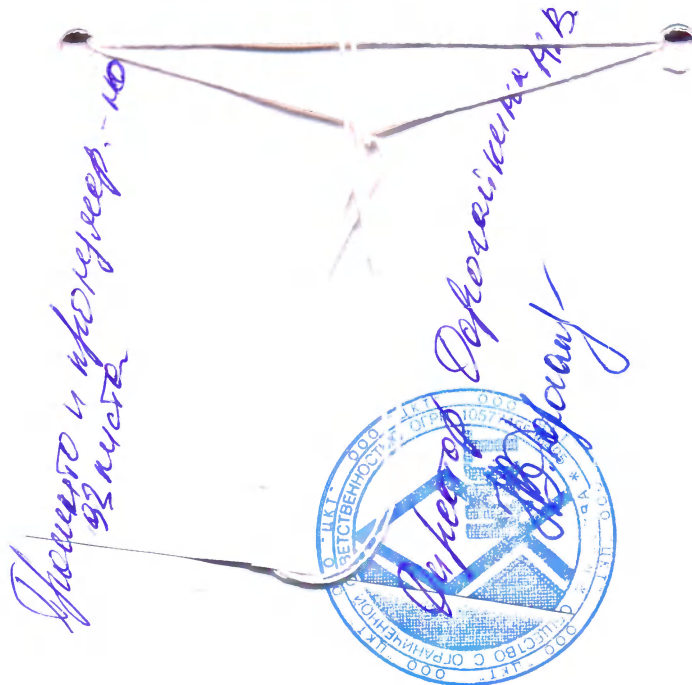
Вентилятор для охлаждения реагентов, ACL TOP 700/750 CTS, 1 шт. (при необходимости)



Программное обеспечение НемоHub, 1 шт. (при необходимости)

KIT, INSTALL-HEMOSHUB V1.0
N. P.M.: 00011300314 Rev. 00
Date 11/16/2017

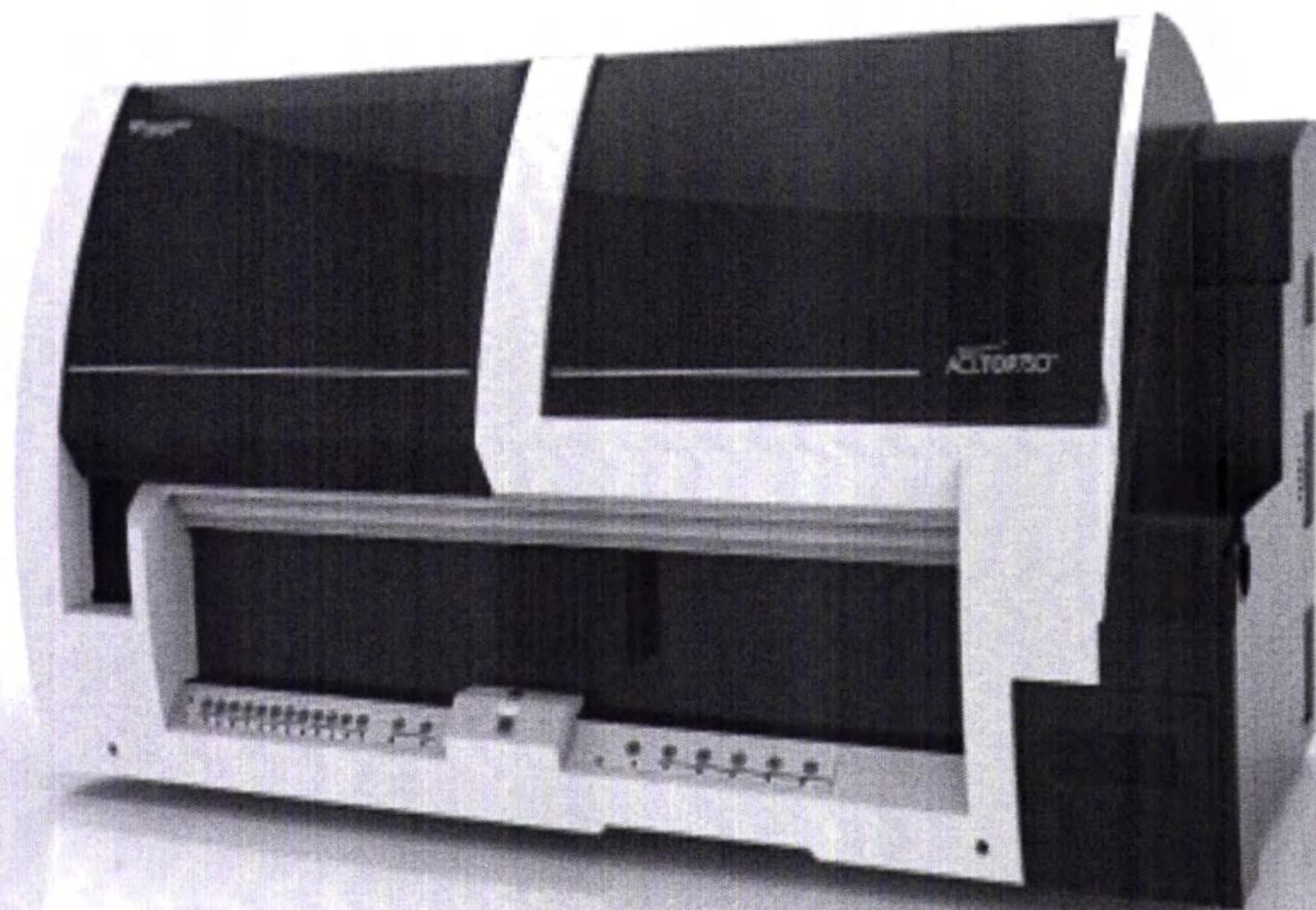




ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ МЕДИЦИНСКОГО ИЗДЕЛИЯ

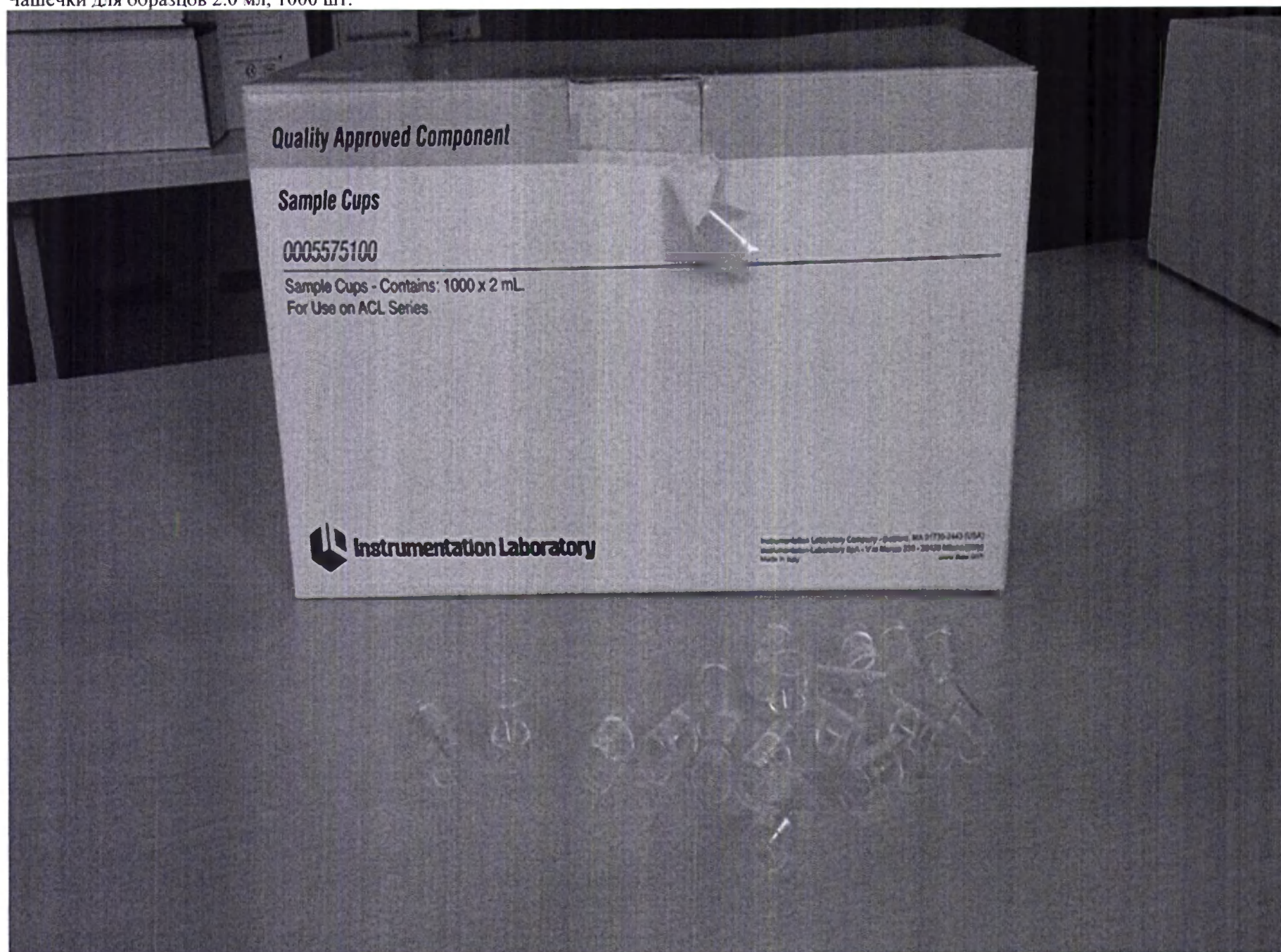
Анализатор автоматический коагулометрический для диагностики in vitro ACL TOP, вариант исполнения ACL TOP 750 CTS.

Анализатор





Чашечки для образцов 2.0 мл, 1000 шт.



Магнитные мешалки, 6 шт.

MAGNETIC STIR BARS, 6/PK

Q.ty : 1

Item N° : 0009746606

Instrumentation Laboratory Company - Bedford, MA 01730-2443 (USA)
Instrumentation Laboratory SpA - V.le Monza 338 - 20126 Milano (Italy)



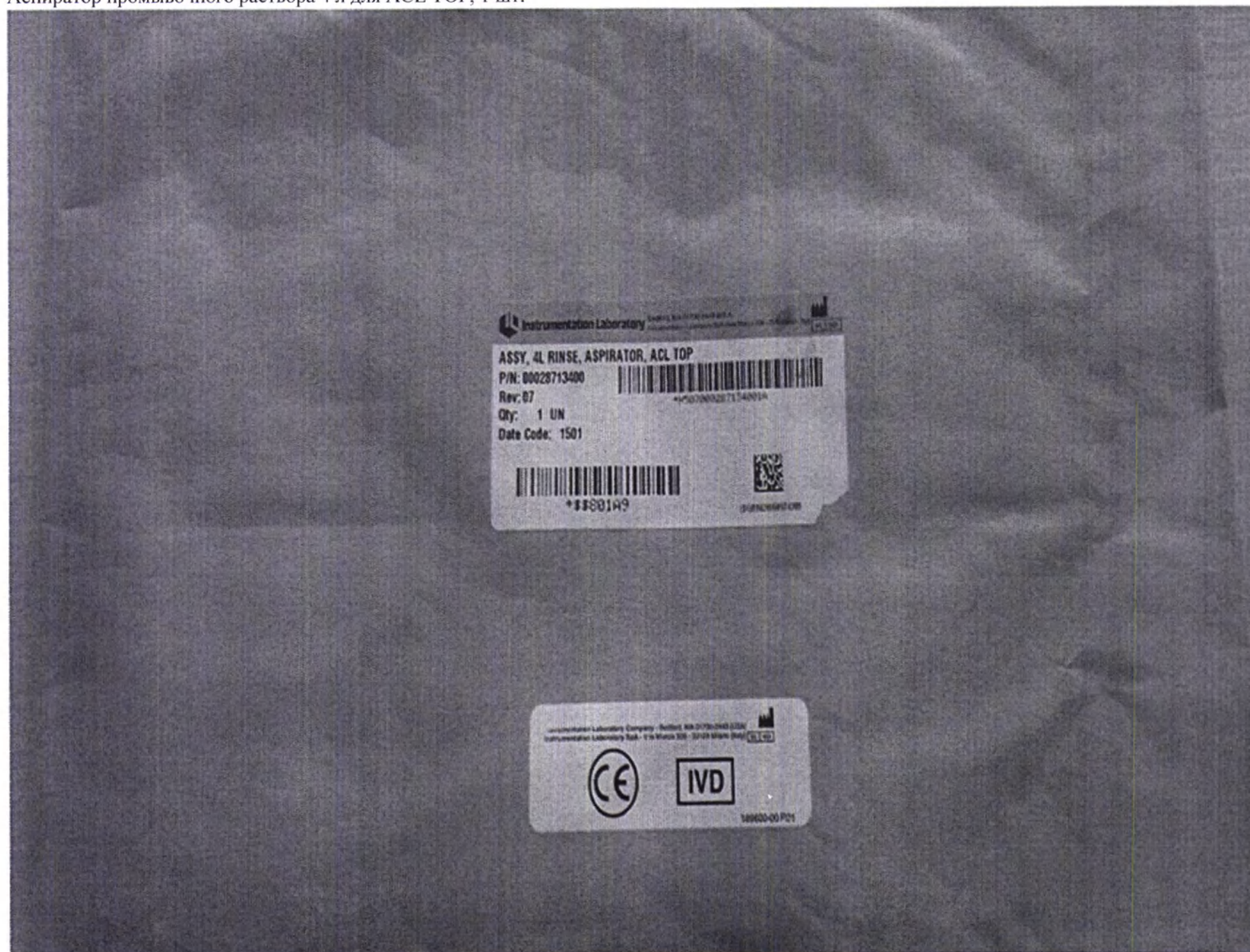
EC REP

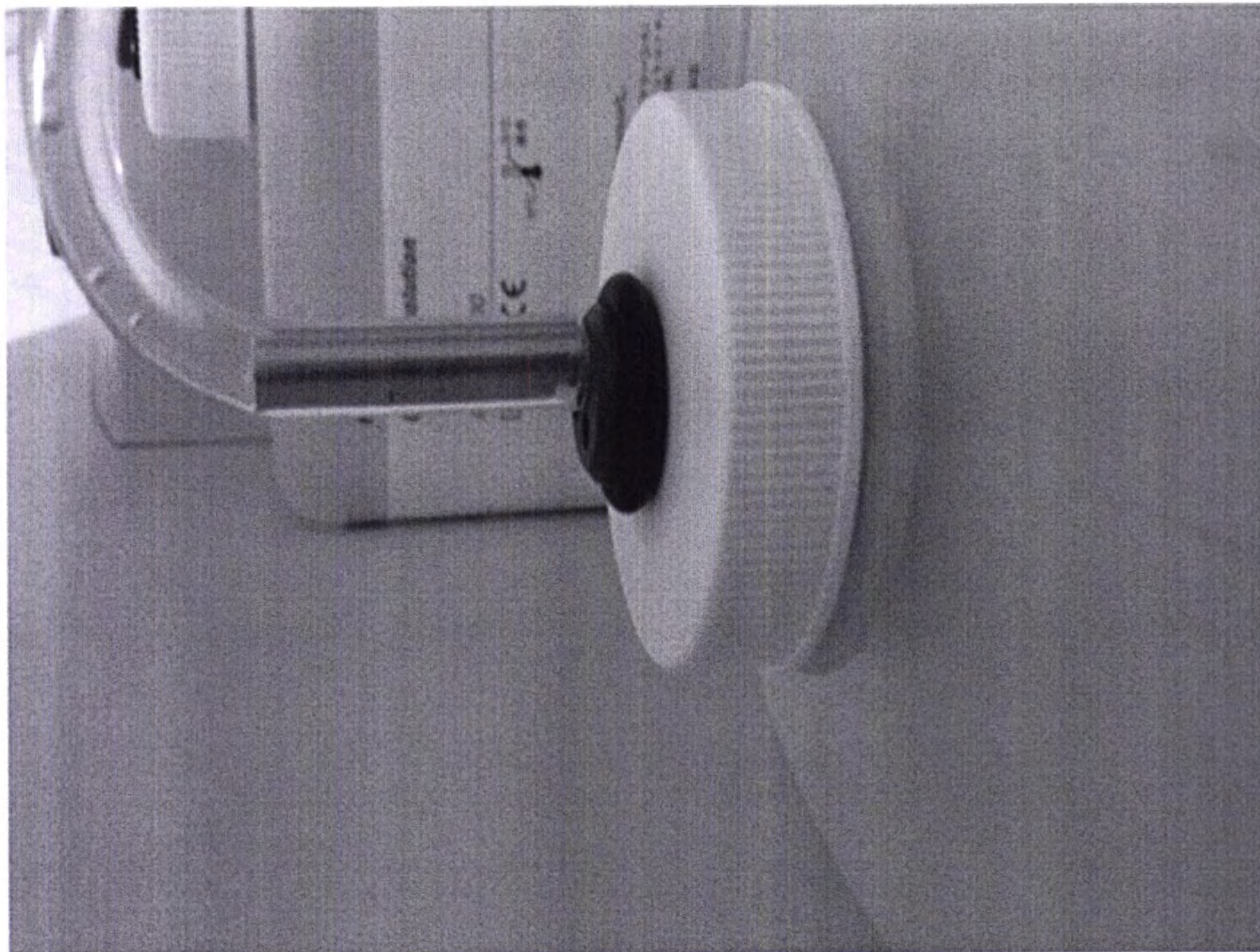
ily)



189600-00 R01

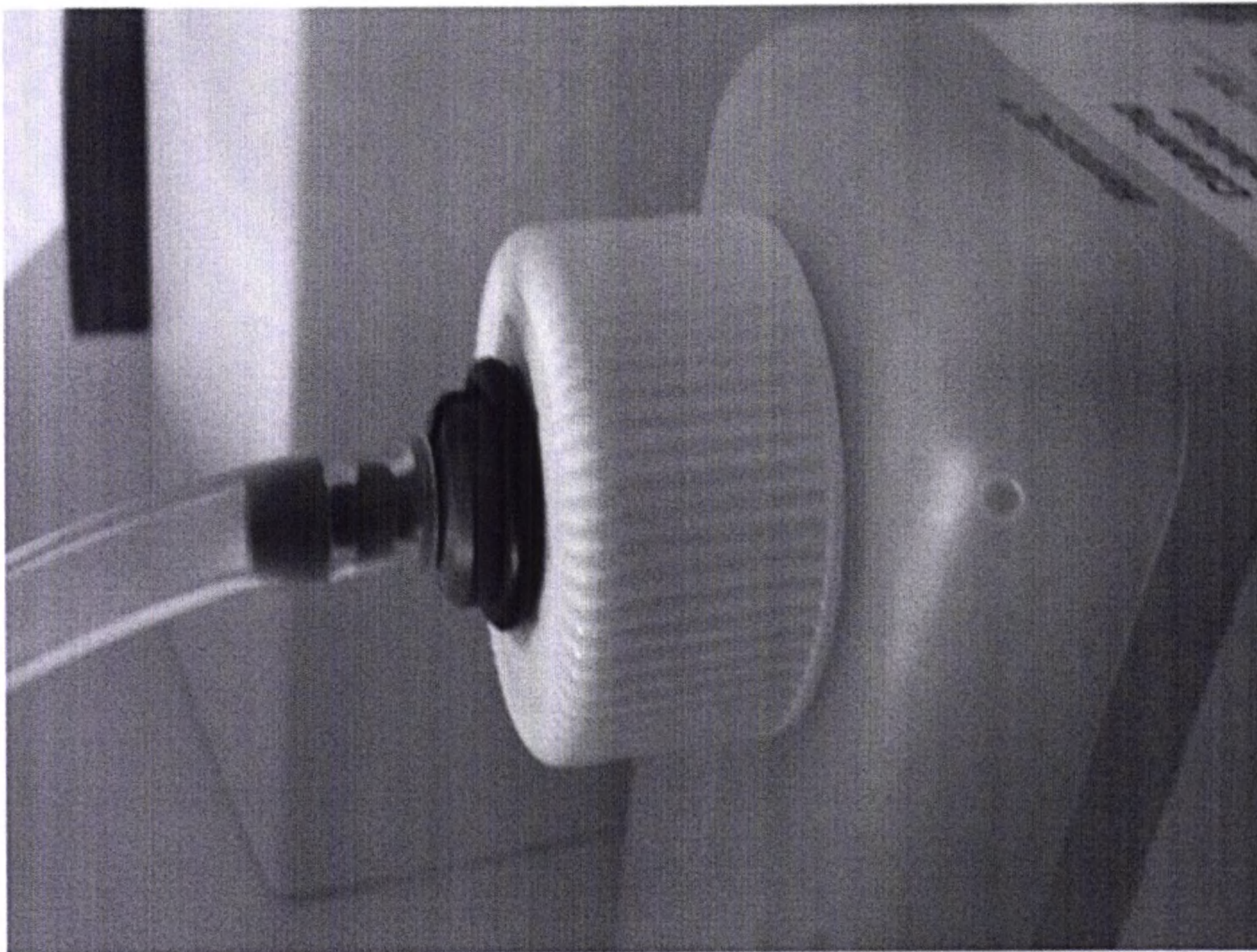
Аспиратор промывочного раствора 4 л для ACL TOP, 1 шт.



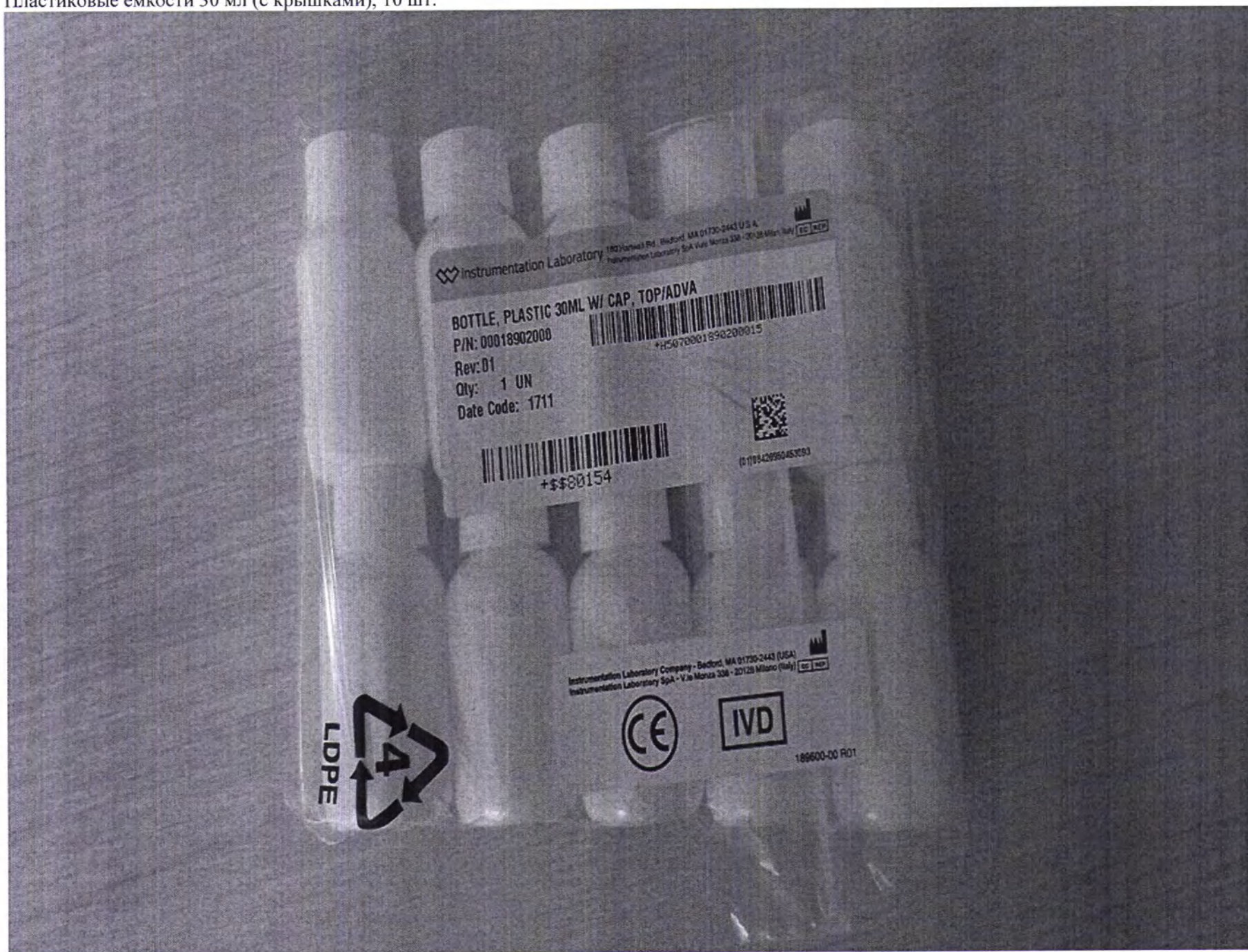


Аспиратор моющего раствора для ACL TOP, 1 шт.

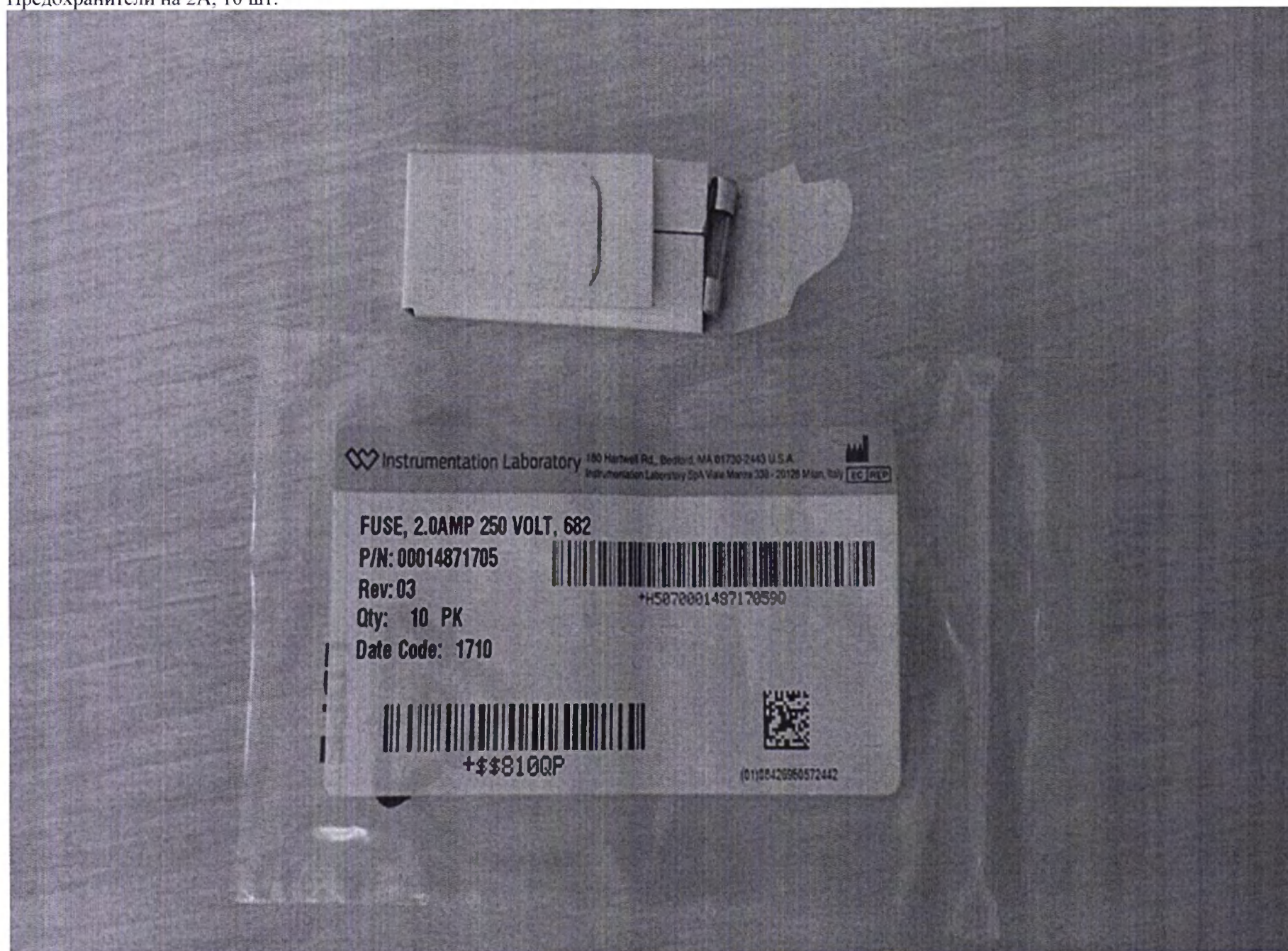




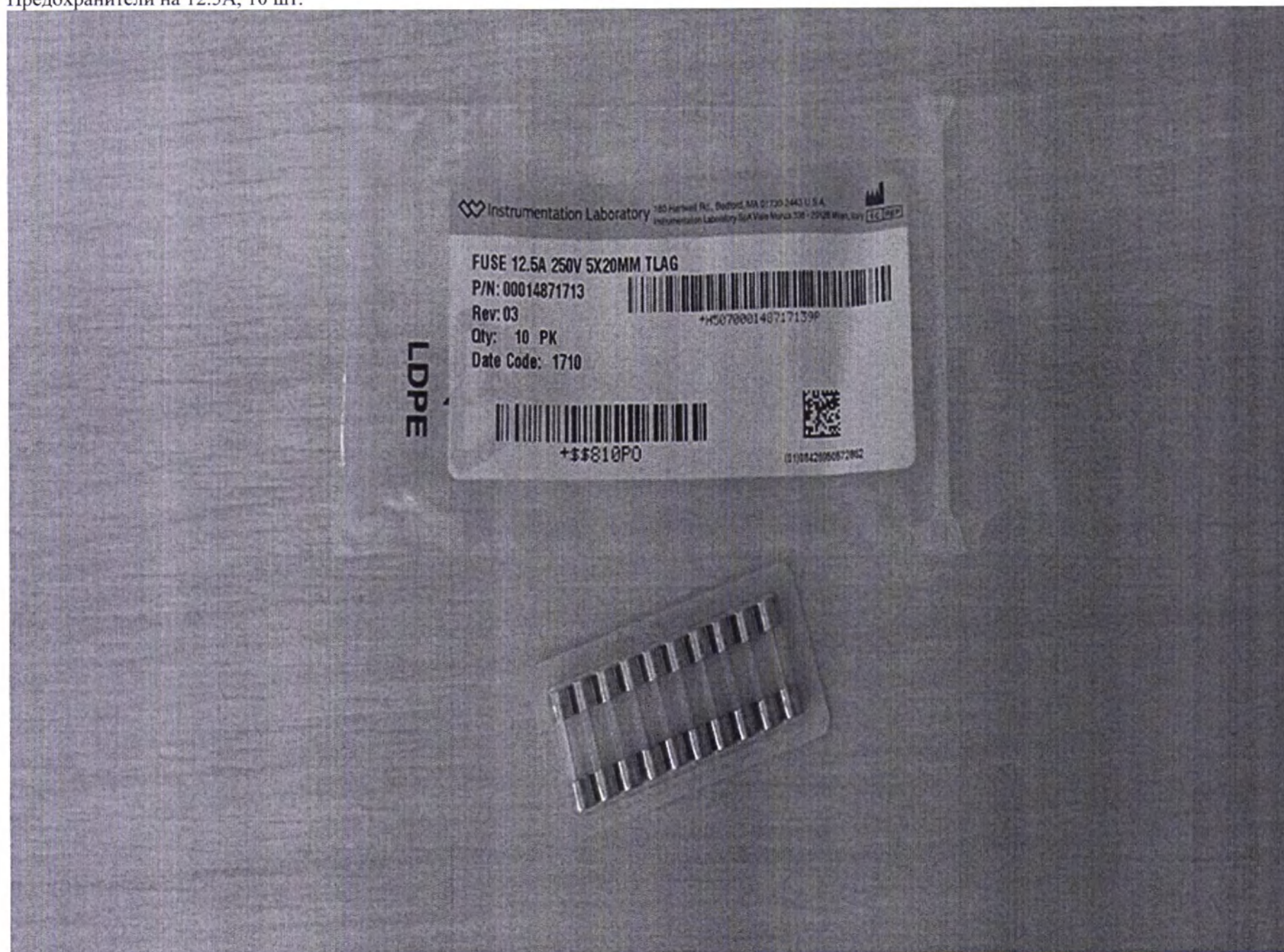
Пластиковые емкости 30 мл (с крышками), 10 шт.



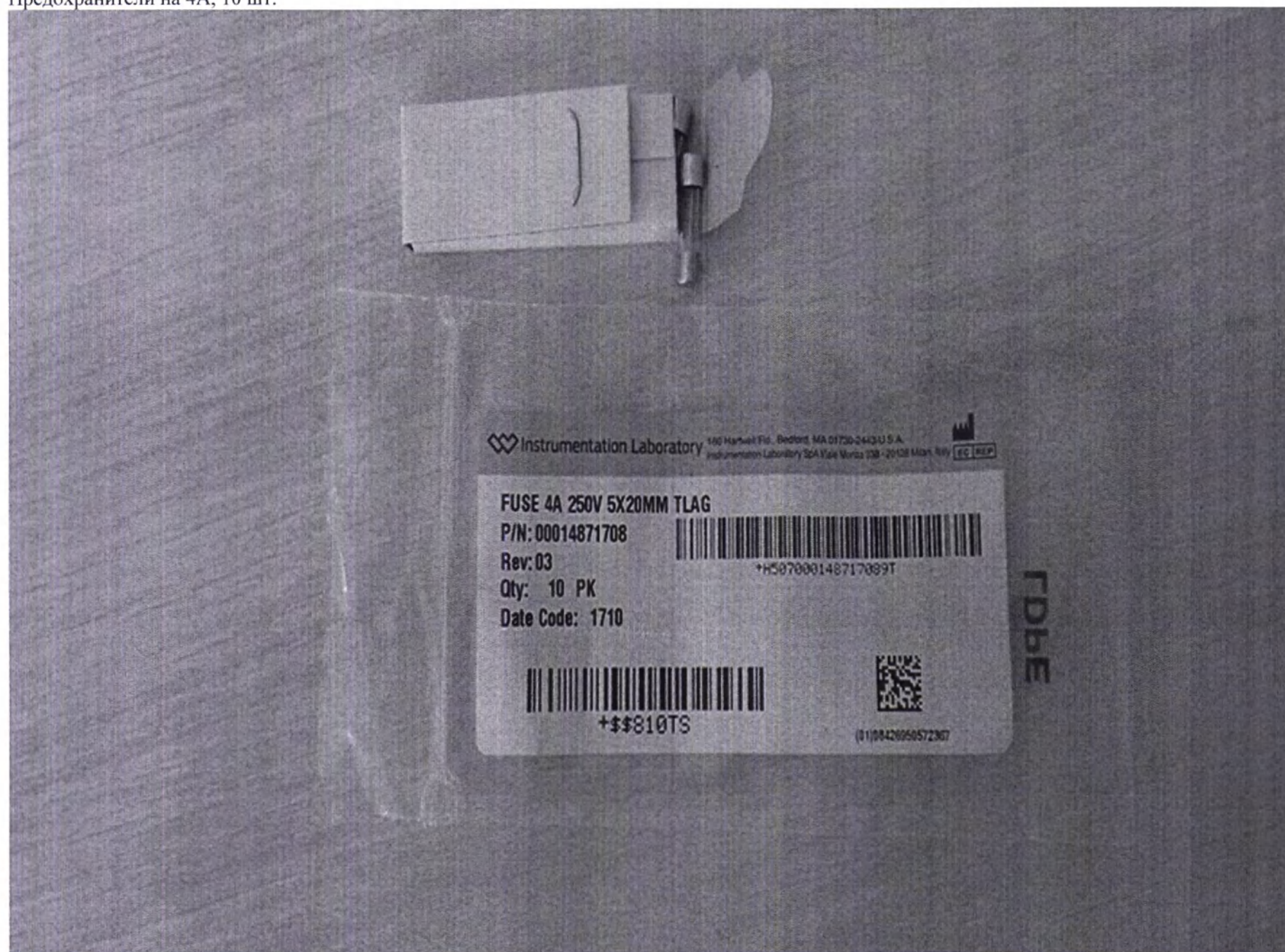
Предохранители на 2А, 10 шт.



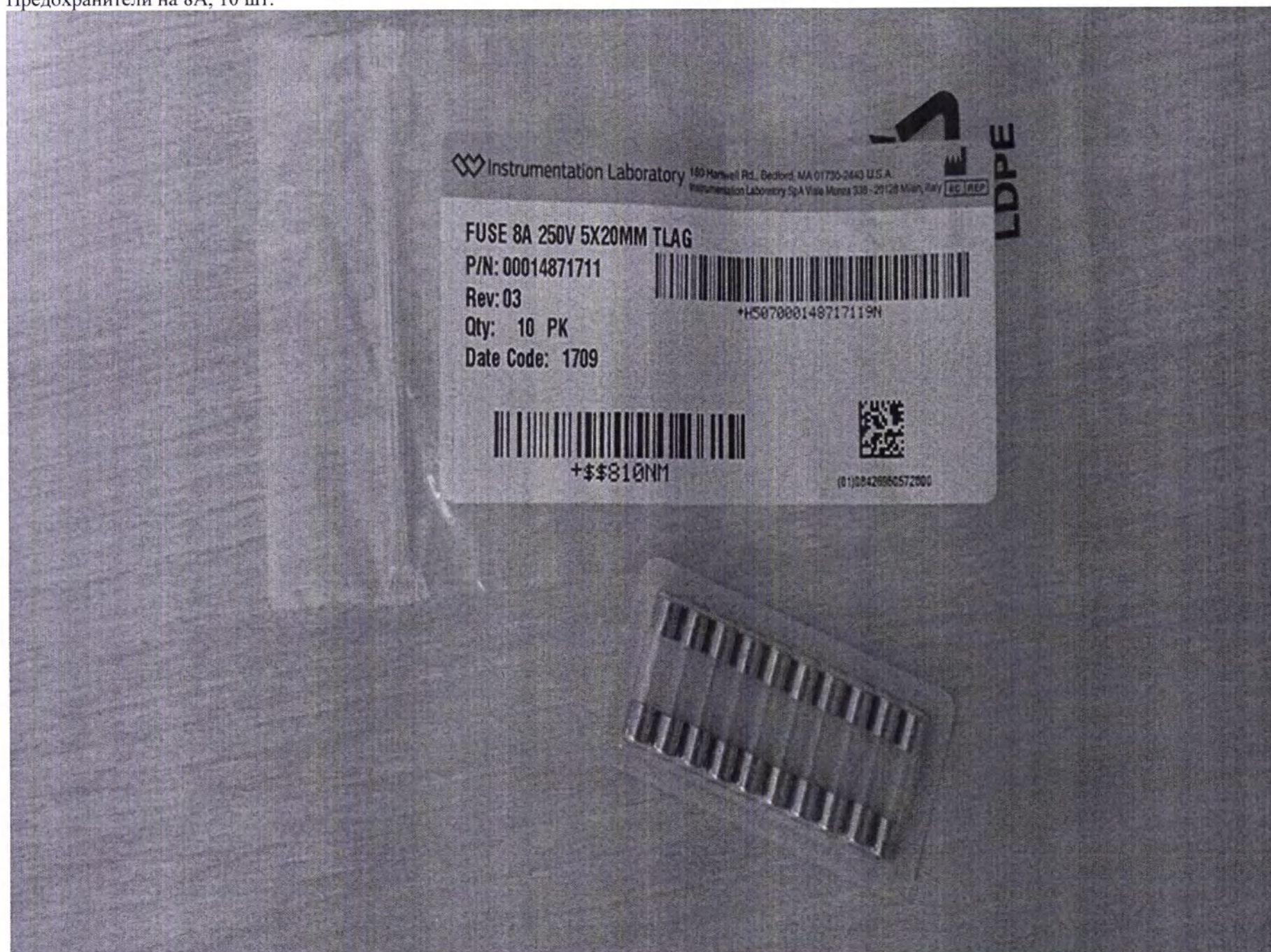
Предохранители на 12.5А, 10 шт.



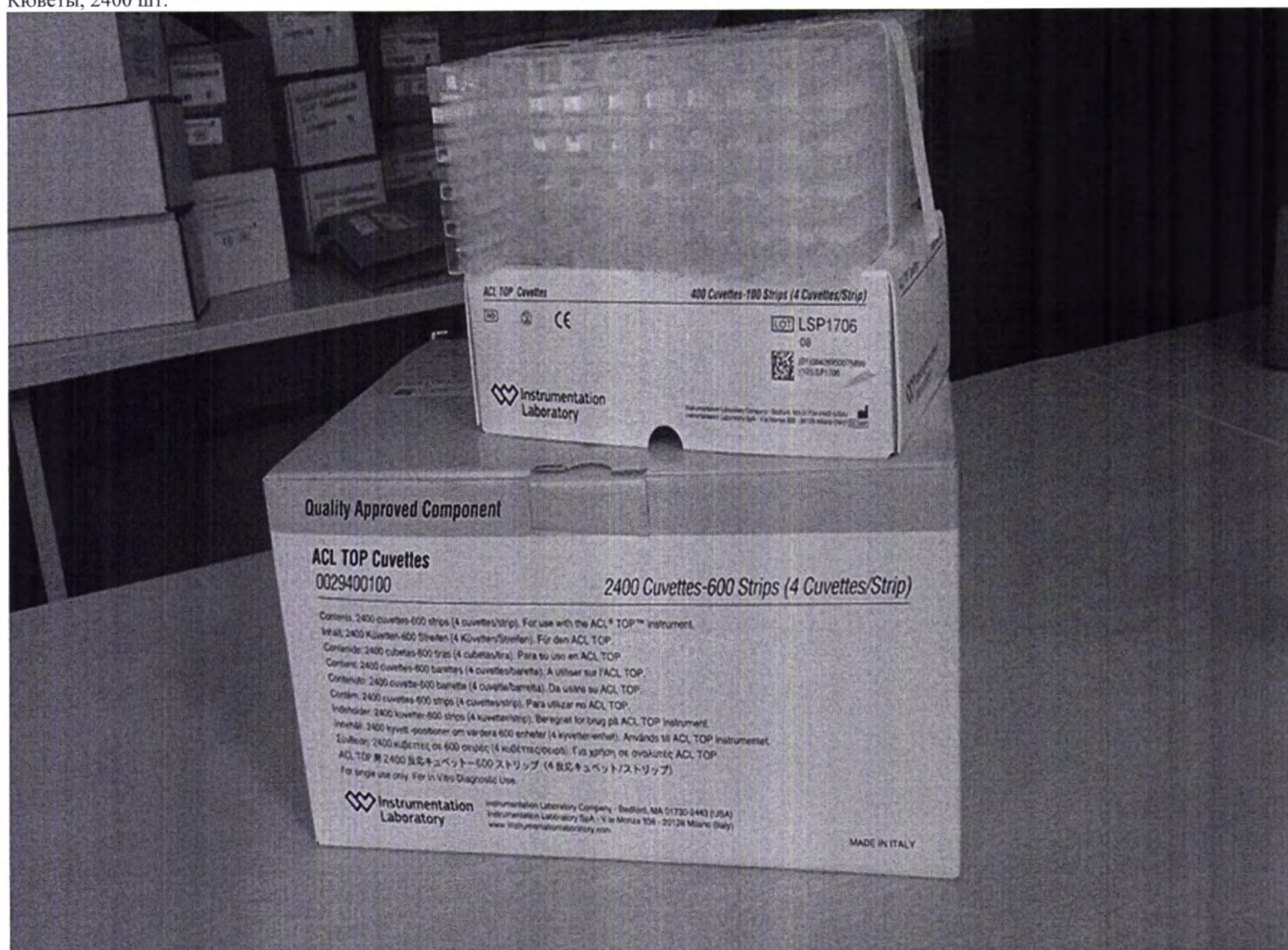
Предохранители на 4А, 10 шт.



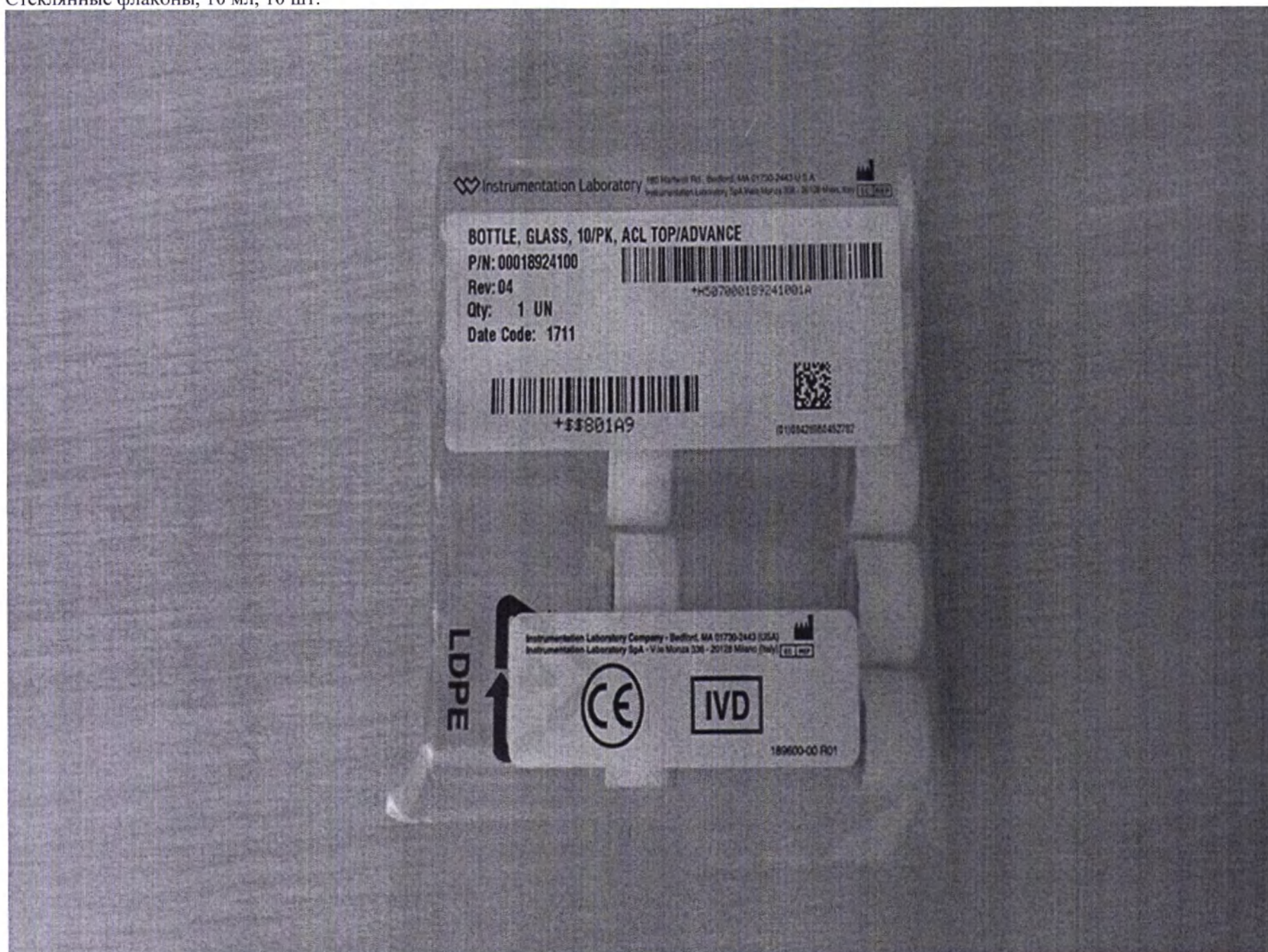
Предохранители на 8А, 10 шт.



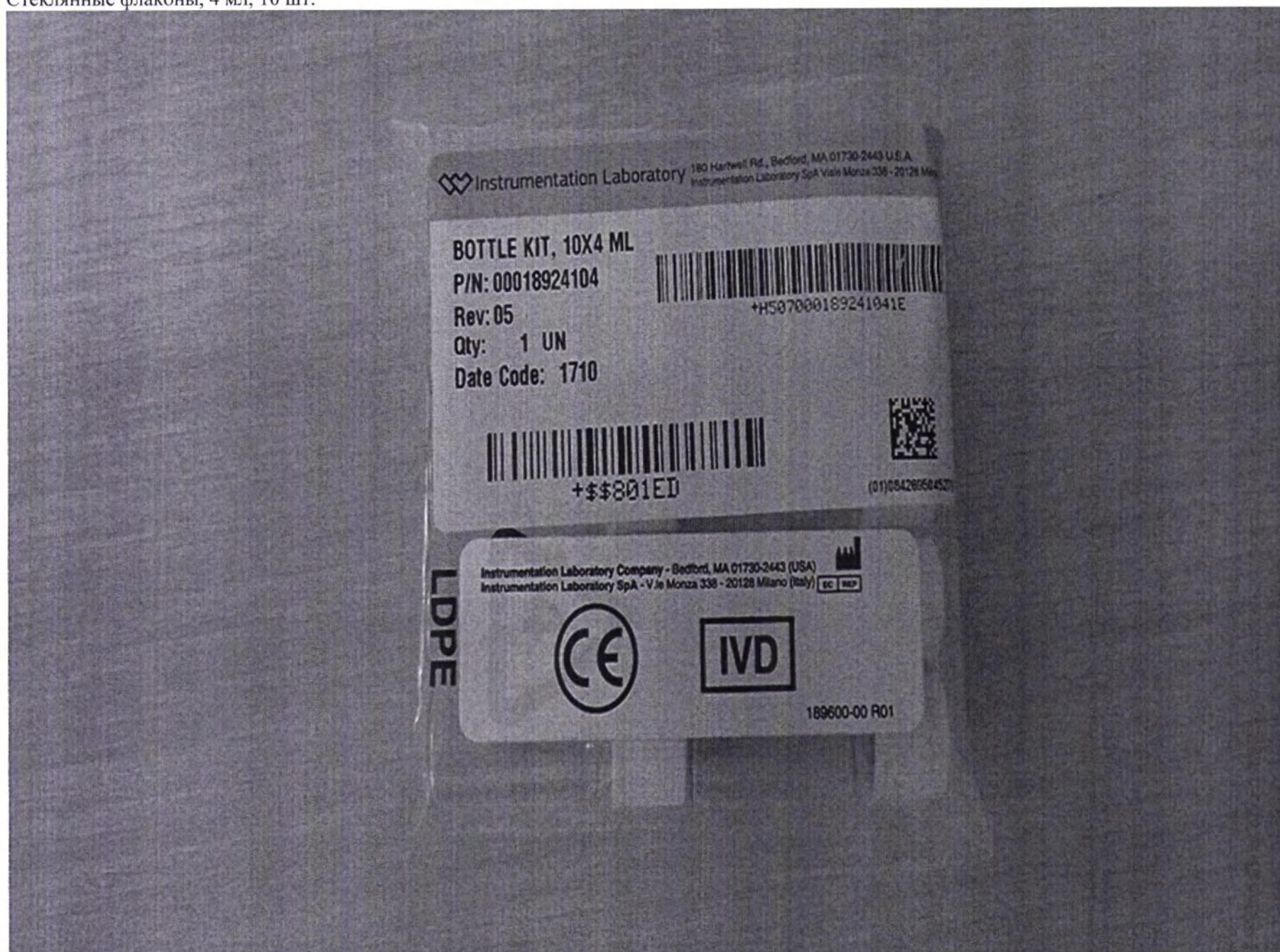
Кюветы, 2400 шт.



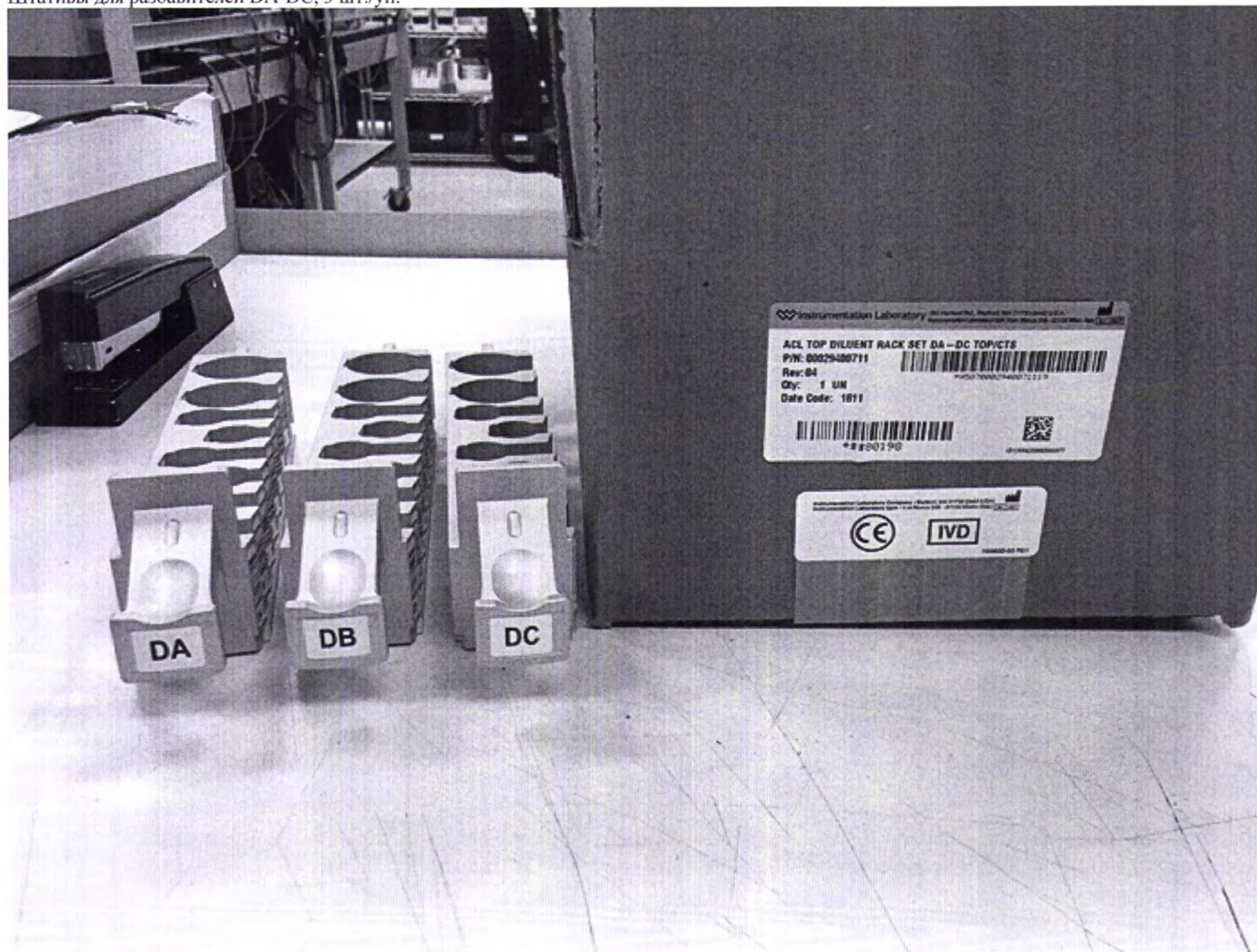
Стеклянные флаконы, 10 мл, 10 шт.



Стеклянные флаконы, 4 мл, 10 шт.



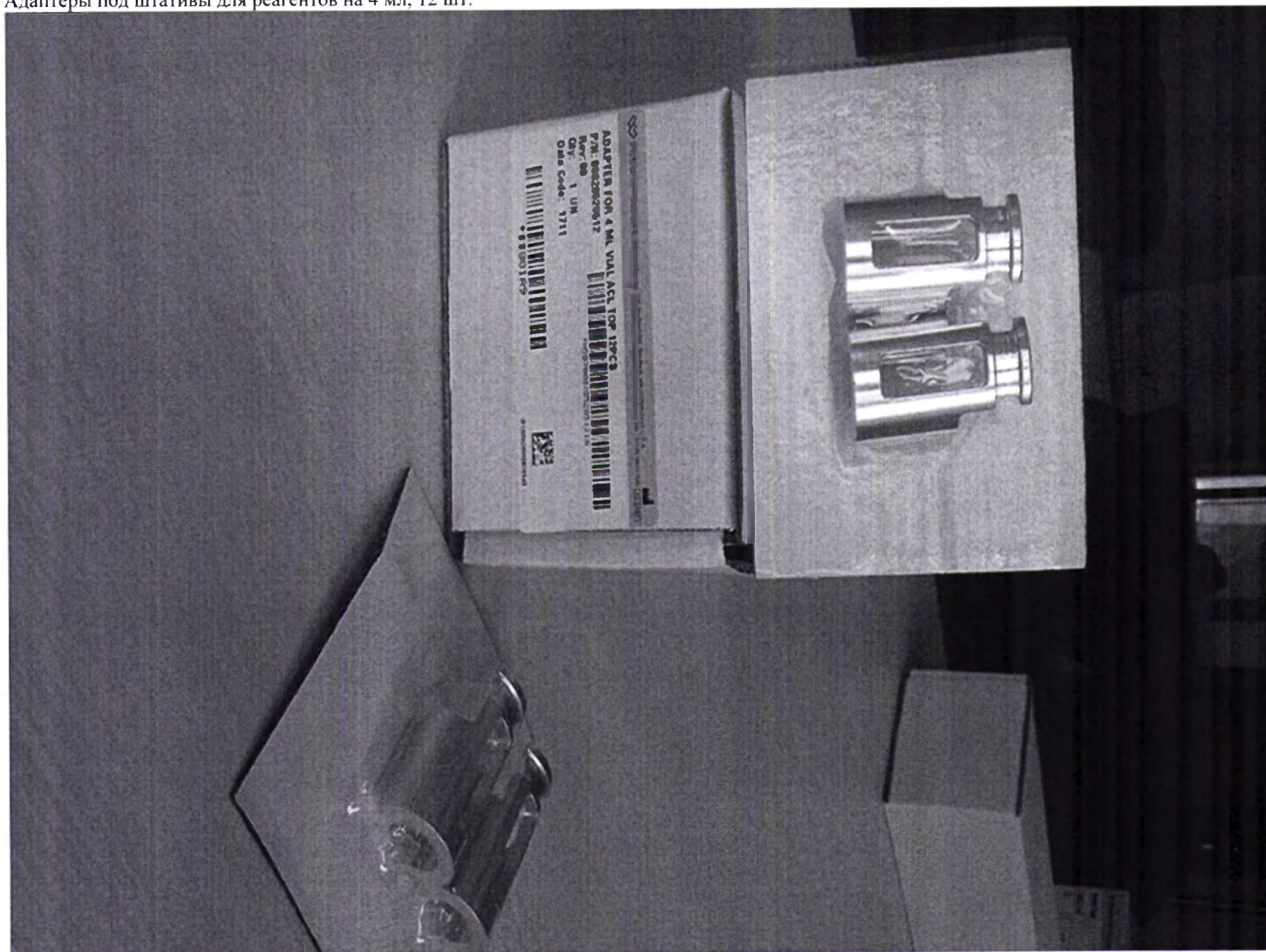
Штативы для разбавителей DA-DC, 3 шт./уп.



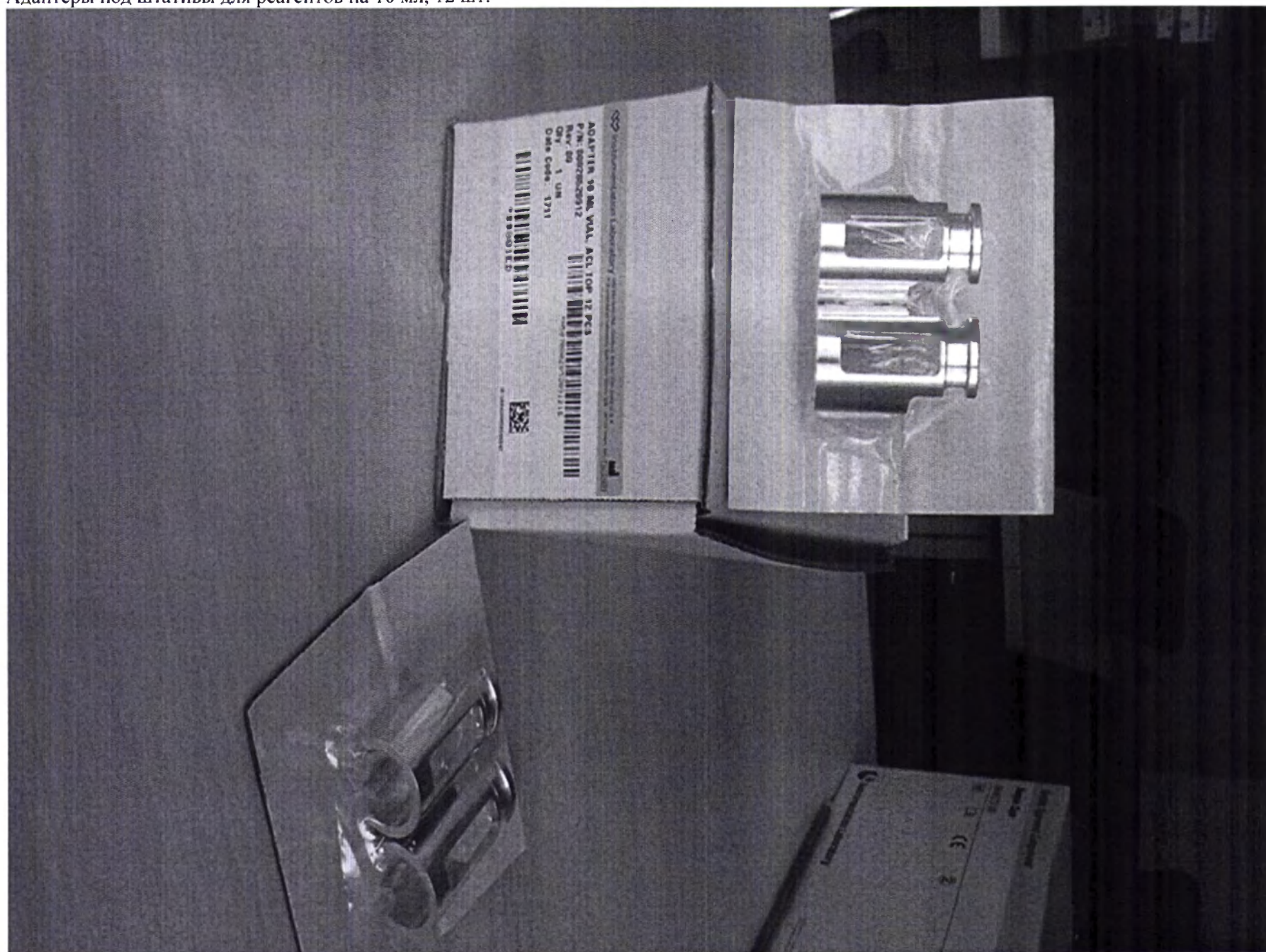
Штативы для реагентов RA-RF, 6 шт./уп.



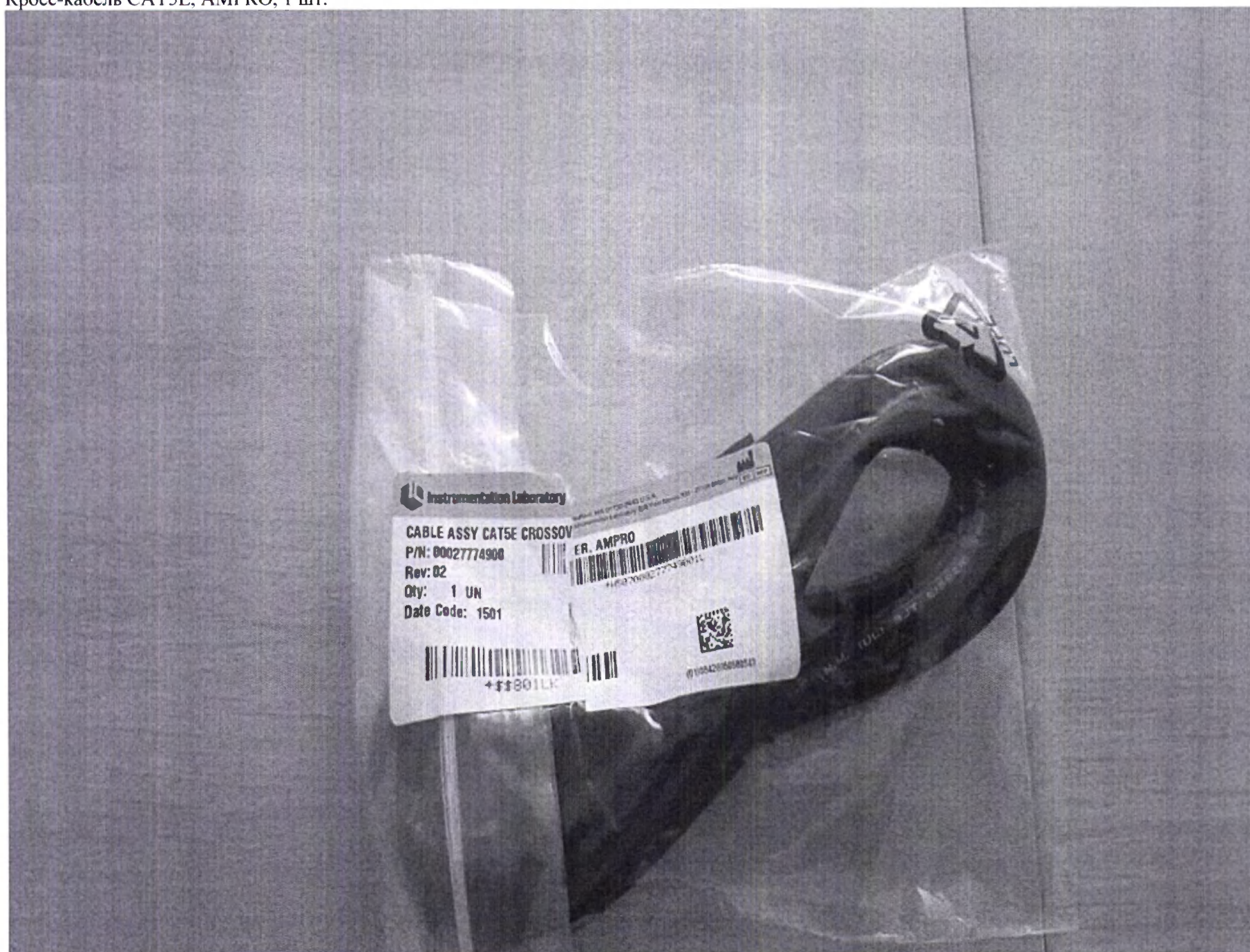
Адаптеры под штативы для реагентов на 4 мл, 12 шт.



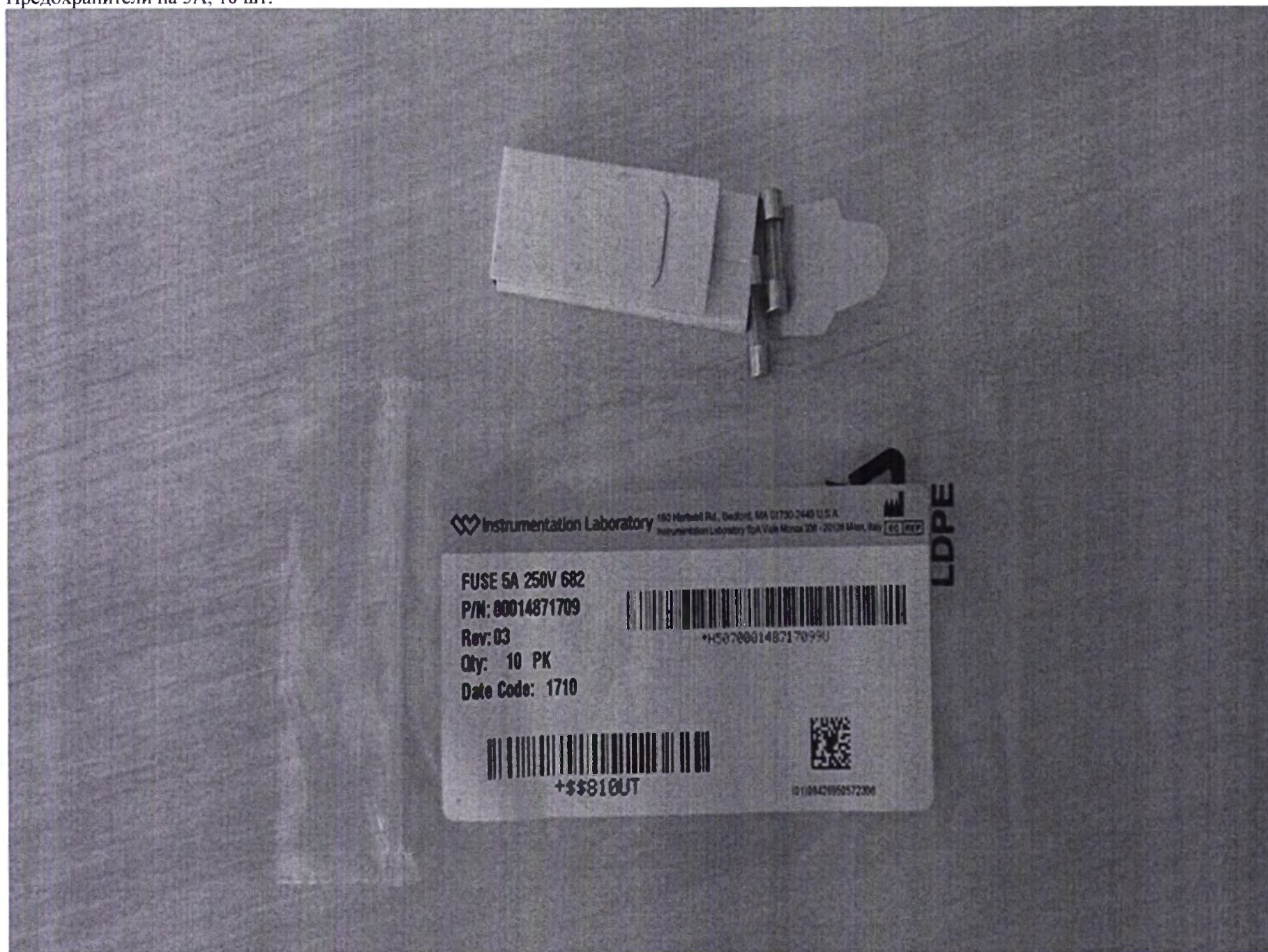
Адаптеры под штативы для реагентов на 10 мл, 12 шт.



Кросс-кабель CAT5E, AMPRO, 1 шт.



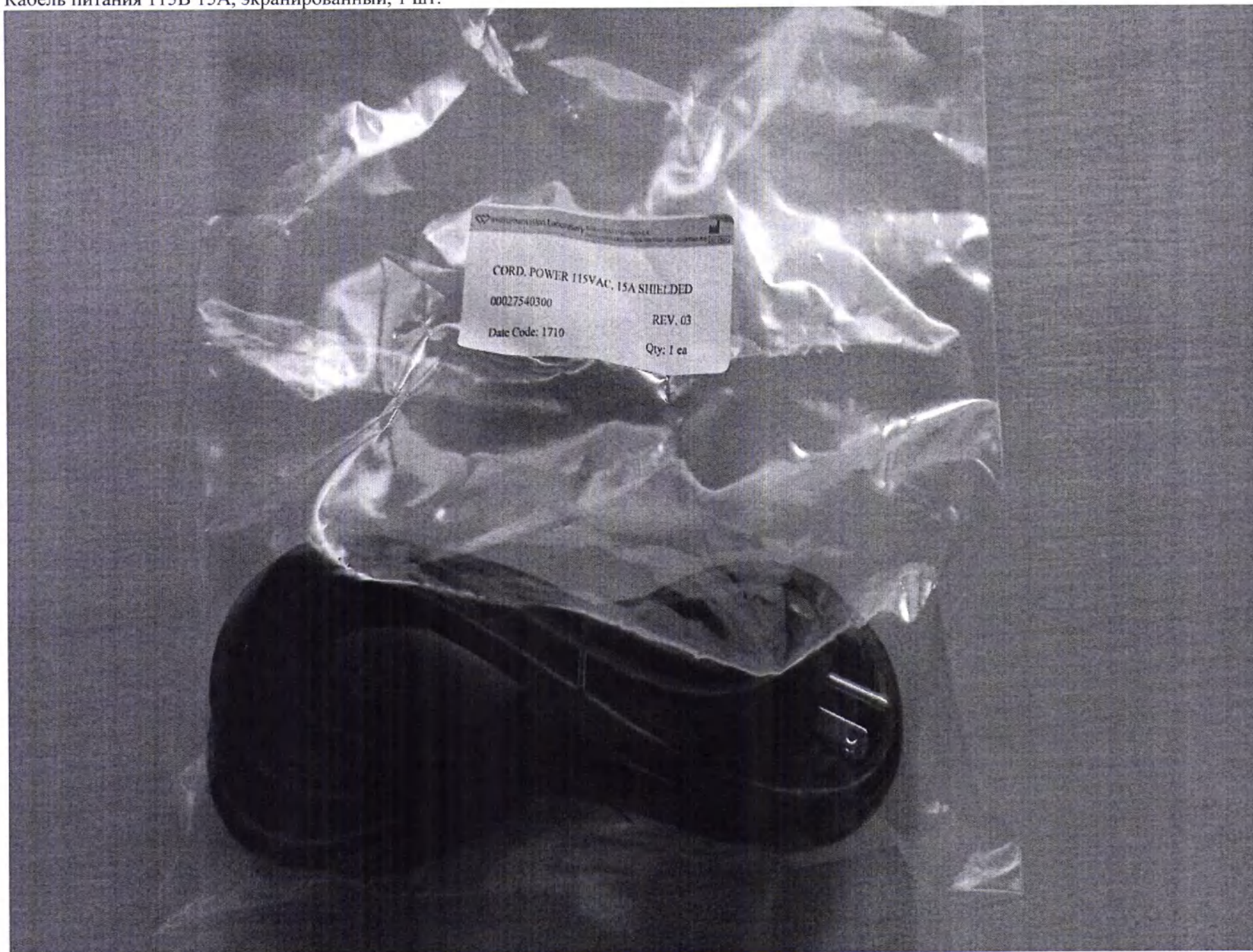
Предохранители на 5А, 10 шт.



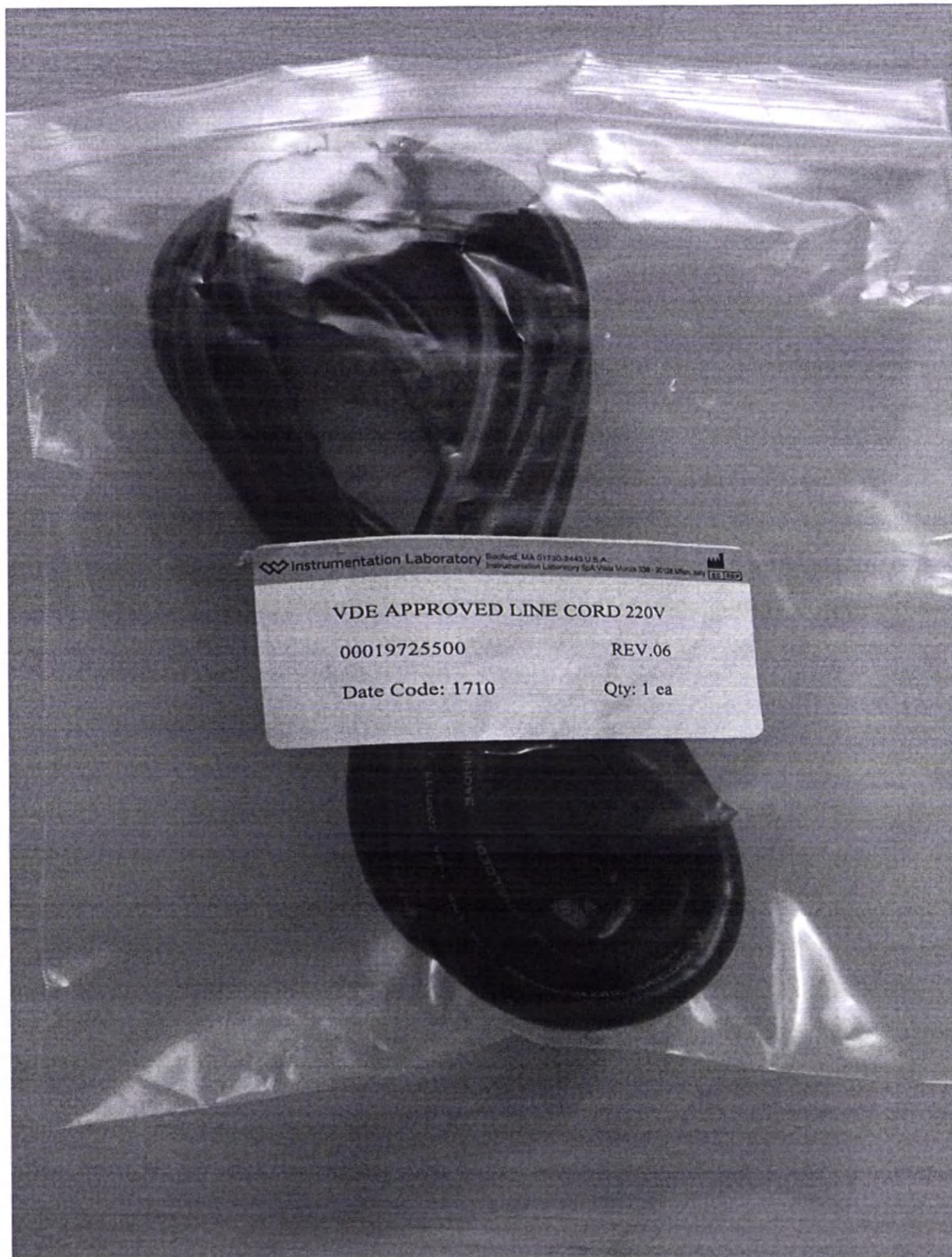
Предохранители на 1.25A, 10 шт.



Кабель питания 115В 15А, экранированный, 1 шт.



Кабель питания 220 В, 1 шт.



Instrumentation Laboratory Bedford, MA 01730-3443 U.S.A.
Instrumentation Laboratory SpA Viale Monza 338 - 20128 Milan, Italy

VDE APPROVED LINE CORD 220V

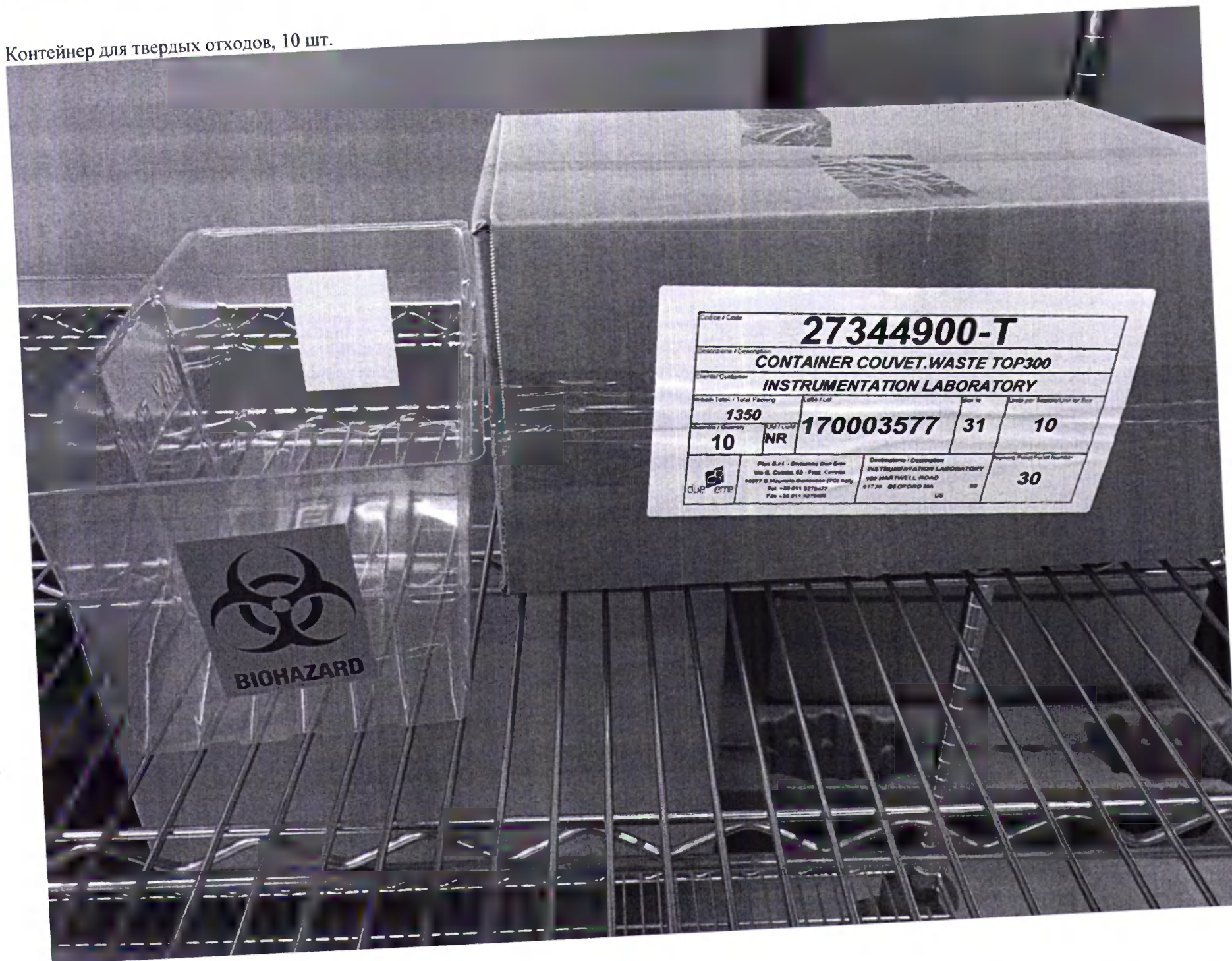
00019725500

REV.06

Date Code: 1710

Qty: 1 ea

Контейнер для твердых отходов, 10 шт.

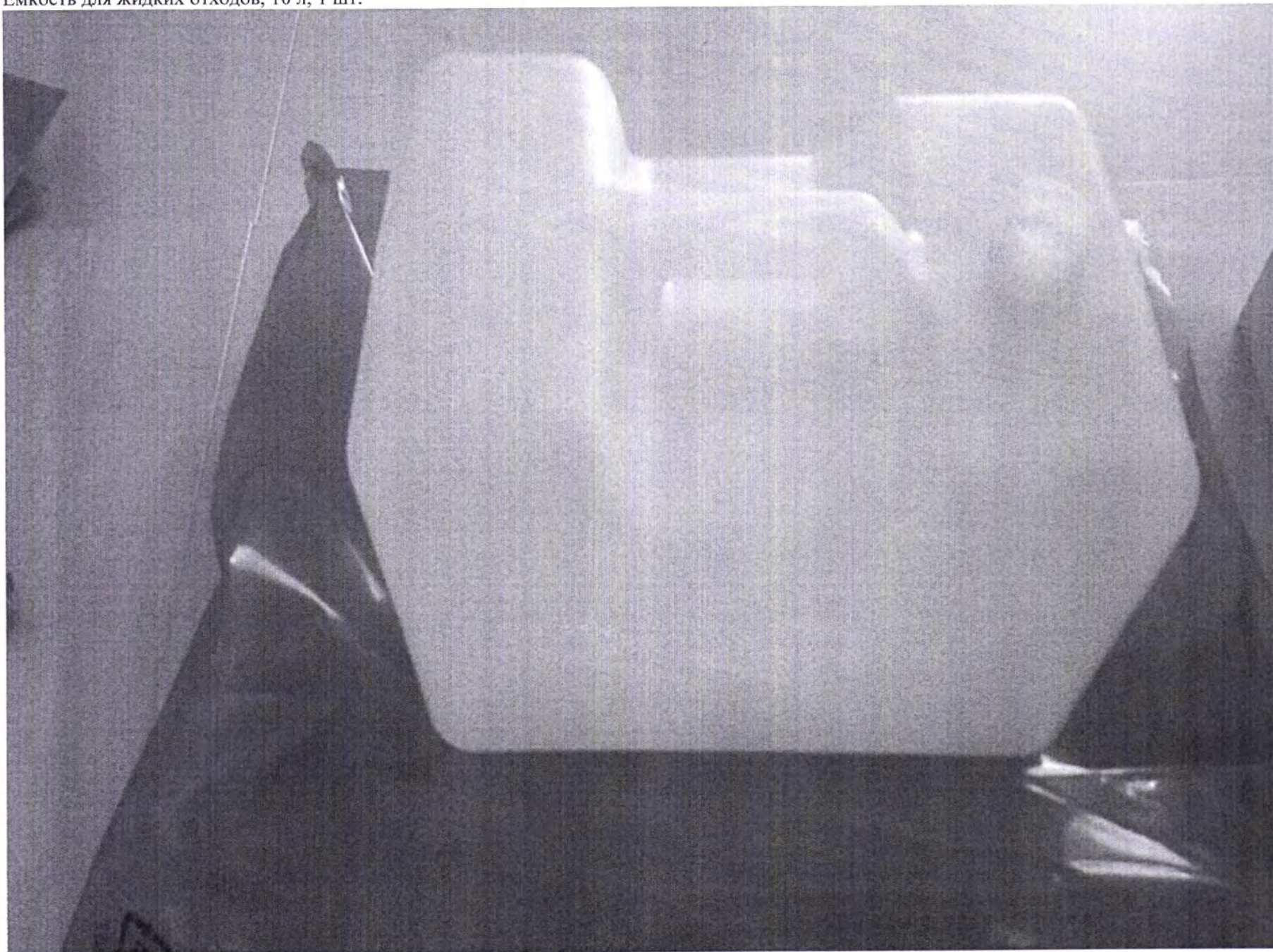


Датчик контейнера для жидких отходов, 1 шт.



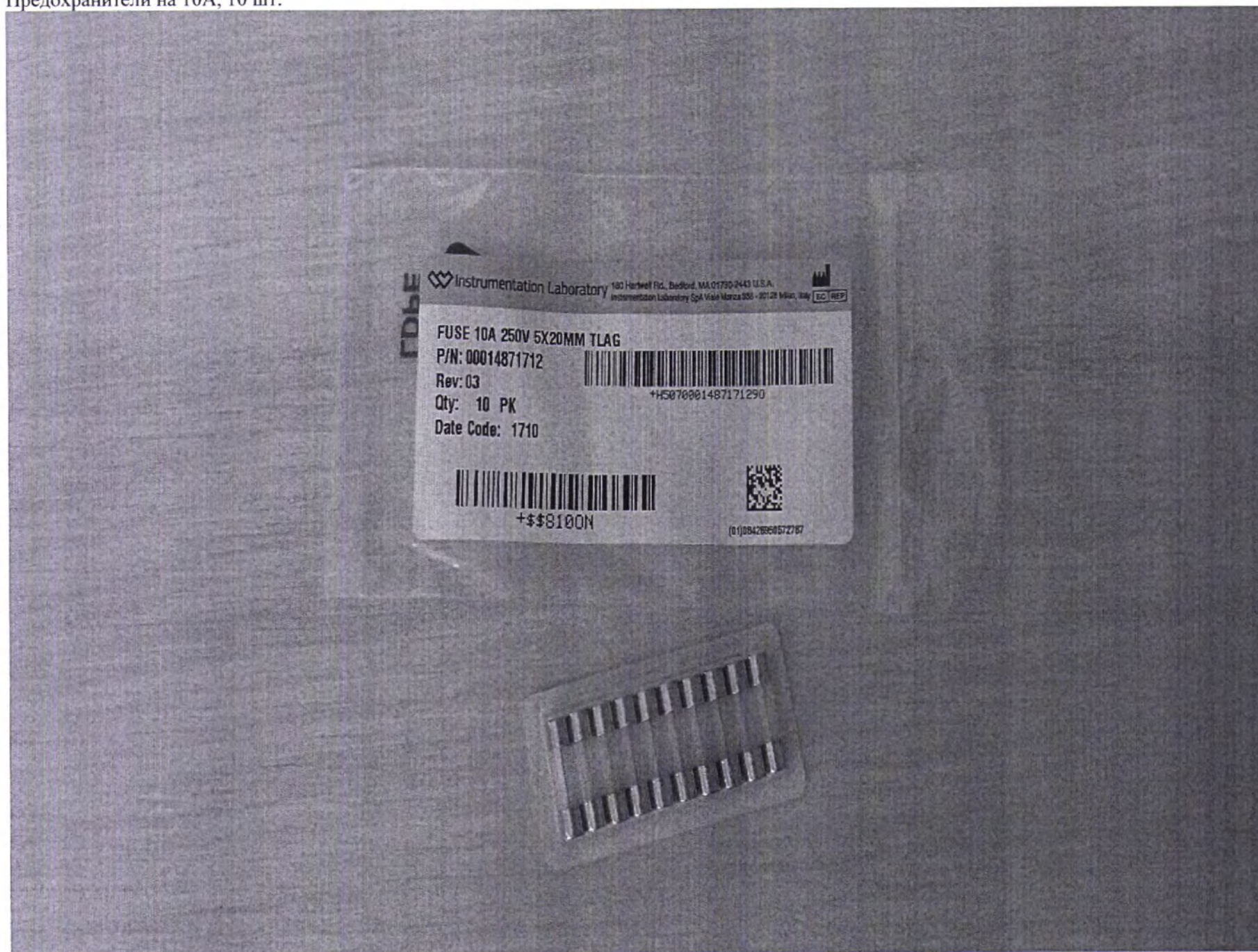


Емкость для жидких отходов, 10 л, 1 шт.

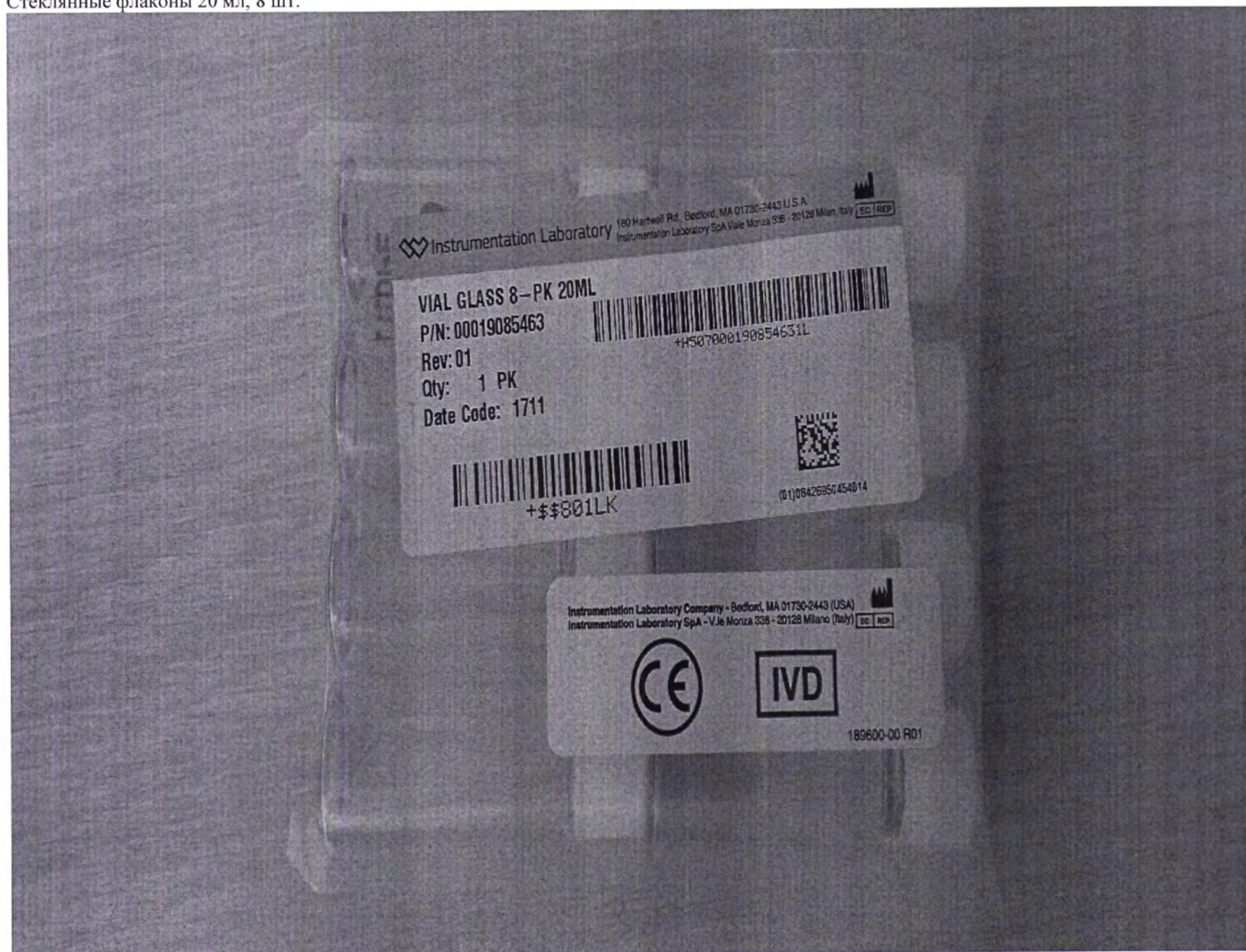




Предохранители на 10А, 10 шт.



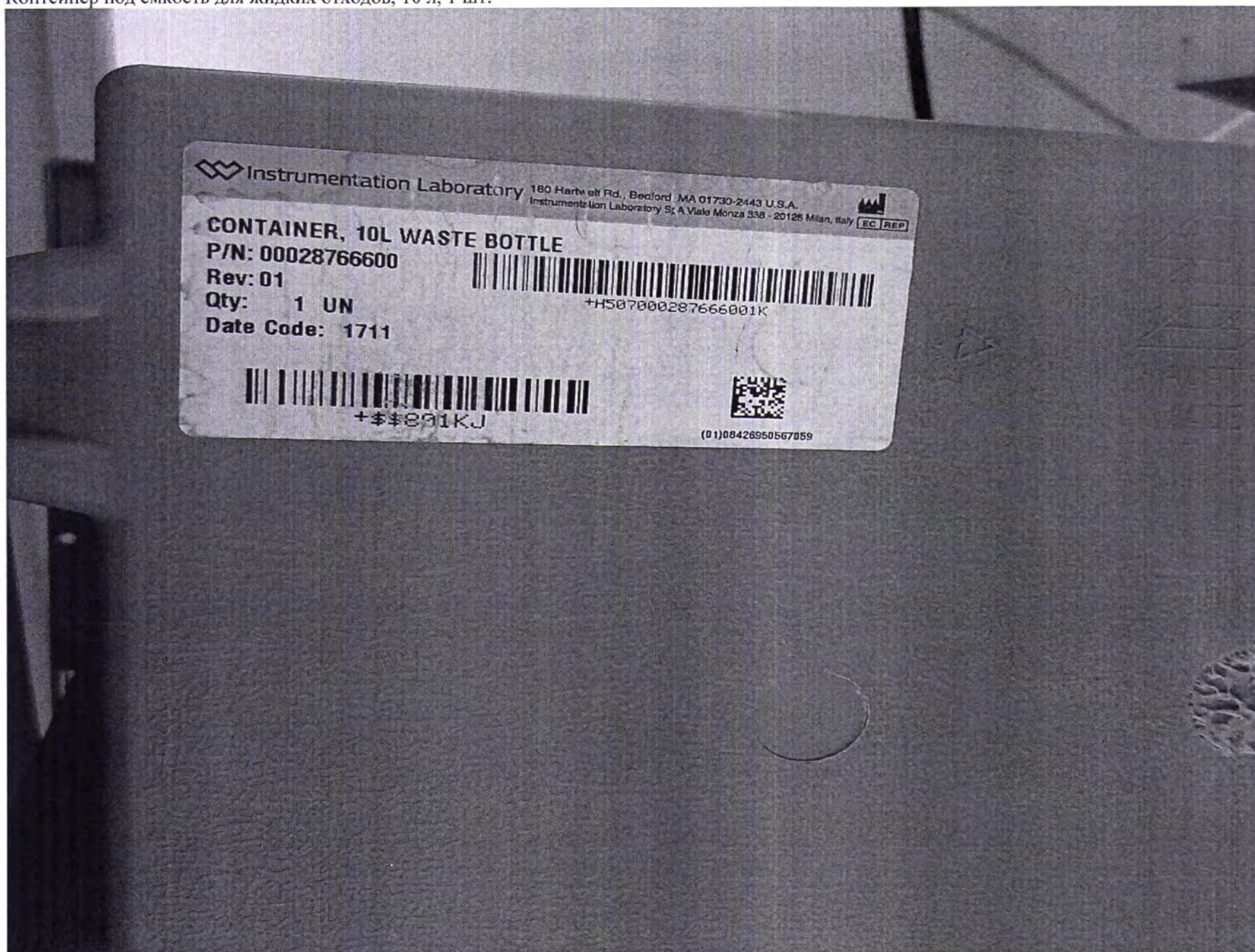
Стеклянные флаконы 20 мл, 8 шт.



Адаптеры под штативы для образцов: адаптеры для аликвотных пробирок, 5 шт.; адаптеры для педиатрических пробирок, 5шт.



Контейнер под емкость для жидких отходов, 10 л, 1 шт.

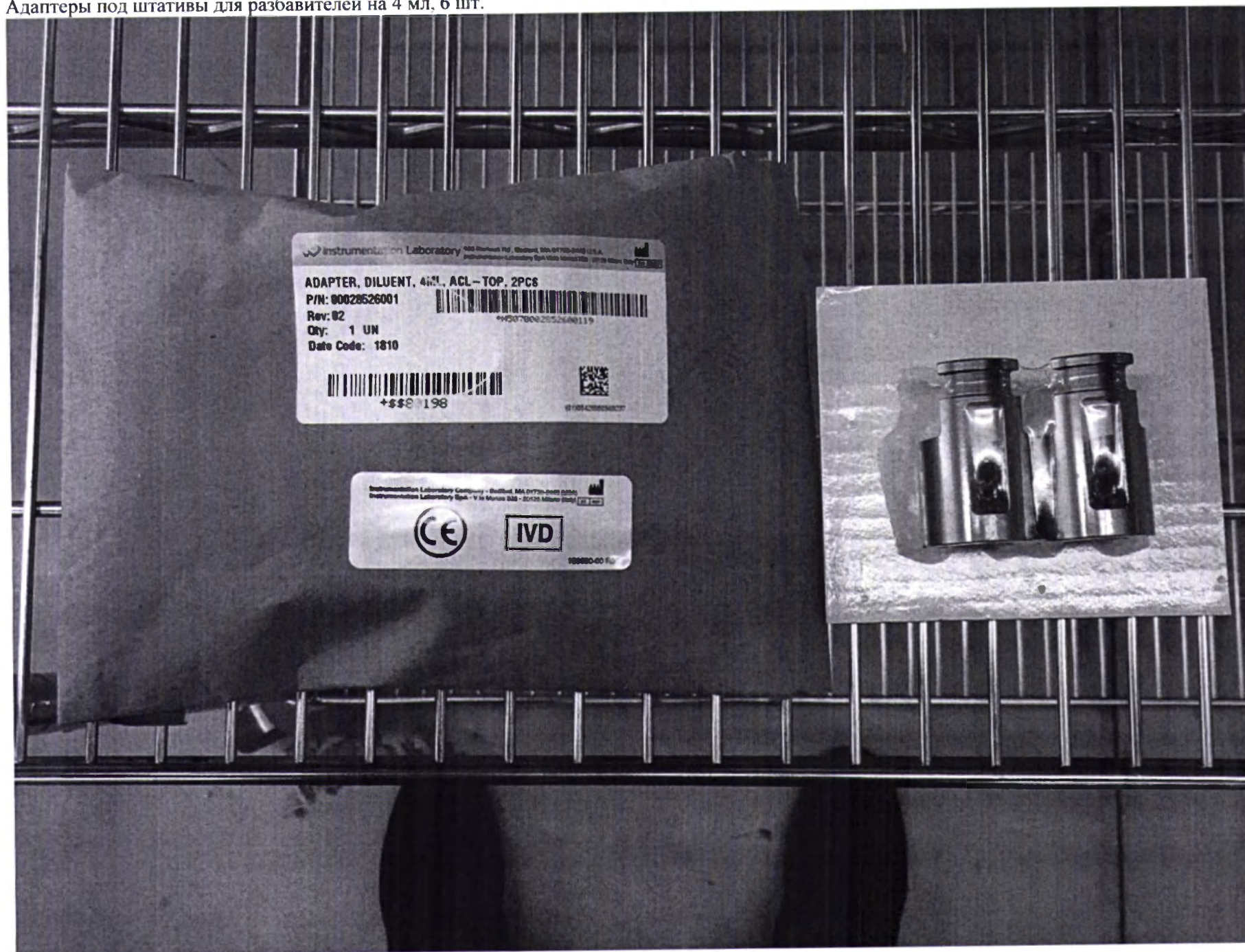




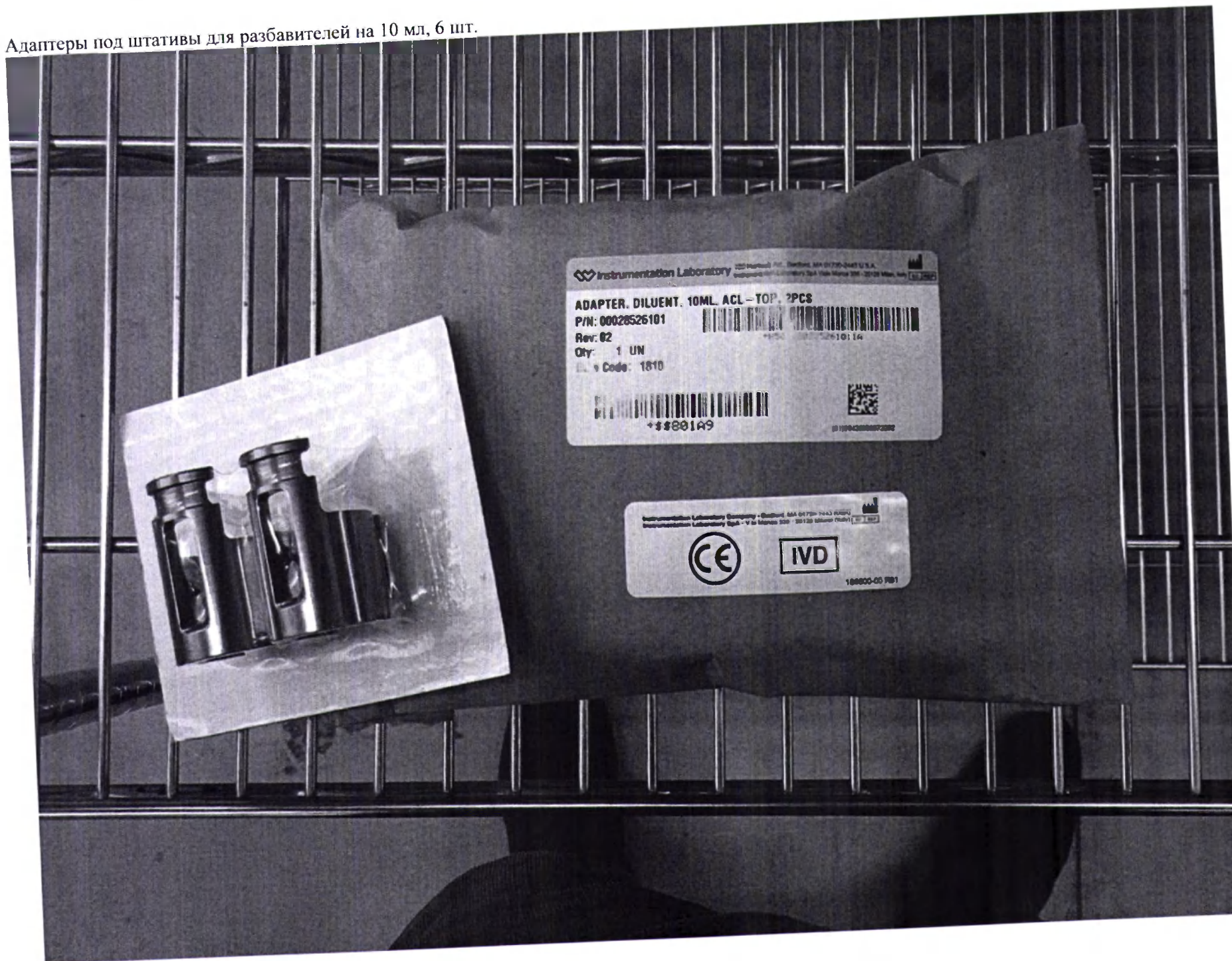
Подставка под 6 штативов для образцов, 1 шт.



Адаптеры под штативы для разбавителей на 4 мл, 6 шт.



Адаптеры под штативы для разбавителей на 10 мл, 6 шт.



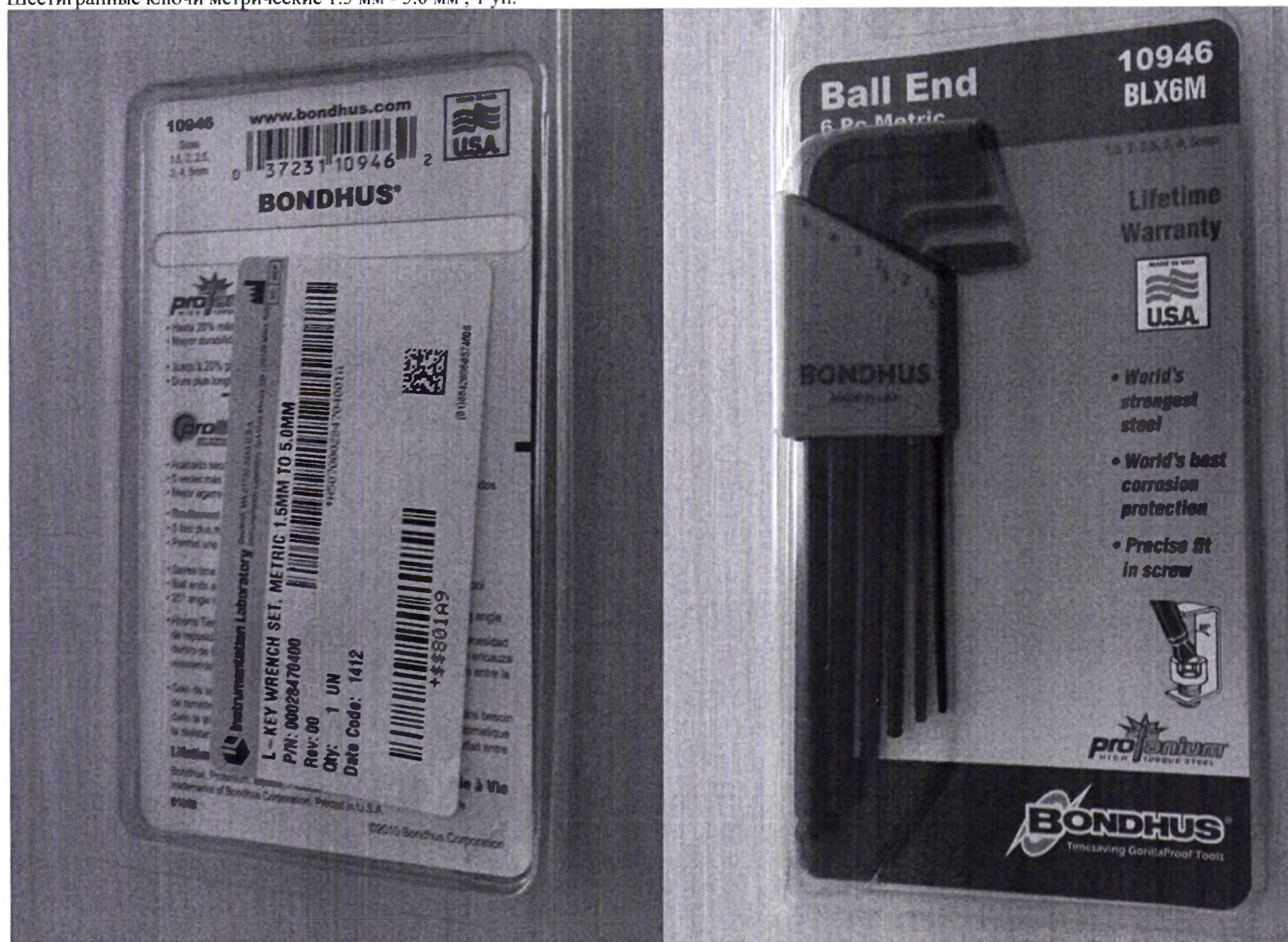
Адаптеры под штативы для разбавителей на 20 мл, 6 шт.

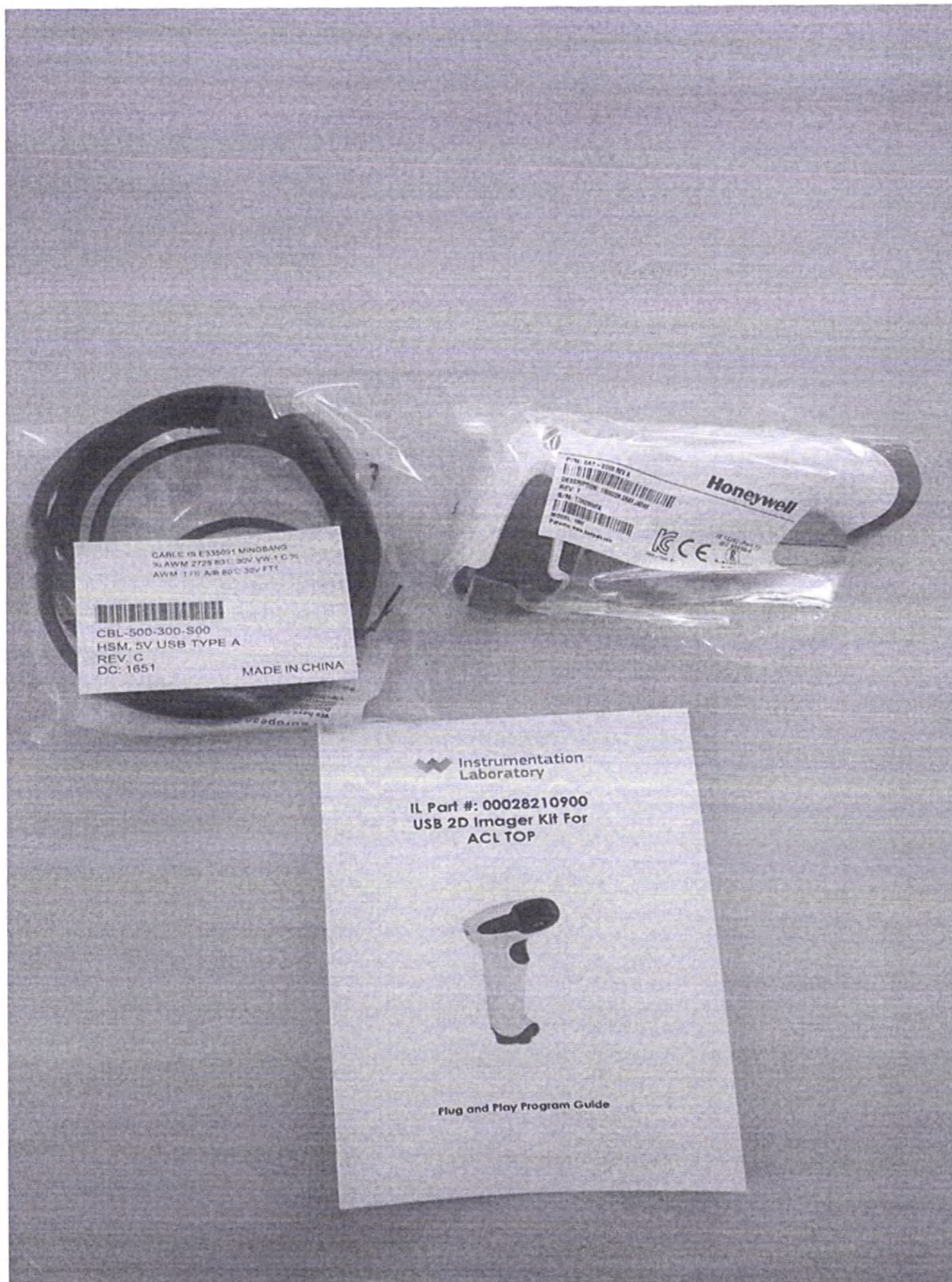


Трубки для помпы жидких отходов, 3 шт.



Шестигранные ключи метрические 1.5 мм - 5.0 мм , 1 уп.





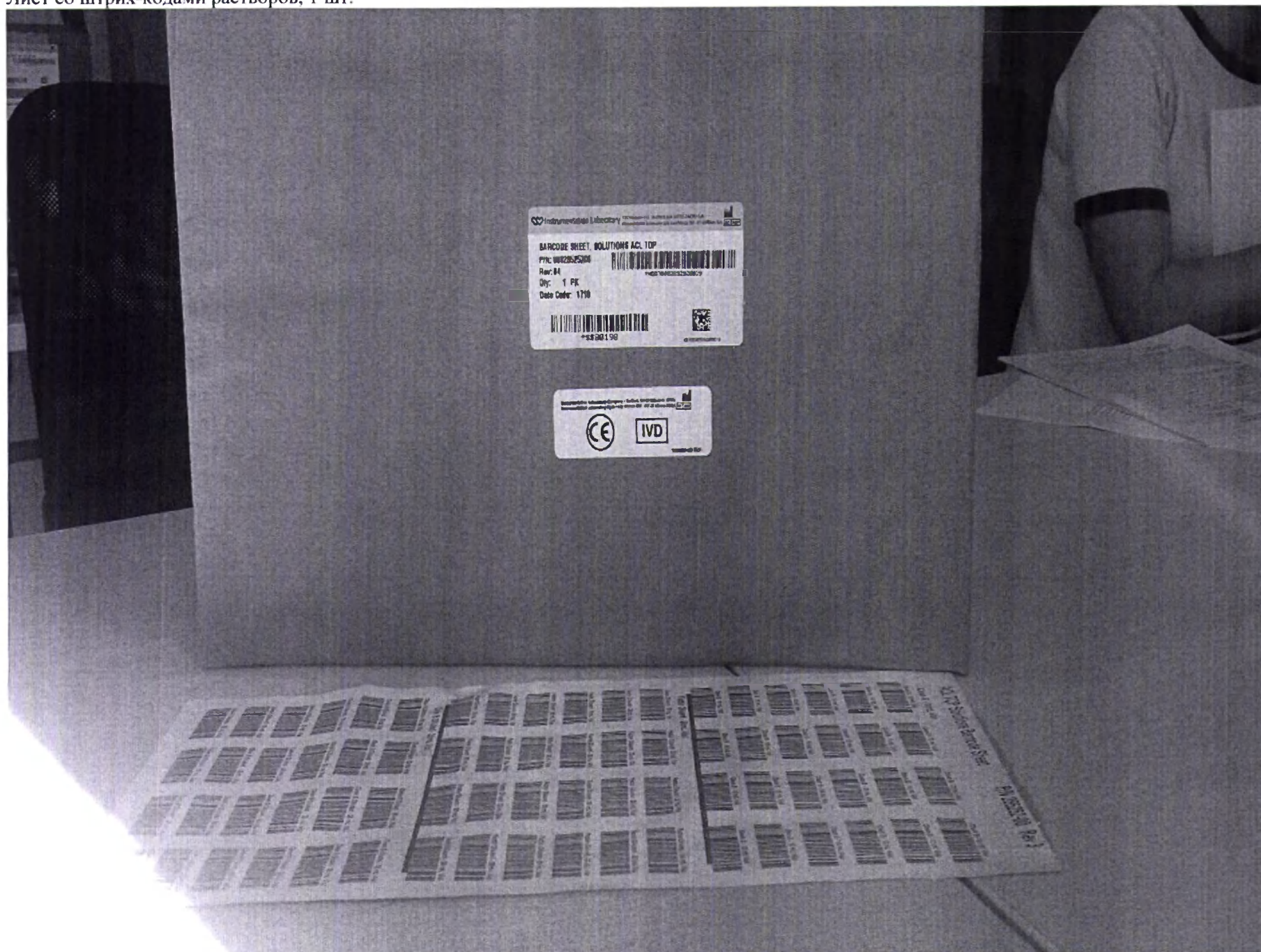
Кабель RS232, AMPRO, 1 шт.



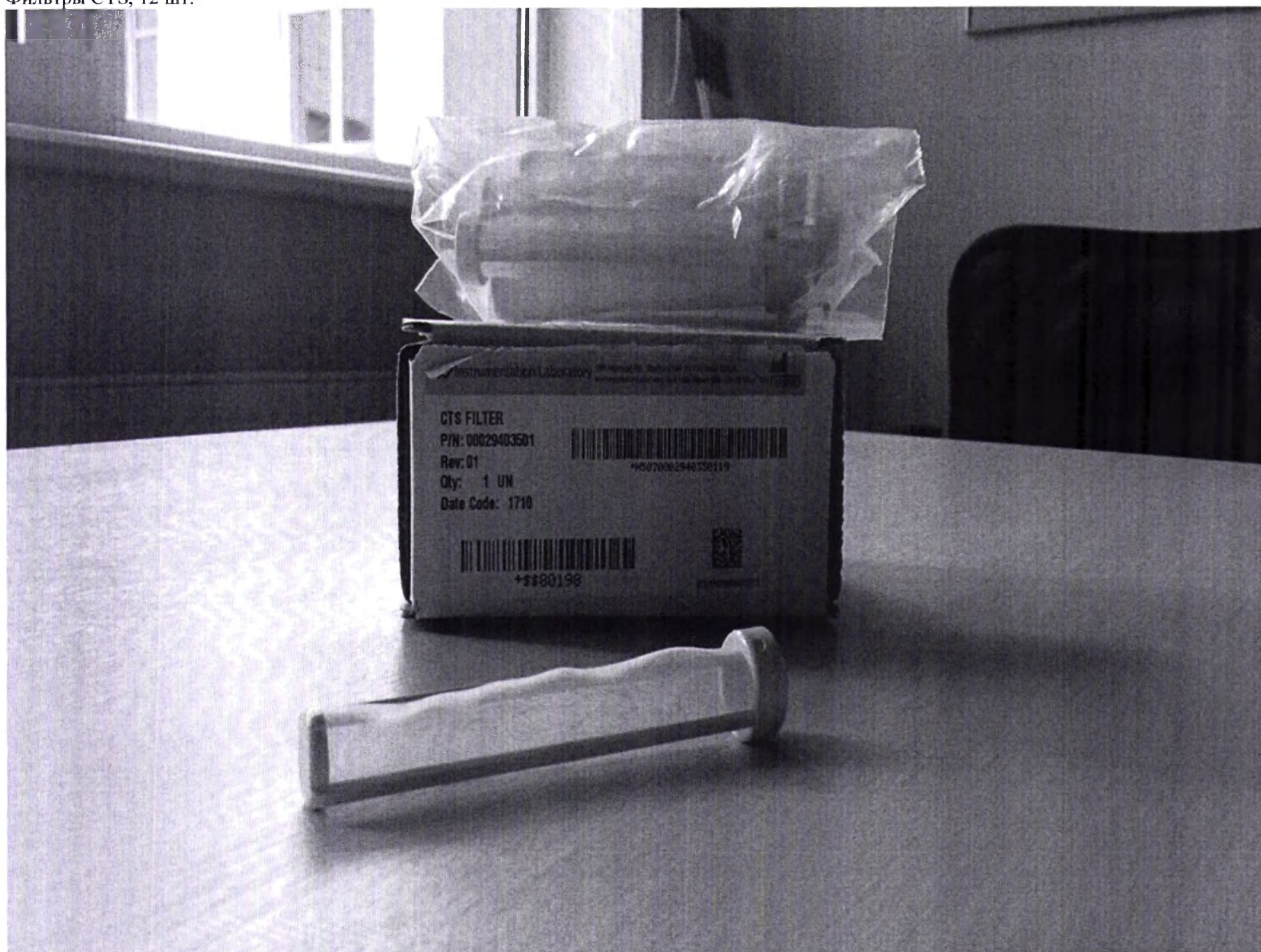
Штативы для образцов под открытые пробирки 85-96, 12 шт./уп.



Лист со штрих-кодами растворов, 1 шт.



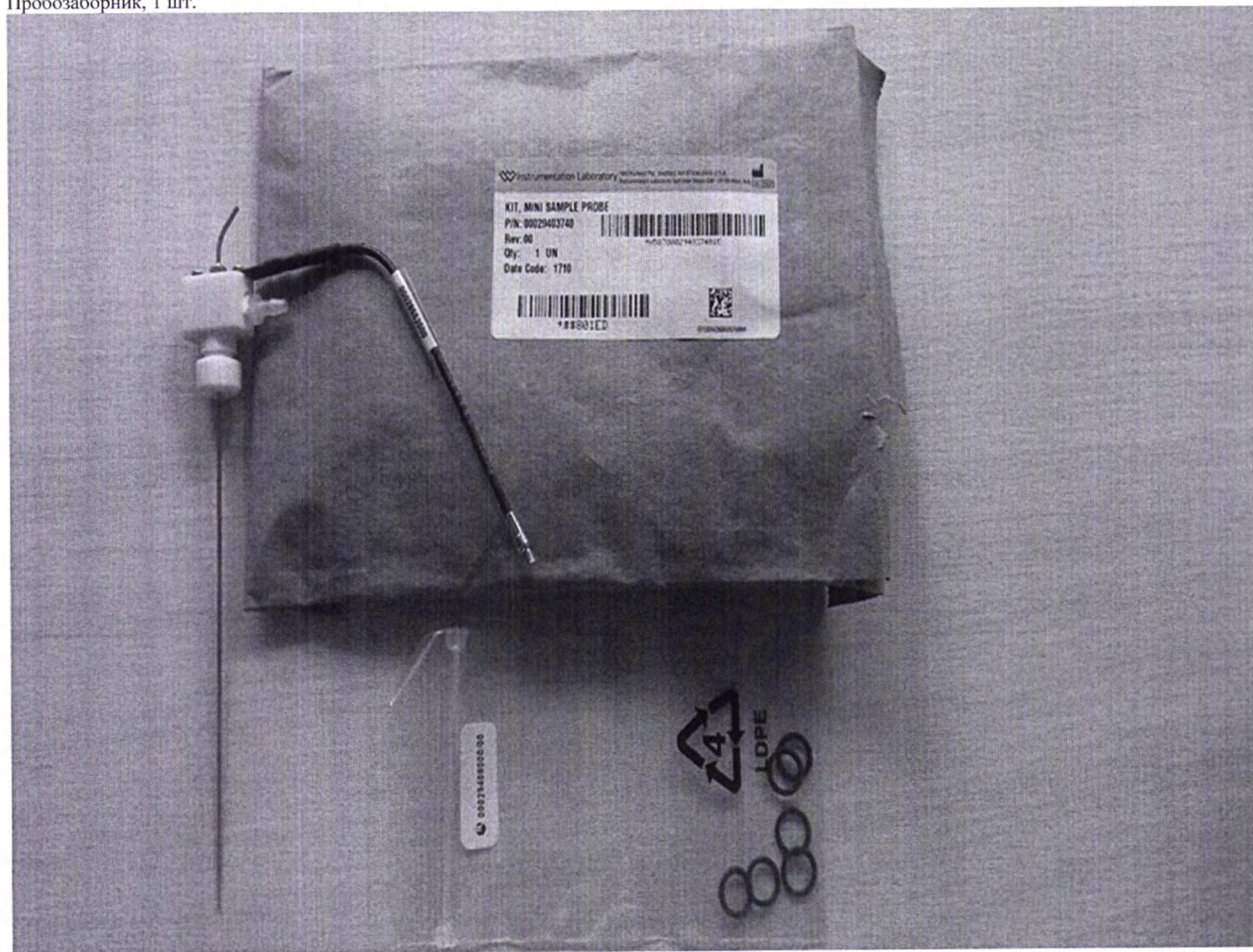
Фильтры CTS, 12 шт.



Набор для замены прокалывателя CTS: прокалыватель, 1 шт.; винт, 1 шт.; кольца, 6 шт.



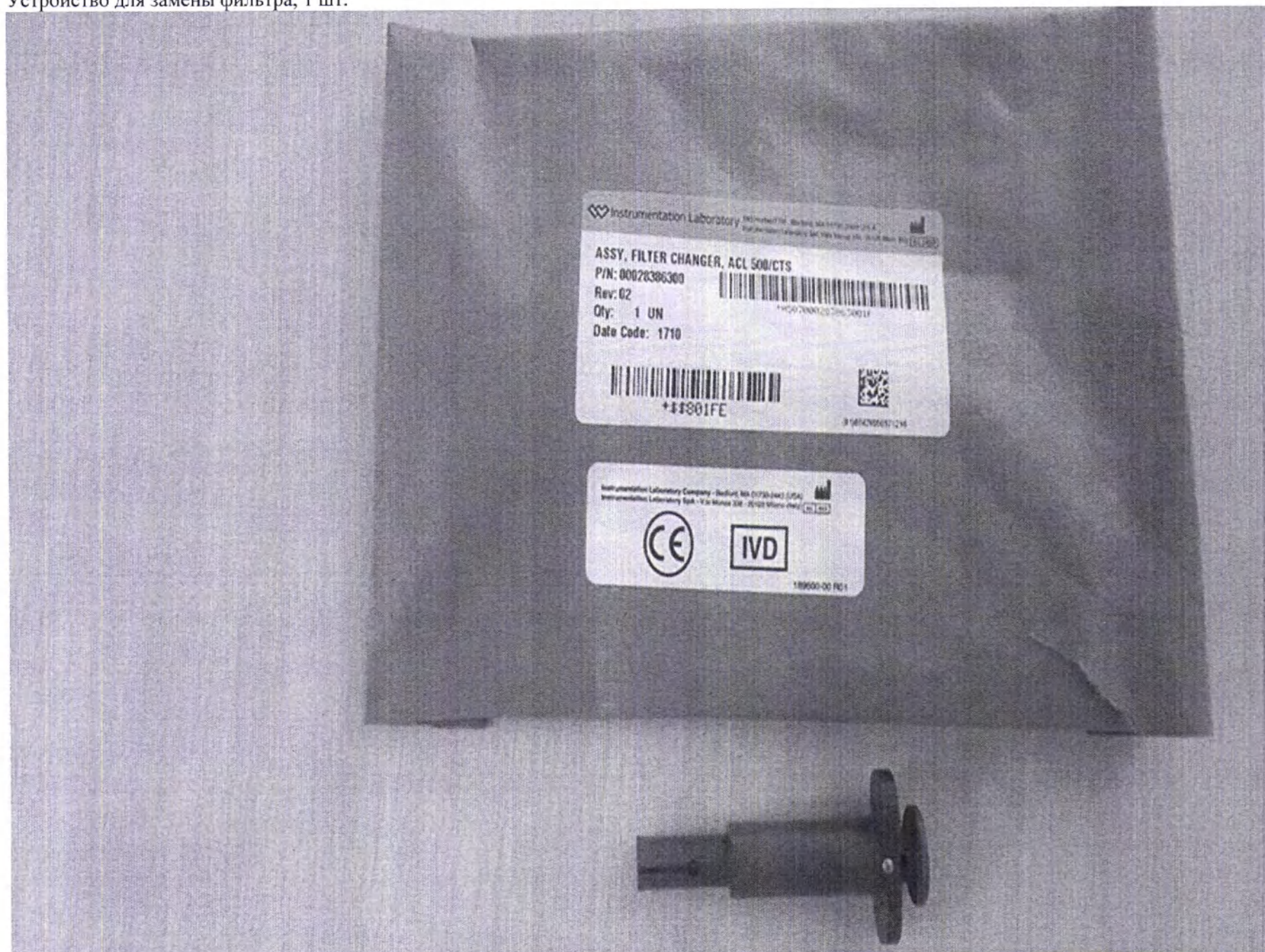
Пробозаборник, 1 шт.

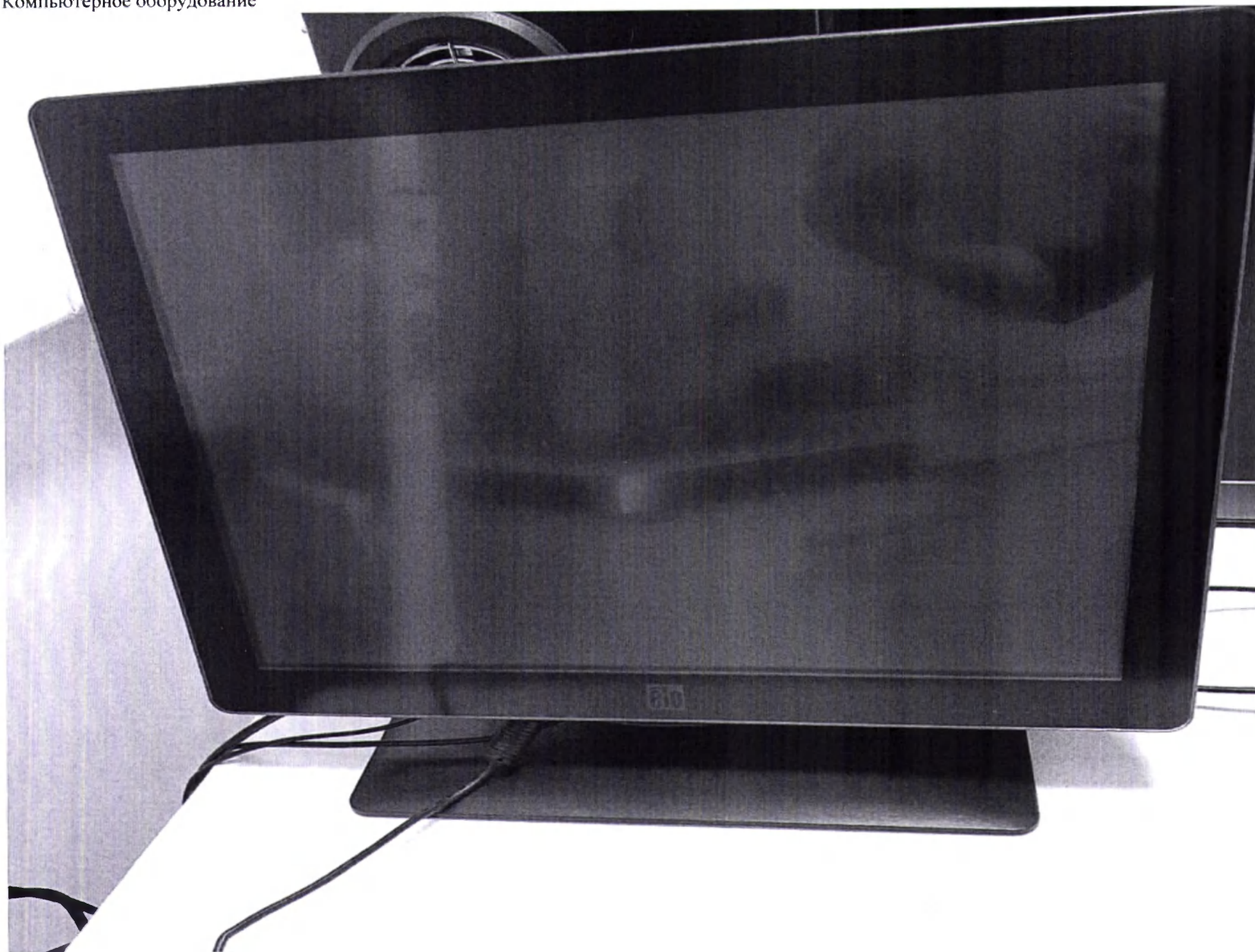


Штативы для образцов под закрытые пробирки 01-12, 12 шт./уп.

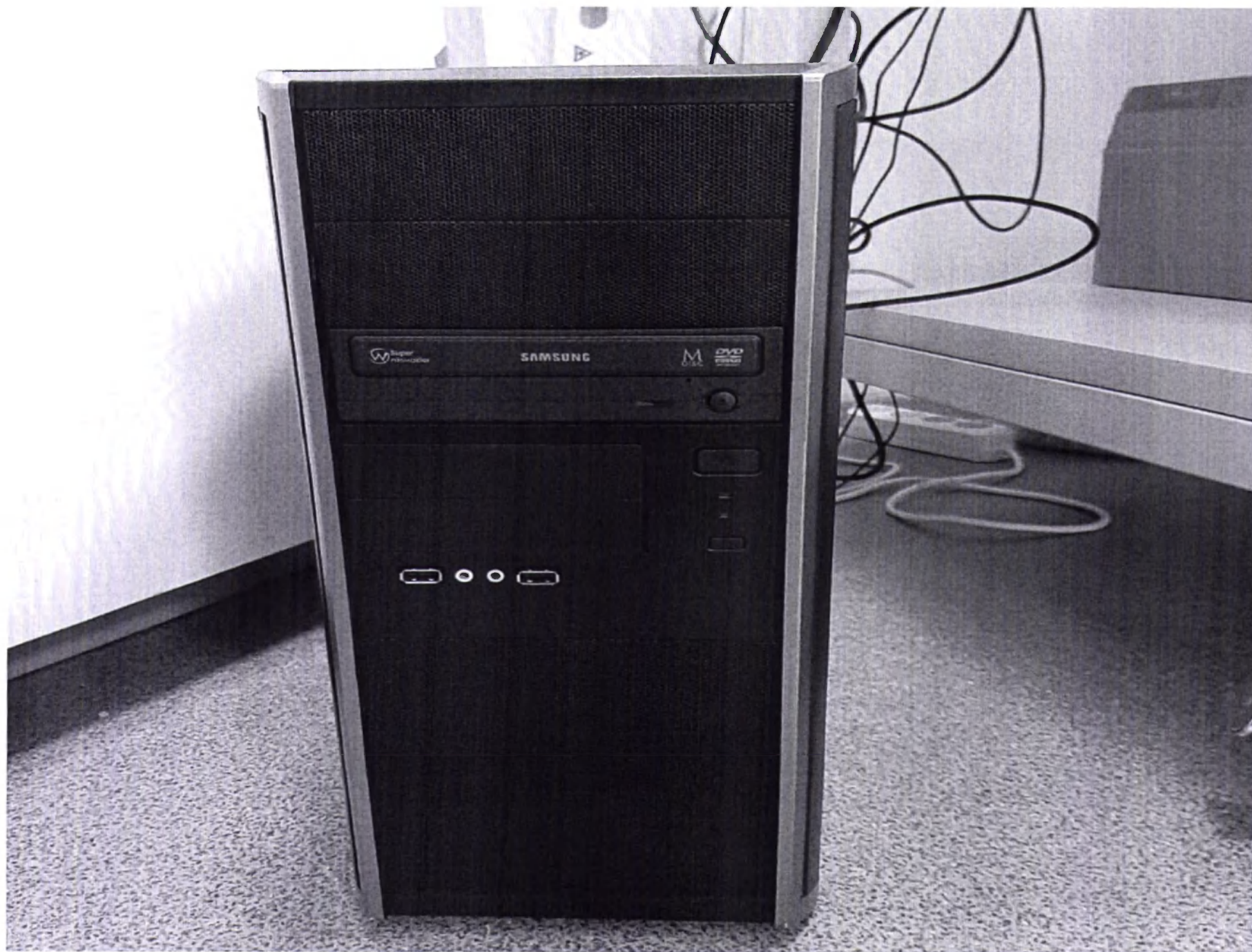


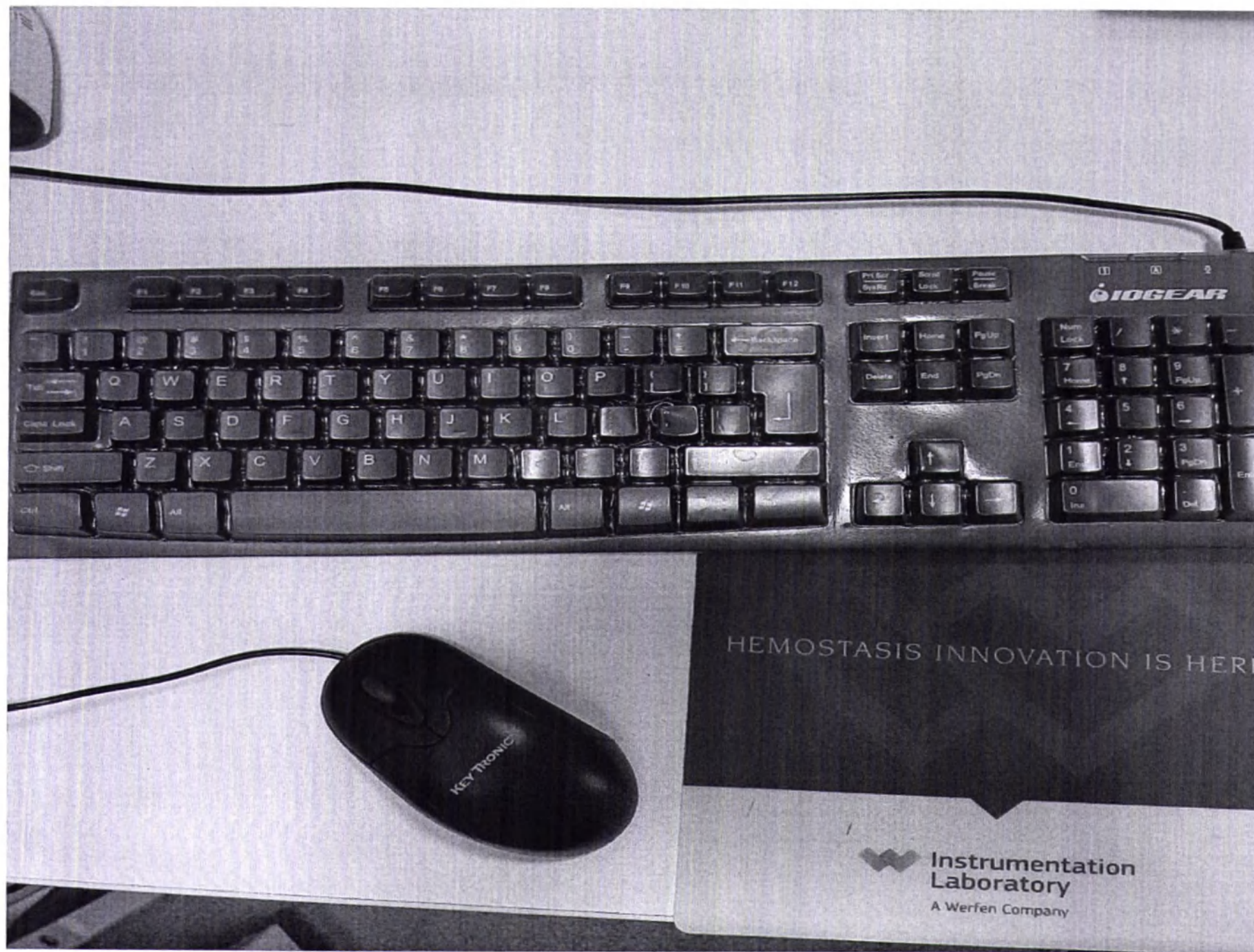
Устройство для замены фильтра, 1 шт.



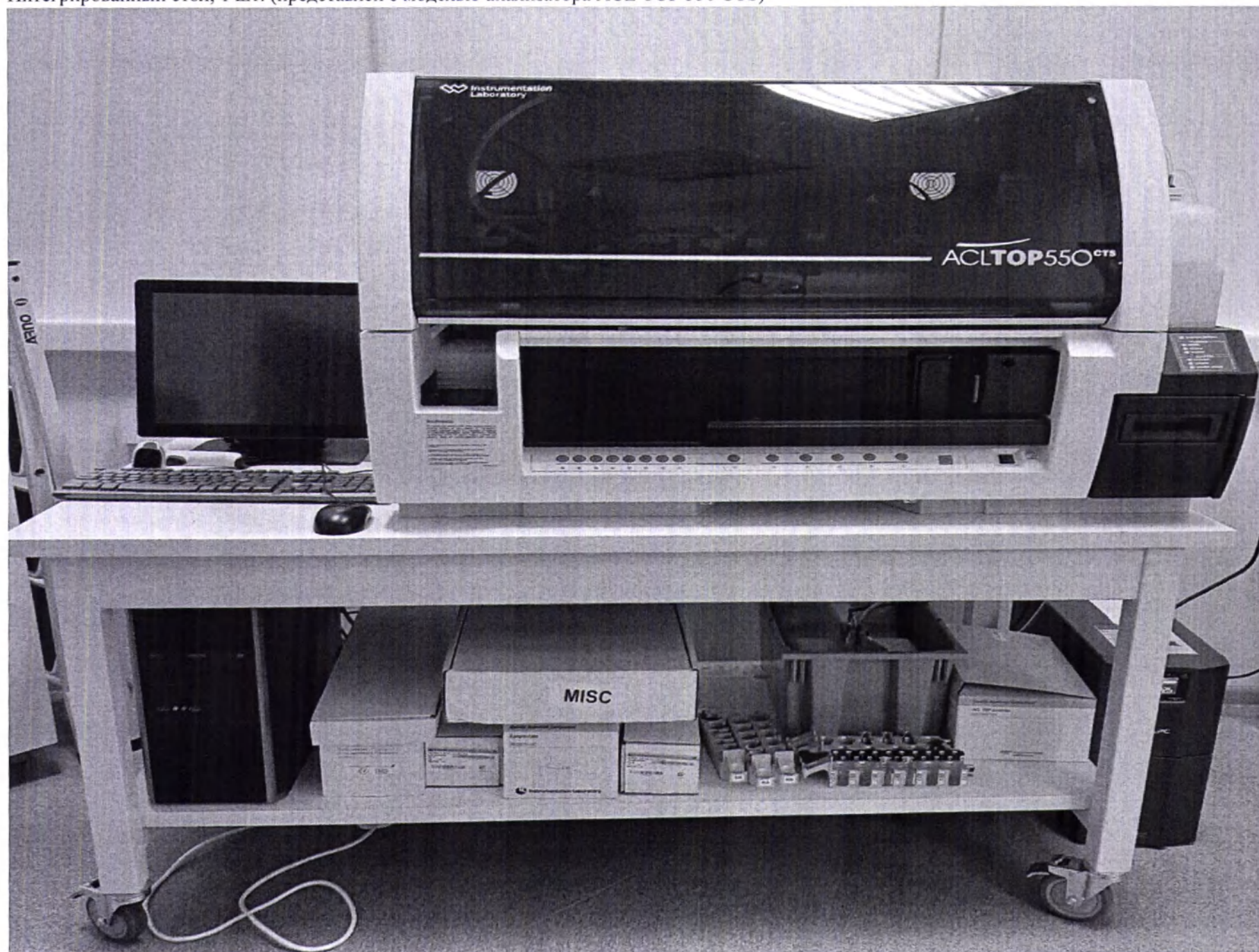




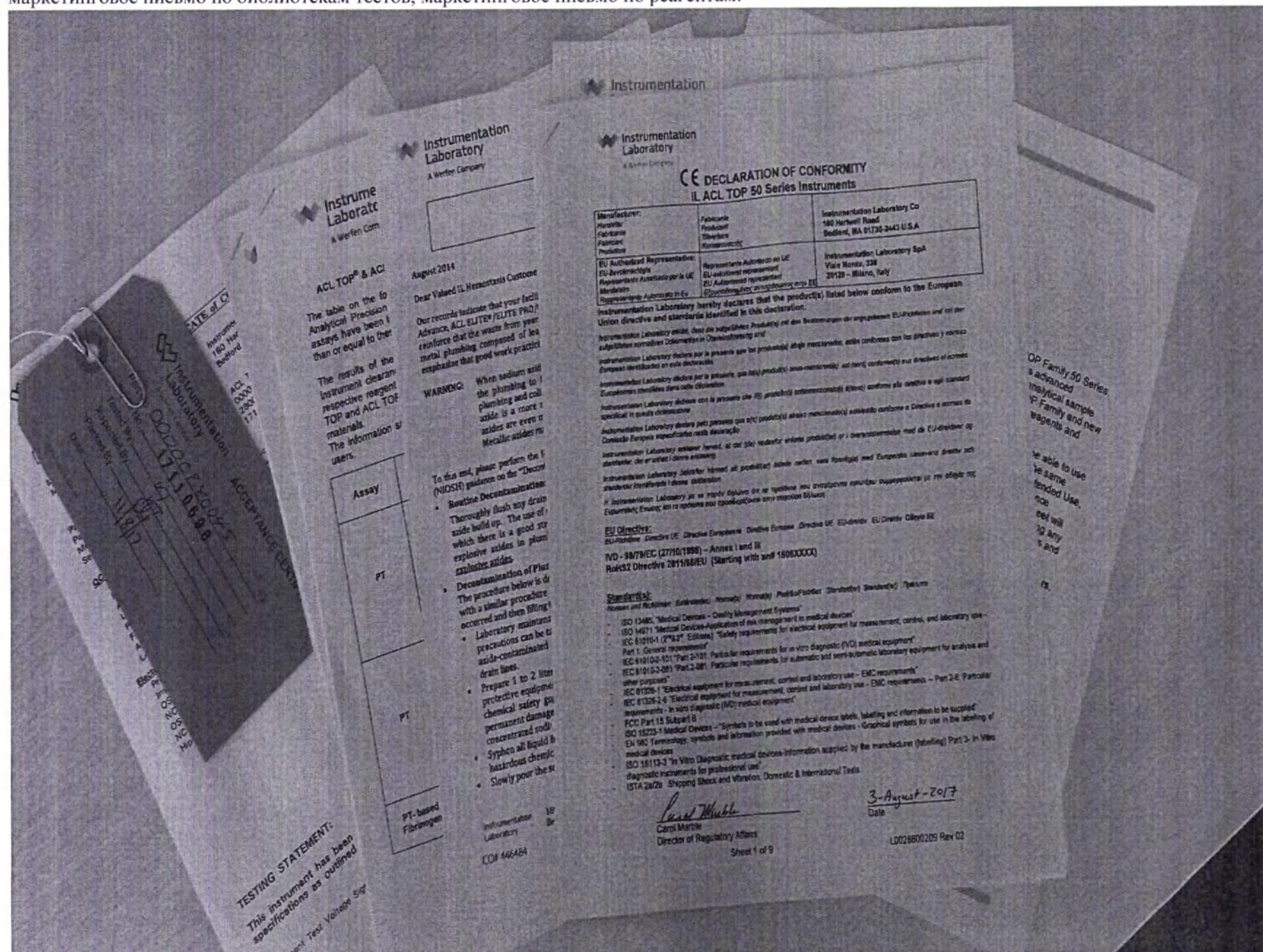




Интегрированный стол, 1 шт. (представлен с моделью анализатора ACL TOP 550 CTS)



Документация: декларация соответствия, сертификат соответствия, спецификация точности измерений, письмо-уведомление про Азид натрия, маркетинговое письмо по библиотекам тестов, маркетинговое письмо по реагентам.



February, 2016

ACL TOP Family 50 Series with Software Release V6.1.0, Parameters P-18.1.00 and User Manual (On Line Help) V6.1.0

Dear Valued ACL TOP™ Customer,

Welcome to the ACL TOP Family 50 Series of Analyzers. The ACL TOP Family 50 Series are the newest members of the ACL TOP Family: the best-in-class analyzers for the hemostasis laboratory. These high performance consolidated workstations are for routine and specialty assays: Clotting, Chromogenic and Latex-Immunoassay with pre-analytical sample integrity checks and advanced audit trail and accreditation support tools. They are part of Instrumentation Laboratory's commitment to develop and introduce products that meet the needs of today's demanding hemostasis laboratory. The ACL TOP Family 50 Series is configured with Software V6.1.0, Parameters P-18.1.00, and User Manual (On Line Help) V6.1.0 and available to select regions worldwide.

The ACL TOP Family 50 Series includes the following analyzers:

ACL TOP 350 CTS	Part Number: 00000280065
ACL TOP 550 CTS	Part Number: 00000280045
ACL TOP 750	Part Number: 00000280015
ACL TOP 750 CTS	Part Number: 00000280055
ACL TOP 750 LAS	Part Number: 00000280035

All models of the ACL TOP Family 50 Series offer:

- Same quality results
- Same comprehensive reagent portfolio
- Same powerful and intuitive software
- Same features and usability
- Same assay-specific sample checks
- Same advanced lab accreditation support tools

Software Version 6.1.0 with Parameters P-18.1.00 includes the following parameter files:

- | | |
|--|---|
| <ul style="list-style-type: none"> • Liquid Anti-Xa [Anti-Xa] • Antithrombin Liquid [AT LIQ] • APCR V with APC [APCR V+] • APCR V without APC [APCR V-] • APTT Syn Phospholip [APTT-SP] • APTT SynthASil [APTT-SS] • D-Dimer HS 500 [DDHS 500] • D-Dimer HS [DDHS] • D-Dimer [DD] • Factor II-RP [FII-RP] • Factor II- ReadiPlasTin [FIIRead] • Factor II-RP-8 [FIIIRP-8] • Factor IX-SS [FIX-SS] • Factor V- ReadiPlasTin [FVRead] • Factor V-RP-8 [FVRP-8] • Factor VIII-SS [FVIII-SS] | <ul style="list-style-type: none"> • Factor VIII-SS with normal WWF [F8v-SS] • Factor VII-RP [FVII-RP] • Factor VII-RP-8 [FVIIIRP-8] • Factor VII- ReadiPlasTin [FVIIRead] • Factor V-RP [FV-RP] • Factor X HS Plus [FX-HS+] • Factor X -RP [FX-RP] • FX ReadiPlasTin [FXRead] • Factor XI-SS [FXI-SS] • Factor XII-SS [FXII-SS] • Factor VIII-SP [FVIII-SP] • Factor IX-SP [FIX-SP] • Factor XI-SP [FXI-SP] • Factor XII-SP [FXII-SP] • Fib RecombiPlasTin [Fib-RP] |
|--|---|



**Instrumentation
Laboratory**

A Werfen Company

November, 2014

Dear Valued ACL TOP 50 customer,

Instrumentation Laboratory is pleased to announce the launch of the new ACL TOP Family 50 Series. The ACL TOP Family 50 Series offer low- to high- volume hemostasis laboratories advanced automation of routine to specialty assays with the added benefit of integrated pre-analytical sample integrity checks, and advanced laboratory accreditation support tools. The ACL TOP Family and new ACL TOP Family 50 Series will be able to use the same comprehensive portfolio of reagents and produce the same quality results.

Since the new ACL TOP Family 50 Series evolved from the ACL TOP Family, you will be able to use the same comprehensive portfolio of HemosIL reagents, calibrators and controls using the same assigned values as listed on the insert sheets for the ACL TOP Family. In addition, the Intended Use, Reagent Storage/Stability, Limitations/Interfering Substances, Expected Values, Performance Characteristics, and any other instrument specific claims on any HemosIL reagent insert sheet will apply to both the ACL TOP Family and the ACL TOP Family 50 Series. Therefore, when using any HemosIL reagent on the ACL TOP Family 50 Series analyzer, please use the assigned values and claims listed on the insert sheet for the ACL TOP Family.

IL is committed to delivering innovative and practical solutions to meet the needs of our customers. The features of the new ACL TOP Family 50 Series will minimize the risk of errors and enhance quality assurance leading to better patient care. Thank you for choosing IL as a partner in Hemostasis testing.

Please contact your local representative if you have any questions.

Sincerely,

Catherine Quirbach Ph.D.

Group Product Manager, Hemostasis Reagents
Instrumentation Laboratory

CO#446005

00027503098 R00

180 Hartwell Road, Bedford, MA 01730

781-861-0710

www.ilus.com



**Instrumentation
Laboratory**

A Werfen Company

**IL HEMOSTASIS SYSTEMS
URGENT SAFETY NOTIFICATION**

August 2014

Dear Valued IL Hemostasis Customer:

Our records indicate that your facility has in use one or more IL Hemostasis Systems: ACL TOP® Family, ACL Futura/ACL Advance, ACL ELITE®/ELITE PRO/8/9/10000, ACL Classic (100-7000) and ACL AcuStar. This notification is intended to reinforce that the waste from your IL Hemostasis System contains sodium azide that may potentially form explosives in metal plumbing composed of lead, brass, tin, copper or zinc or containing solder in the plumbing system and to emphasize that good work practices should be followed to mitigate the risk of explosion.

WARNING: When sodium azide preservative in reagents is disposed down the drain, it can react with the metals in the plumbing to form insoluble metallic azides, such as copper and lead azide, which settle in the plumbing and collect in traps, threads, etc. These metallic azides are highly explosive. For example, lead azide is a more sensitive primary explosive than nitroglycerine and copper azide and other metallic azides are even more explosive and are considered too sensitive to be used commercially as explosives. Metallic azides may explode if subjected to friction, heat, shock or by reaction with other chemicals.

To this end, please perform the following steps taken directly from the National Institute of Occupational Safety and Health (NIOSH) guidance on the "Decontamination Procedures for Azide Contaminated Plumbing" (1976):

- **Routine Decontamination:**

Thoroughly flush any drain used for waste disposal with copious amounts of water several times a day to prevent azide build up. The use of copper- and lead-free lines between the point of discharge of azide and the nearest pipe in which there is a good stream of water, or the use of azide-free reagents, may prevent future accumulation of explosive azides in plumbing. NOTE: These measures will NOT decontaminate plumbing already containing explosive azides.

- **Decontamination of Plumbing Containing Explosive Azides:**

The procedure below is designed to decontaminate a drain trap. Longer lengths of drain lines can be decontaminated with a similar procedure after plugging the drain below the point at which any azide contamination is likely to have occurred and then filling the entire length of pipe with 10% sodium hydroxide solution.

- Laboratory maintenance workers, especially plumbers, should be alerted to the azide hazard so that proper precautions can be taken. Violent explosions have resulted when plumbers have attempted to penetrate blocked azide-contaminated drainage systems with a flexible metal probe (snake) or to cut or saw azide-contaminated drain lines.
- Prepare 1 to 2 liters of 10% sodium hydroxide solution (100 g NaOH per liter of water). Wear appropriate protective equipment when preparing and handling this corrosive material including gloves, protective clothing, chemical safety goggles and face shield. Contact with eyes or skin will cause severe burns and may cause permanent damage. Carefully read and follow the manufacturer's safety instructions and instructions for diluting concentrated sodium hydroxide or sodium hydroxide solid in water.
- Syphon all liquid from the trap and drain using a soft rubber or plastic hose. Use proper precautions against any hazardous chemicals which may be present.
- Slowly pour the sodium hydroxide solution into the trap.

Instrumentation Laboratory 180 Hartwell Road
Bedford, MA 01730

Tel 781-861-0710

www.ilus.com

CO# 446484

Page 1 of 2

L0019014800 R03



**Instrumentation
Laboratory**

A Werfen Company

ACL TOP® & ACL TOP Family 50 Series Analytical Precision Performance Requirements

The table on the following pages reflects the current ACL TOP and ACL TOP Family 50 Series Analytical Precision Performance Requirements. The released parameters for each of the noted assays have been tested by Instrumentation Laboratory, and the imprecision data generated is less than or equal to these requirements.

The results of the internal testing have been submitted to the respective governing bodies for instrument clearance where the reagent is sold, and is also published in the insert sheets of the respective reagent products. Those published values reflect the testing performed on specific ACL TOP and ACL TOP Family 50 Series instruments using specific lots of reagent, calibrator, and control materials.

The information supplied here can serve as a guide to ACL TOP and ACL TOP Family 50 Series users.

Assay	Reagent	Result Unit	Control	Within Run Imprecision (%CV)	Total Imprecision (%CV)
PT	PT-Fib HS + PT-Fibrinogen	Seconds	HemosIL® Normal Control	≤ 2.0	≤ 3.0
			HemosIL Normal Control 1	≤ 2.0	≤ 3.0
			HemosIL Low Abnormal Control	≤ 3.0	≤ 4.0
			HemosIL Abnormal Control 2	≤ 3.0	≤ 4.0
			HemosIL High Abnormal Control	≤ 5.0	≤ 8.0
			HemosIL Abnormal Control 3	≤ 5.0	≤ 8.0
PT	RecombiPlasTin 2G ReadiPlasTin	Seconds	HemosIL® Normal Control	≤ 3.0	≤ 3.0
			HemosIL Normal Control 1	≤ 3.0	≤ 3.0
			HemosIL Low Abnormal Control	≤ 4.0	≤ 4.0
			HemosIL Abnormal Control 2	≤ 4.0	≤ 4.0
			HemosIL High Abnormal Control	≤ 5.0	≤ 8.0
			HemosIL Abnormal Control 3	≤ 5.0	≤ 8.0
PT-based Fibrinogen	PT-Fib HS + PT-Fibrinogen	mg/dL	HemosIL Normal Control	≤ 10.0	≤ 12.0
			HemosIL Normal Control 1	≤ 10.0	≤ 12.0



**Instrumentation
Laboratory**

A Werfen Company

For North America Customers Only

September 19, 2016

Dear Valued ACL TOP Family 50 Series customer,

When using any HemosIL reagent on the ACL TOP Family 50 Series analyzer, please use the assigned values and the claims listed on the insert sheet for the ACL TOP Family. Since the ACL TOP Family 50 Series evolved from the ACL TOP Family, you will be able to use the same comprehensive portfolio of HemosIL reagents, calibrators and controls. The claims for Intended Use, Reagent Storage/Stability, Limitations/Interfering Substances, Expected Values on a HemosIL reagent insert sheet will apply for both the ACL TOP Family and the ACL TOP Family 50 Series.

In addition, Instrumentation Laboratory performed additional precision and method comparison studies to achieve 510k clearance. While the HemosIL labeling is being updated, the corresponding Precision and Method Comparison data for ACL TOP 50 Series from the current 510k cleared assays are listed in this letter for your reference.

Please share this information with your laboratory staff and retain a copy of this letter for your records. Thank you for choosing IL as a partner in Hemostasis testing.

Please contact your local representative if you have any questions.

Sincerely,

Catherine Quirbach Ph.D.

Group Product Manager, Hemostasis Reagents
Instrumentation Laboratory

Instrumentation Laboratory
a U.S. Company

Part: 00000780045
Serial No: 17110698

Tested By: [Signature]
Inspected By: [Signature]
Passed By: [Signature]
Date: 11/07/17

ACCEPTANCE CERTIFICATE

Certificate of COMPLIANCE

Instrumentation Laboratory
180 Hartwell Road
Bedford, MA US 01730

ACL TOP 550 CTS SYSTEM
00000280045
2800-45 ACL TOP 550 CTS
17110698

V = 1.7 %	0.7	PASS
V = 3.2 %	1.2	PASS
V = 1.7 %	1.2	PASS
V = 3.0 %	2.8	PASS
V = 3.0 %	1.2	PASS
V = 6.0 %	1.4	PASS
V = 2.3 %	1.1	PASS
V = 10.0 %	6.8	PASS

V = 0.200 Ohm	0.070	PASS
V = 2 MOhm	734	PASS
0.1 .. 1000.0 μ A	524.1	PASS
0.1 .. 500.0 μ A	285.3	PASS
0.1 .. 1000.0 μ A	530.4	PASS
0.1 .. 500.0 μ A	268.7	PASS
2.00 .. 10.00 mA	4.21	PASS

TESTING STATEMENT:

This instrument has been certified to meet all applicable electrical and analytical specifications as outlined in Instrumentation Laboratory's final test and QC procedures.

Instrument Test Voltage Signature: JNUON

Date: 11/03/2017

QC Signature: SYI

Date: 11/07/2017

CO # 464262

Sheet 1 of 1

Part No. 00028755200 Rev 18

CE DECLARATION OF CONFORMITY
IL ACL TOP 50 Series Instruments

Manufacturer: Hersteller Fabricante Fabricant Produttore	Fabricante Producent Tilværdere Κατασκευαστής	Instrumentation Laboratory Co 180 Hartwell Road Bedford, MA 01730-2443 U.S.A.
EU Authorized Representative: EU-Bevollmächtigter Representante Autorizado por la UE Mandataire Rappresentante Autorizzato in Eu	Representante Autorizado na UE EU-authorized representative EU Auktoriseret representant Εξουσιοδομημένος αντιπρόσωπος στην ΕΕ	Instrumentation Laboratory SpA Viale Monza, 33B 20128 - Milano, Italy

Instrumentation Laboratory hereby declares that the product(s) listed below conform to the European Union directive and standards identified in this declaration.

Instrumentation Laboratory erklärt, dass die aufgeführten Produkt(e) mit den Bestimmungen der angegebenen EU-Richtlinien und mit den aufgeführten normativen Dokumenten in Übereinstimmung sind.

Instrumentation Laboratory declara por la presente que los producto(s) abajo mencionados, están conformes con las directivas y normas Europeas identificadas en esta declaración.

Instrumentation Laboratory déclare par la présente, que le(s) produit(s) sous-mentionné(s), est (sont) conforme(s) aux directives et normes Européennes identifiées dans cette déclaration.

Instrumentation Laboratory dichiara con la presente che il(i) prodotto(i) sottoelencato(i) è(sono) conformi alle direttive e agli standard specificati in questa dichiarazione.

Instrumentation Laboratory declara pelo presente que o(s) produto(s) abaixo mencionado(s) está(estão) conforme a Directiva e normas da Comissão Europeia especificadas nesta declaração.

Instrumentation Laboratory erklærer herved, at det (de) nedenfor anførte produkt(er) er i overensstemmelse med de EU-direktiver og standarder, der er anført i denne erklæring.

Instrumentation Laboratory bekräftar härmed att produkt(er) listade nedan, vara förenliga med Europeiska Union-ens direktiv och standarder identifierade i denna deklaration.

H Instrumentation Laboratory με το παρόν δηλώνει ότι τα προϊόντα που αναφέρονται κατωτέρω συμμορφούνται με την οδηγία της Ευρωπαϊκής Ένωσης και τα πρότυπα που προσδιορίζονται στην παρούσα δήλωση.

EU Directive:

EU-Richtlinie Directiva UE Directive Européenne Directive Europea Directiva UE EU-direktiv EU Direktiv Οδηγία ΕΕ

IVD - 98/79/EC (27/10/1998) - Annex I and III

RoHS2 Directive 2011/65/EU (Starting with sn# 1606XXXX)

Standard(s):

Normen und Richtlinien Estándar(es) Norme(s) Norma(e) Padrão/Padrões Standard(er) Standard(er) Πρότυπα

- ISO 13485, "Medical Devices - Quality Management Systems"
- ISO 14971 "Medical Devices-Application of risk management to medical devices"
- IEC 61010-1 (2nd & 3rd Editions): "Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1. General requirements"
- IEC 61010-2-101 "Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment"
- IEC 61010-2-081 "Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes"
- IEC 61326-1 "Electrical equipment for measurement, control and laboratory use - EMC requirements"
- IEC 61326-2-6 "Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6. Particular requirements - In vitro diagnostic (IVD) medical equipment"
- FCC Part 15 Subpart B
- ISO 15223-1 Medical Devices - "Symbols to be used with medical device labels, labelling and information to be supplied"
- EN 980 Terminology, symbols and information provided with medical devices - Graphical symbols for use in the labelling of medical devices
- ISO 18113-3 "In Vitro Diagnostic medical devices-Information supplied by the manufacturer (labelling) Part 3- In Vitro diagnostic instruments for professional use"
- ISTA 2a/2b Shipping Shock and Vibration, Domestic & International Tests

Carol Marble
Carol Marble
Director of Regulatory Affairs

3-August-2017
Date

Sheet 1 of 9

L0028600209 Rev 02

Наконечники для шприца, 250 мкл, 1 уп. (при необходимости)



Трубка пробозаборника, 1 шт. (при необходимости)



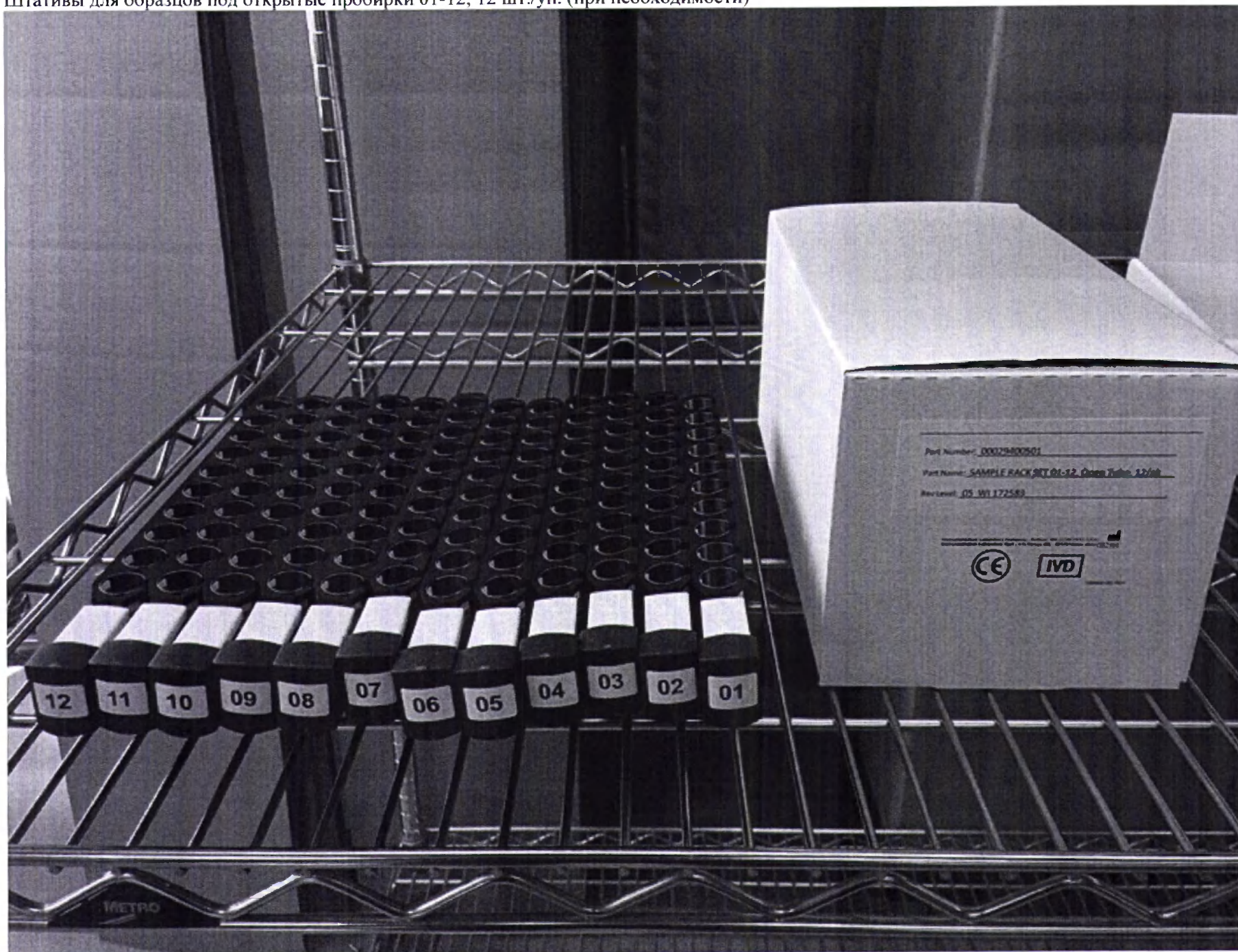
Штативы для реагентов RG-RM, 6 шт./уп. (при необходимости)



Штативы для разбавителей DD-DF, 3 шт./уп. (при необходимости)



Штативы для образцов под открытые пробирки 01-12, 12 шт./уп. (при необходимости)



Штативы для образцов под открытые пробирки 25-36, 12 шт./уп. (при необходимости)



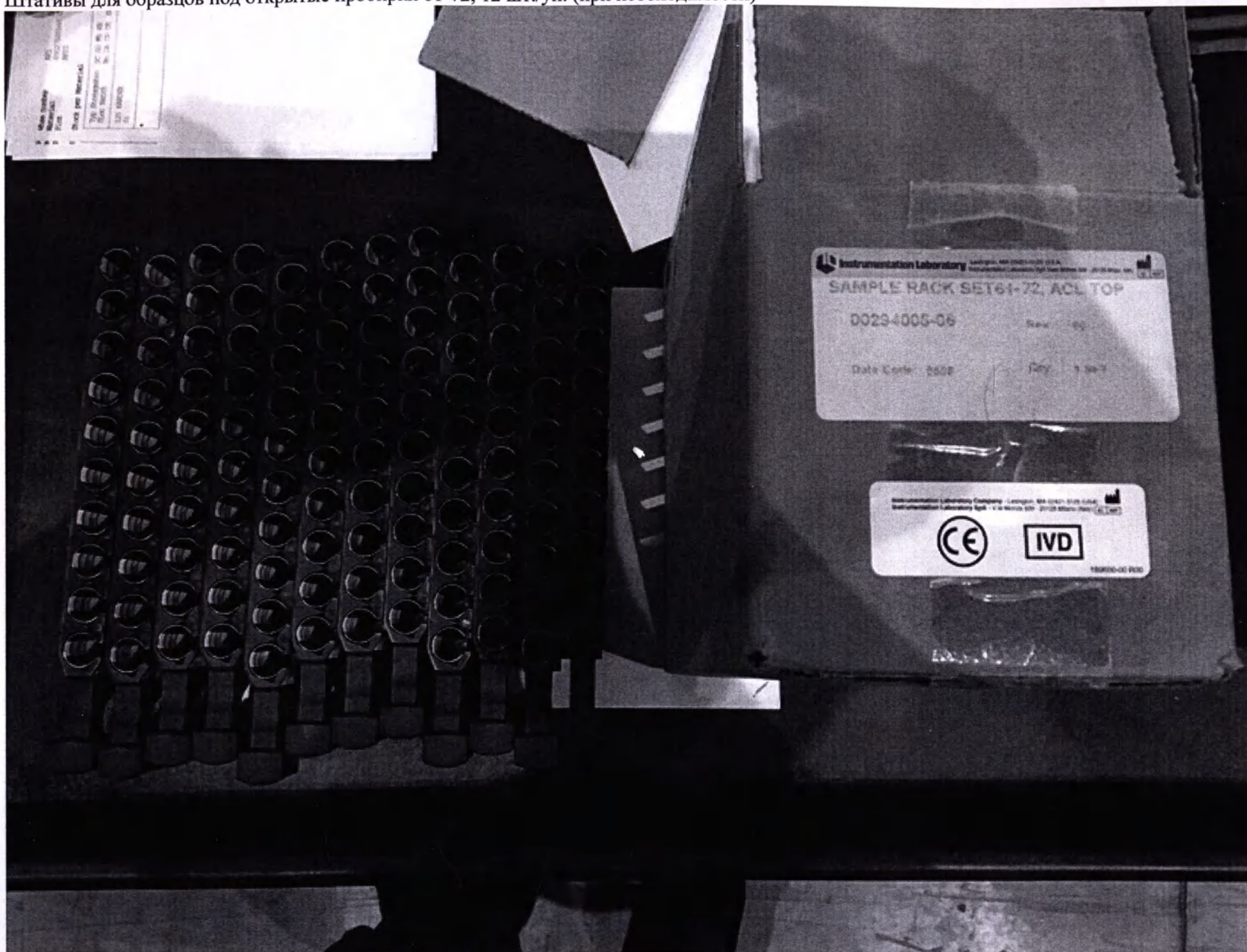
Штативы для образцов под открытые пробирки 37-48, 12 шт./уп. (при необходимости)



Штативы для образцов под открытые пробирки 49-60, 12 шт./уп. (при необходимости)



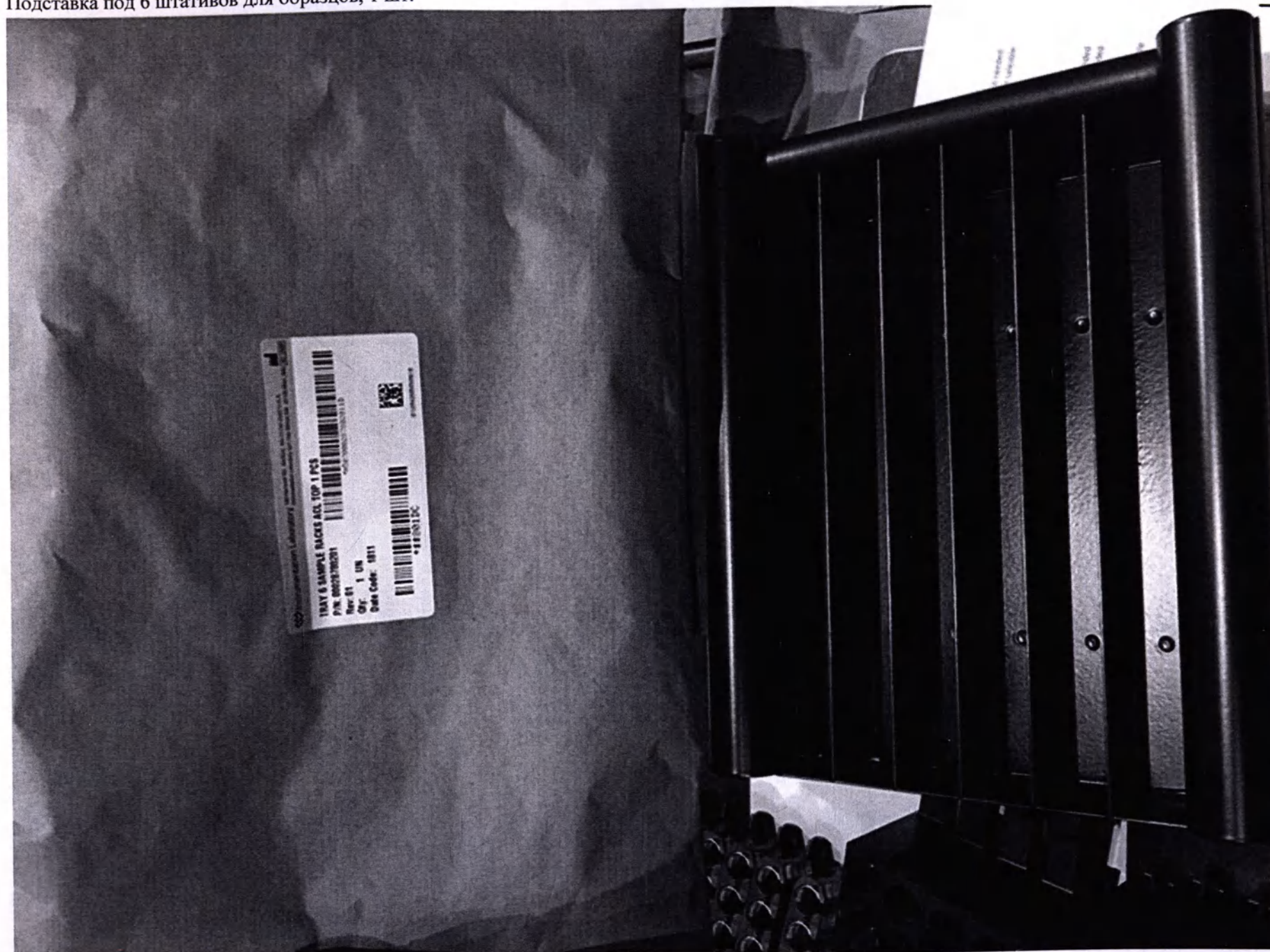
Штативы для образцов под открытые пробирки 61-72, 12 шт./уп. (при необходимости)



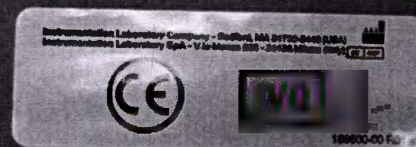
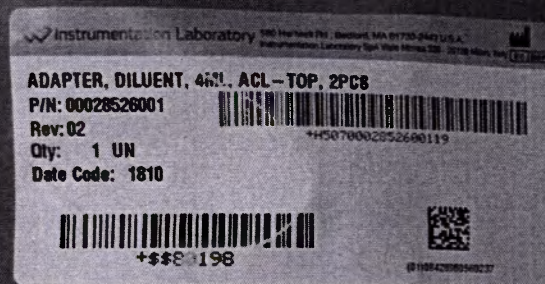
Штативы для образцов под открытые пробирки 73-84, 12 шт./уп. (при необходимости)



Подставка под 6 штативов для образцов, 1 шт.



Адаптеры под штативы для разбавителей на 4 мл, 6 шт.



Адаптеры под штативы для разбавителей на 10 мл, 6 шт.



Адаптеры под штативы для разбавителей на 20 мл, 6 шт.



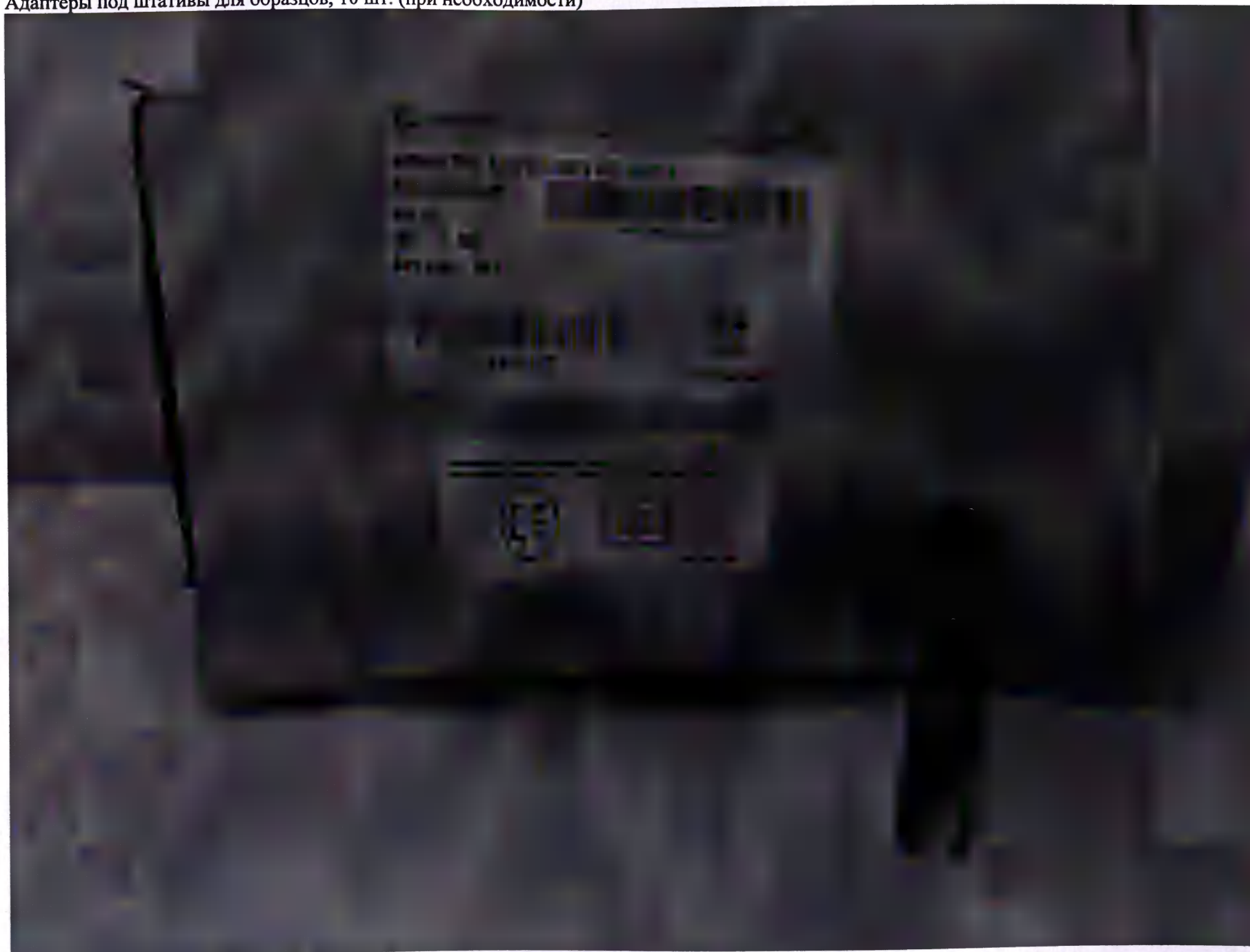
Адаптеры для алиquotных пробирок, 10 шт. (при необходимости)



Адаптеры для педиатрических пробирок, 10 шт. (при необходимости)



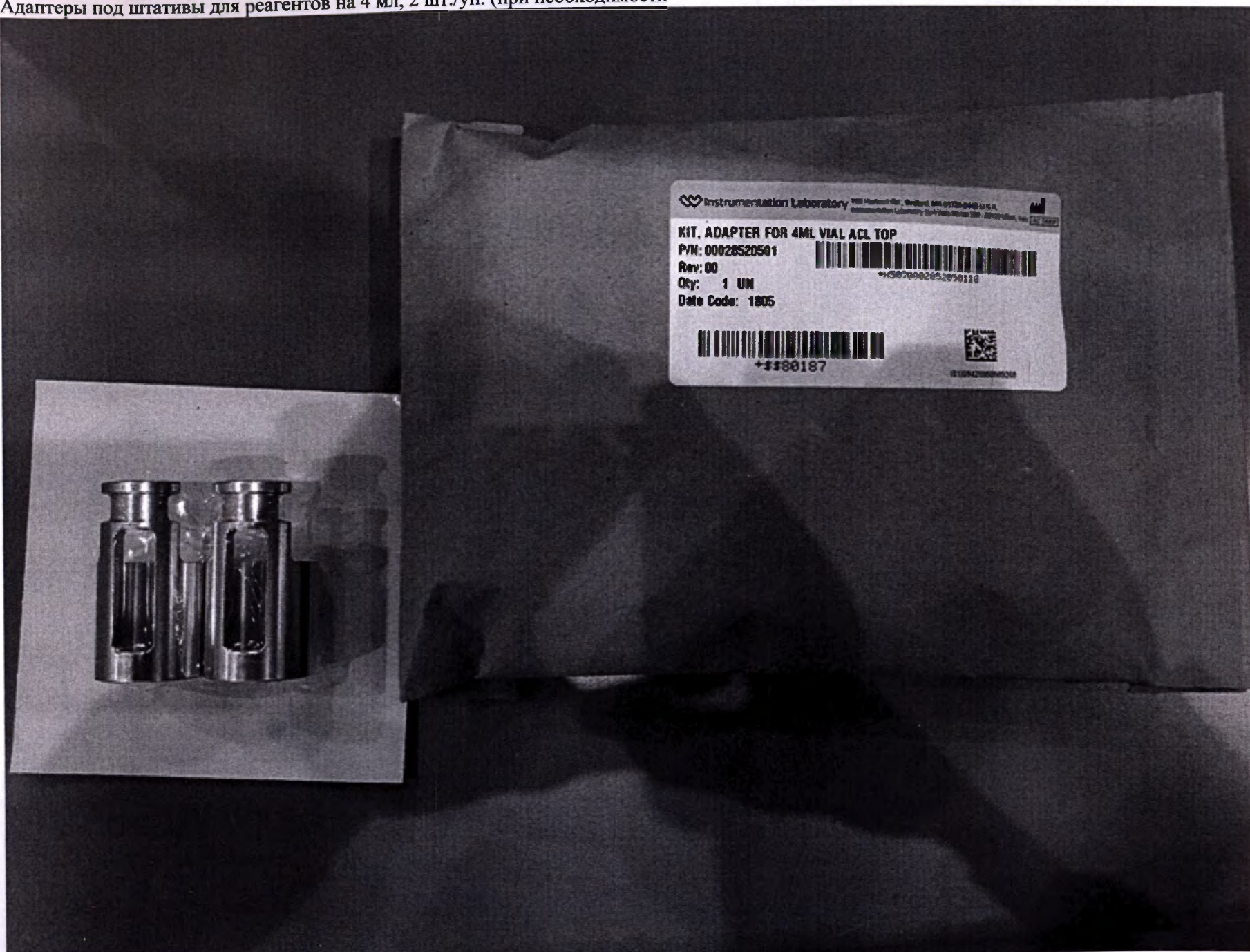
Адаптеры под штативы для образцов, 10 шт. (при необходимости)



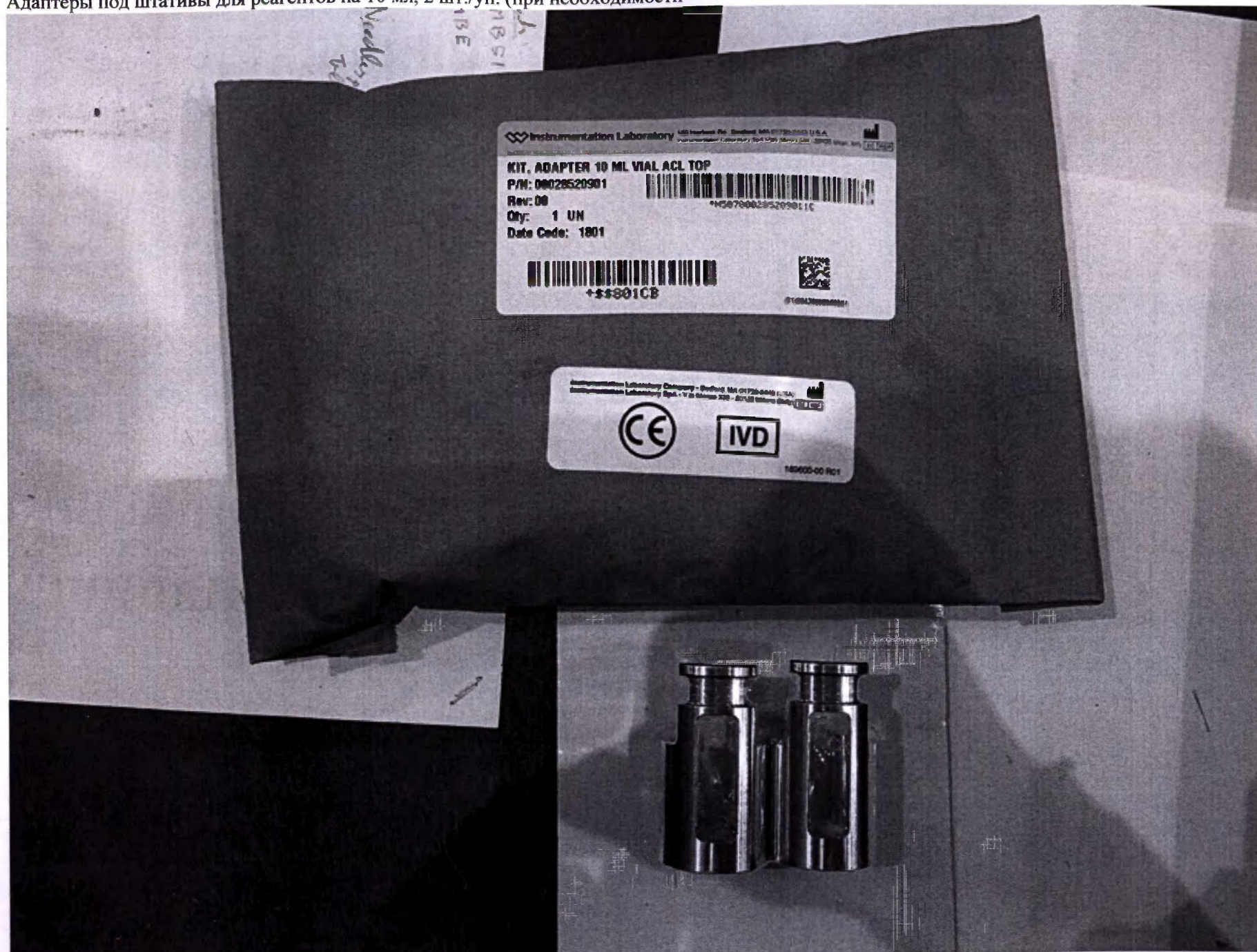
Адаптеры для микропробирок, 10 шт. (при необходимости)



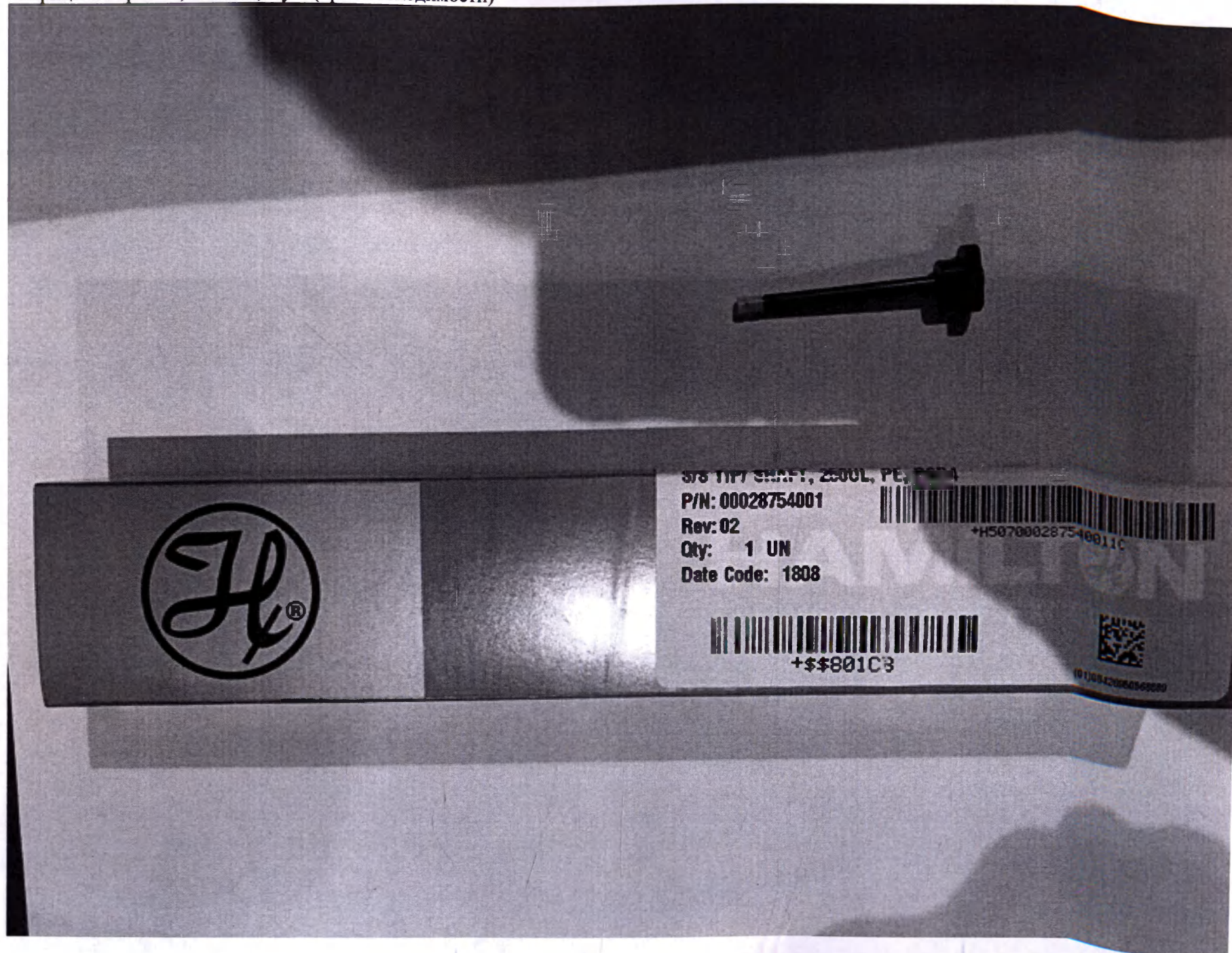
Адаптеры под штативы для реагентов на 4 мл, 2 шт./уп. (при необходимости)



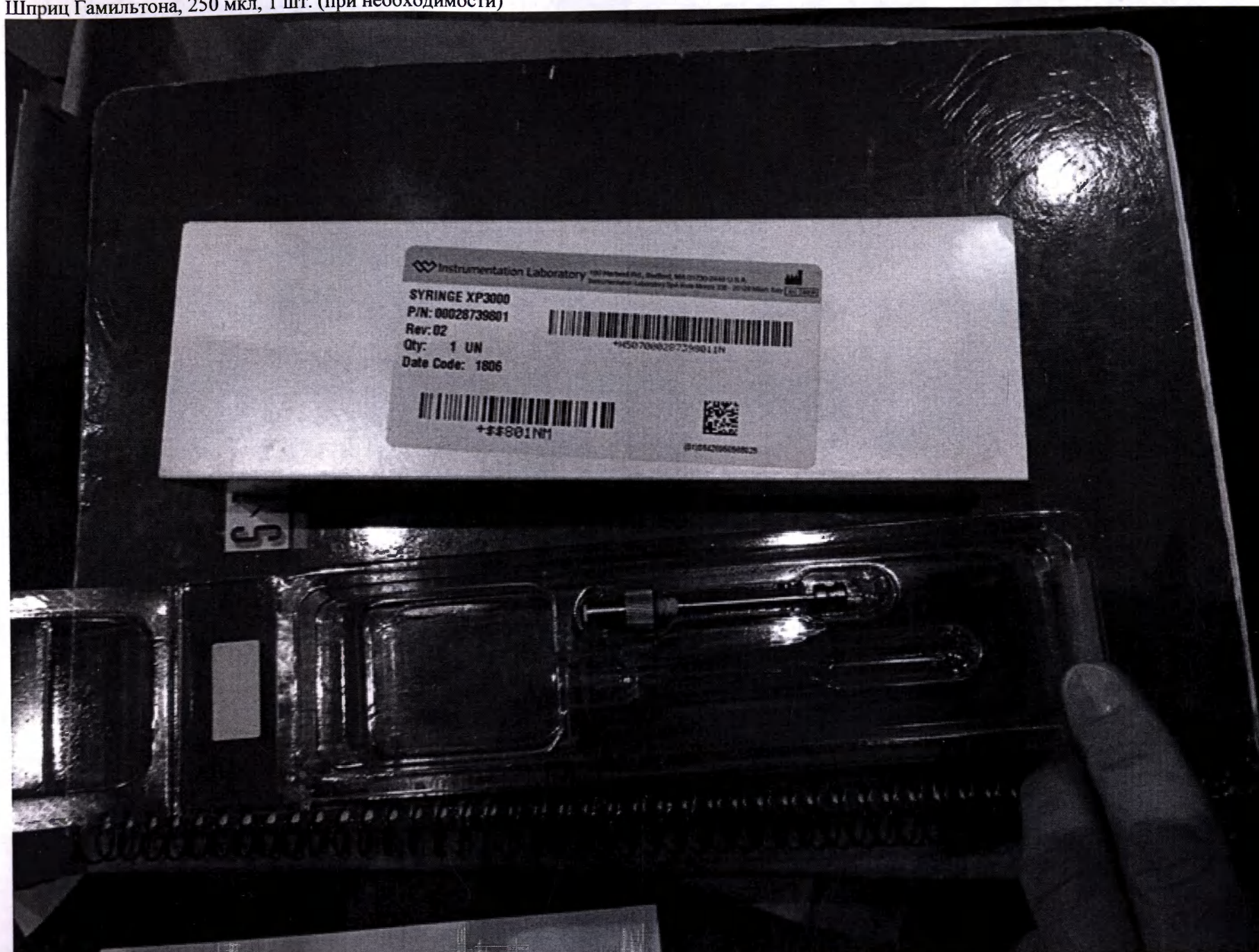
Адаптеры под штативы для реагентов на 10 мл, 2 шт./уп. (при необходимости)



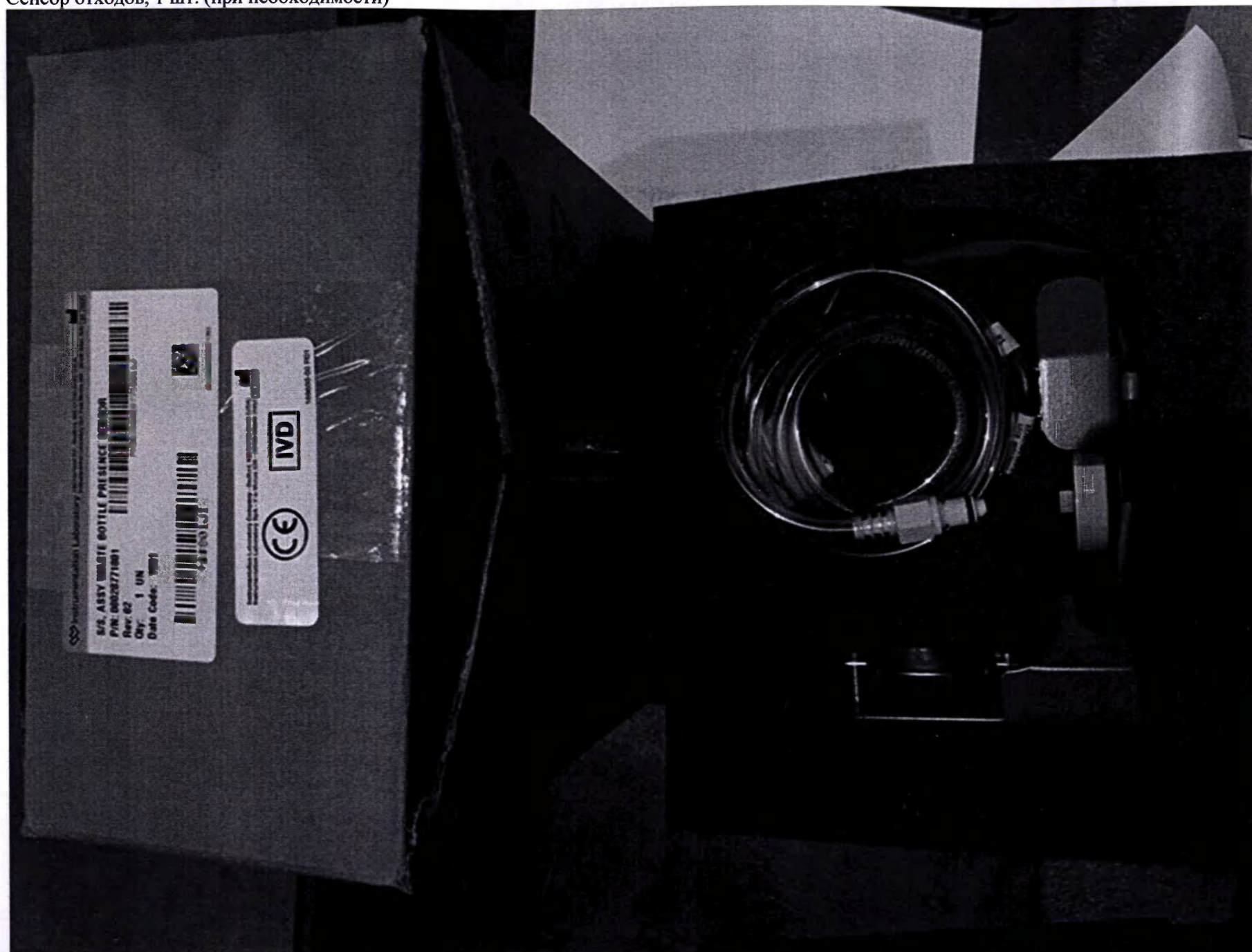
Шприцы и поршень, 250 мкл, 1 уп. (при необходимости)

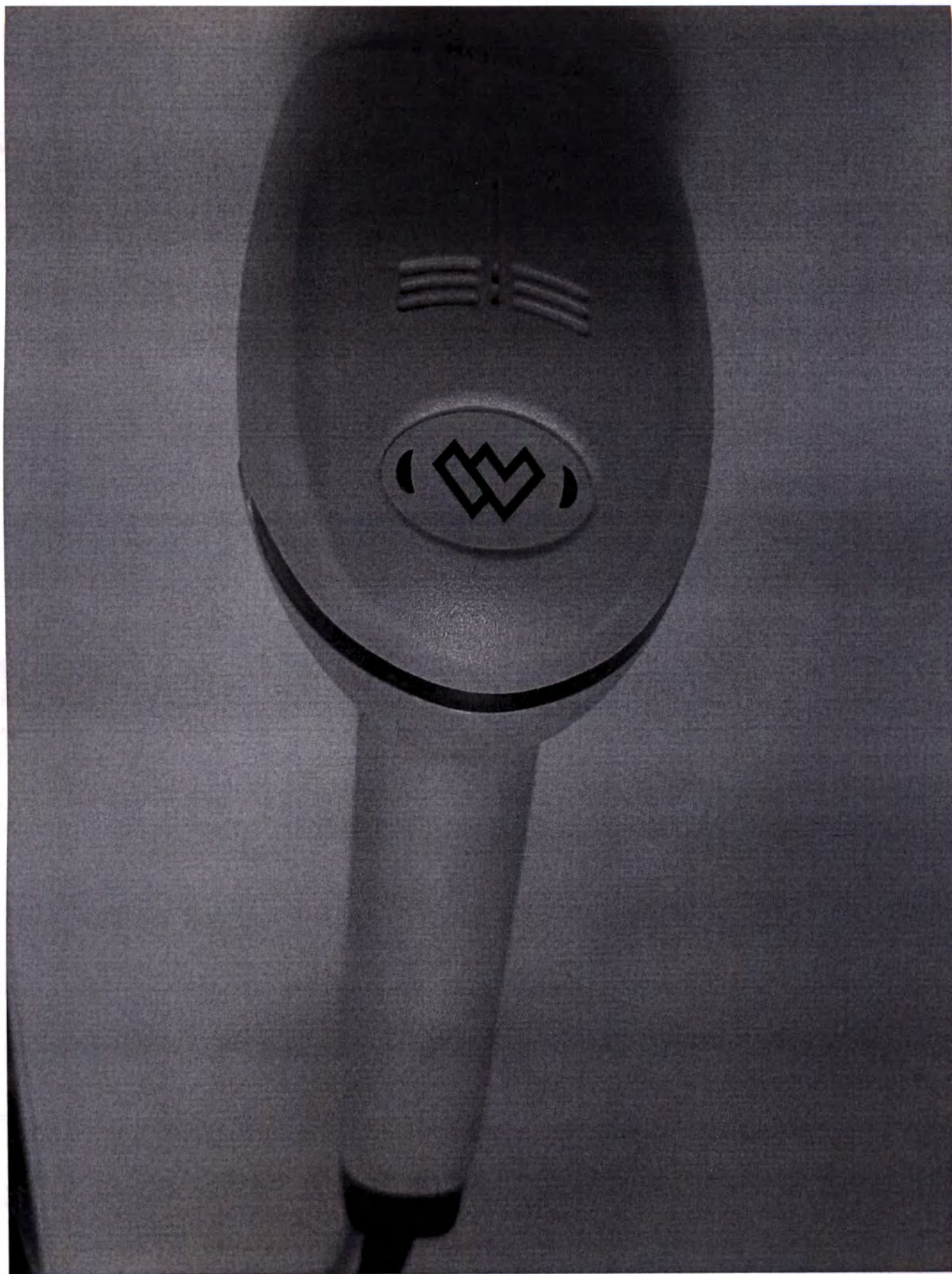


Шприц Гамильтона, 250 мкл, 1 шт. (при необходимости)



Сенсор отходов, 1 шт. (при необходимости)



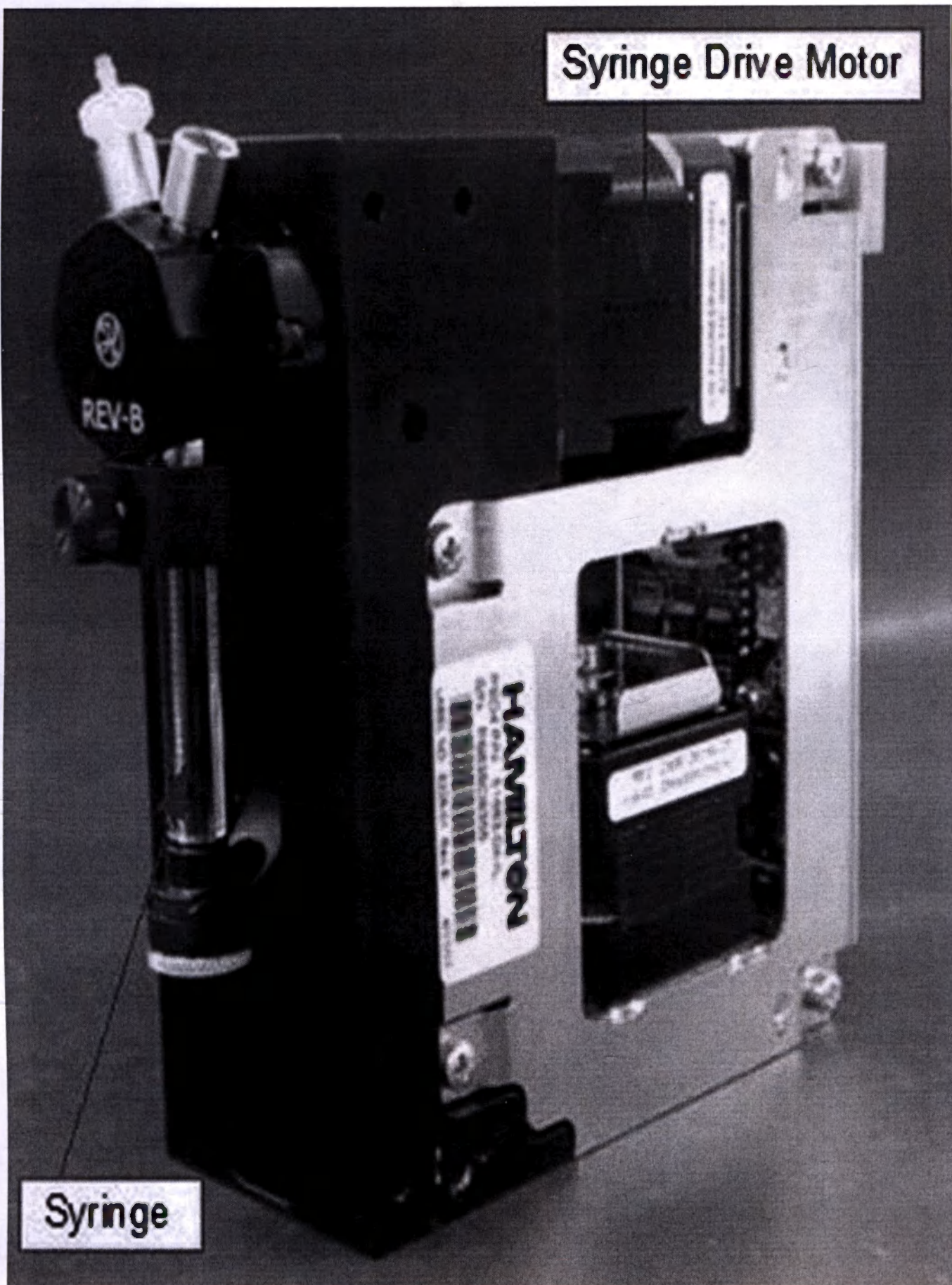




Шприц PE PSD4, 1 шт. (при необходимости)

Syringe Drive Motor

Syringe

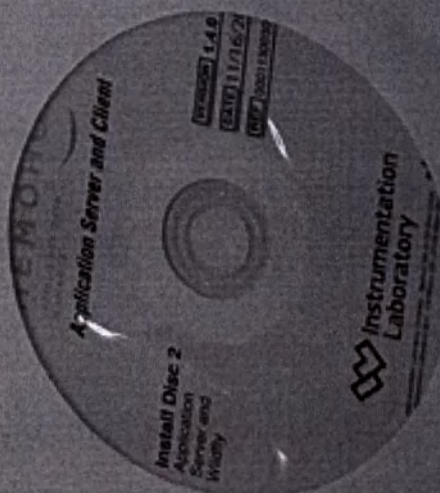
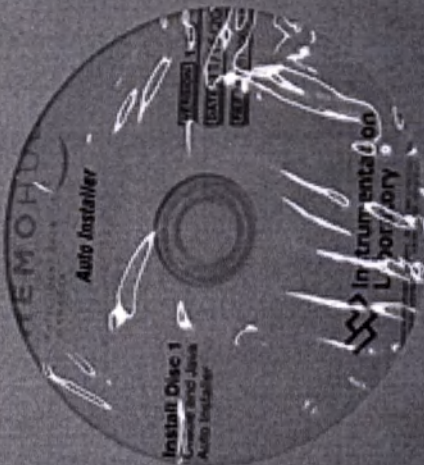
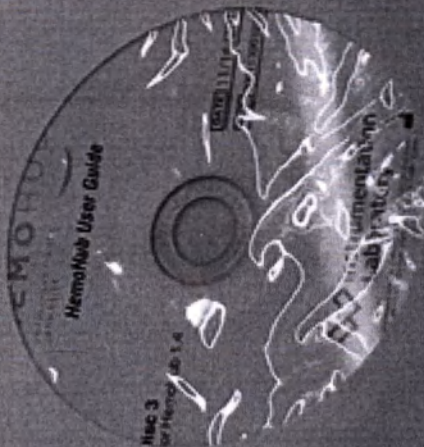


Вентилятор для охлаждения реагентов, ACL TOP 700/750 CTS, 1 шт. (при необходимости)

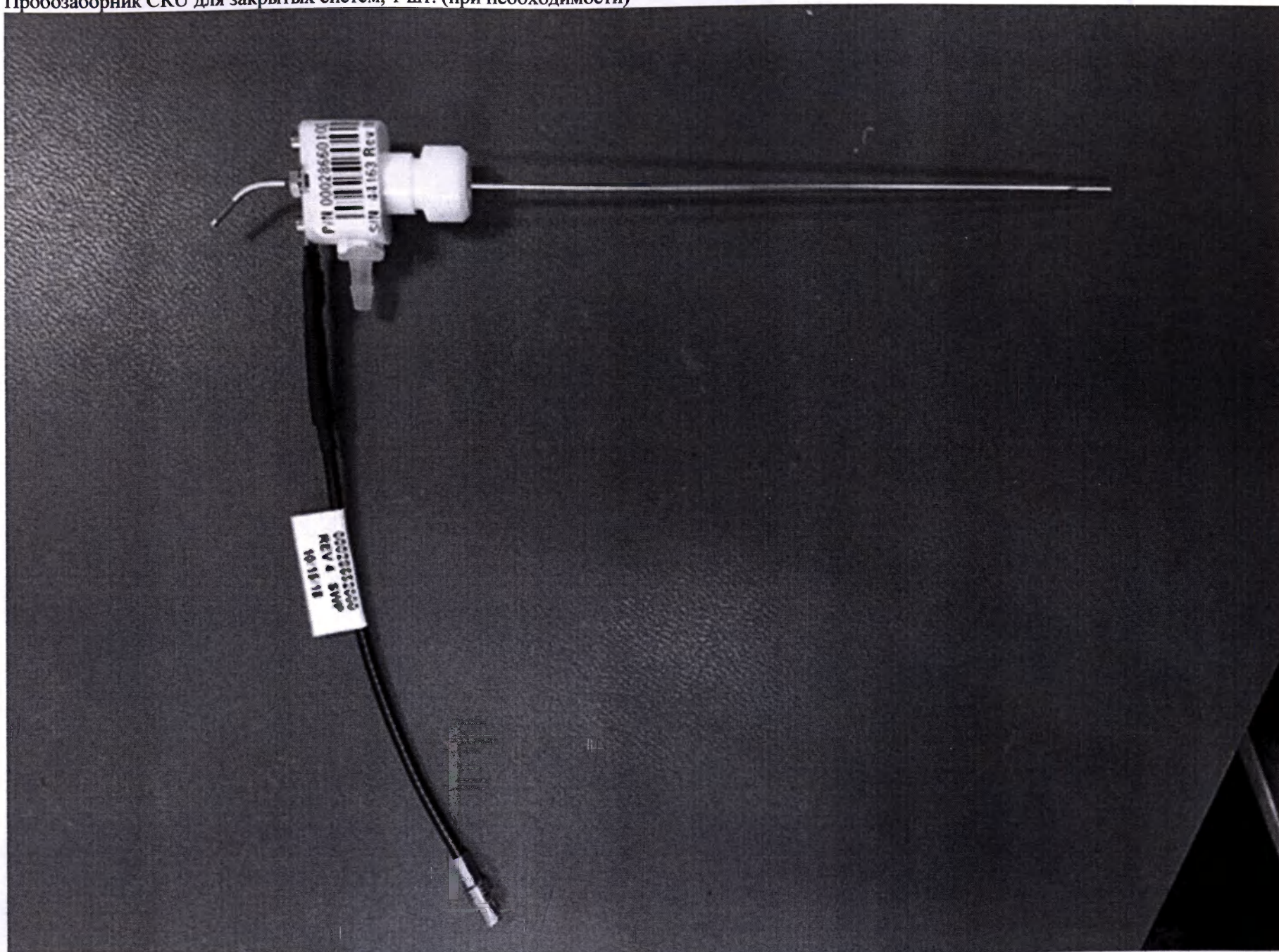


Программное обеспечение НетоHub, 1 шт. (при необходимости)

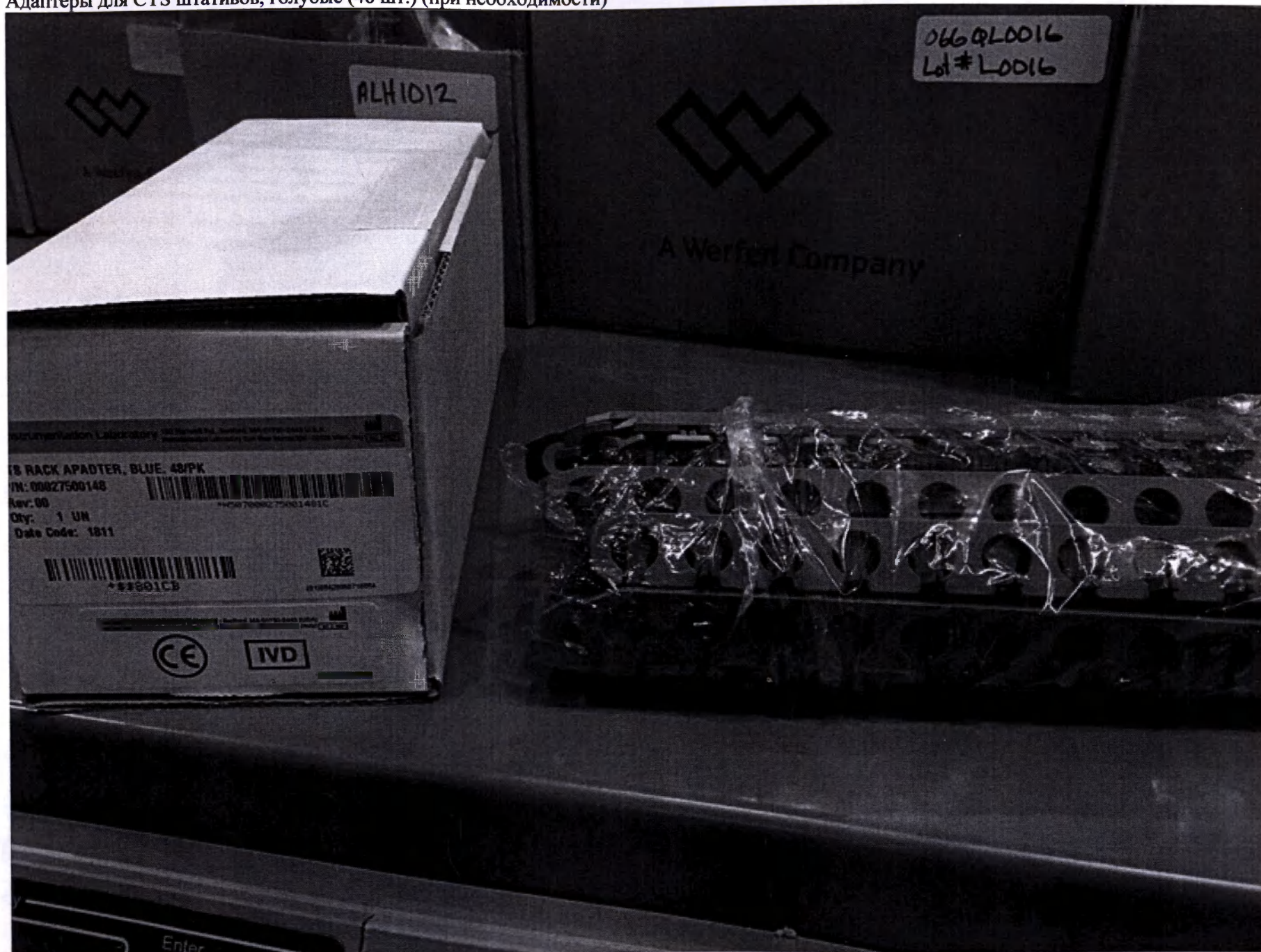
KIT, INSTALL HEMOHUB V1.4.0
PL P/N: 00011300314 Rev: 00
Date 11/16/2017



Пробозаборник CRU для закрытых систем, 1 шт. (при необходимости)



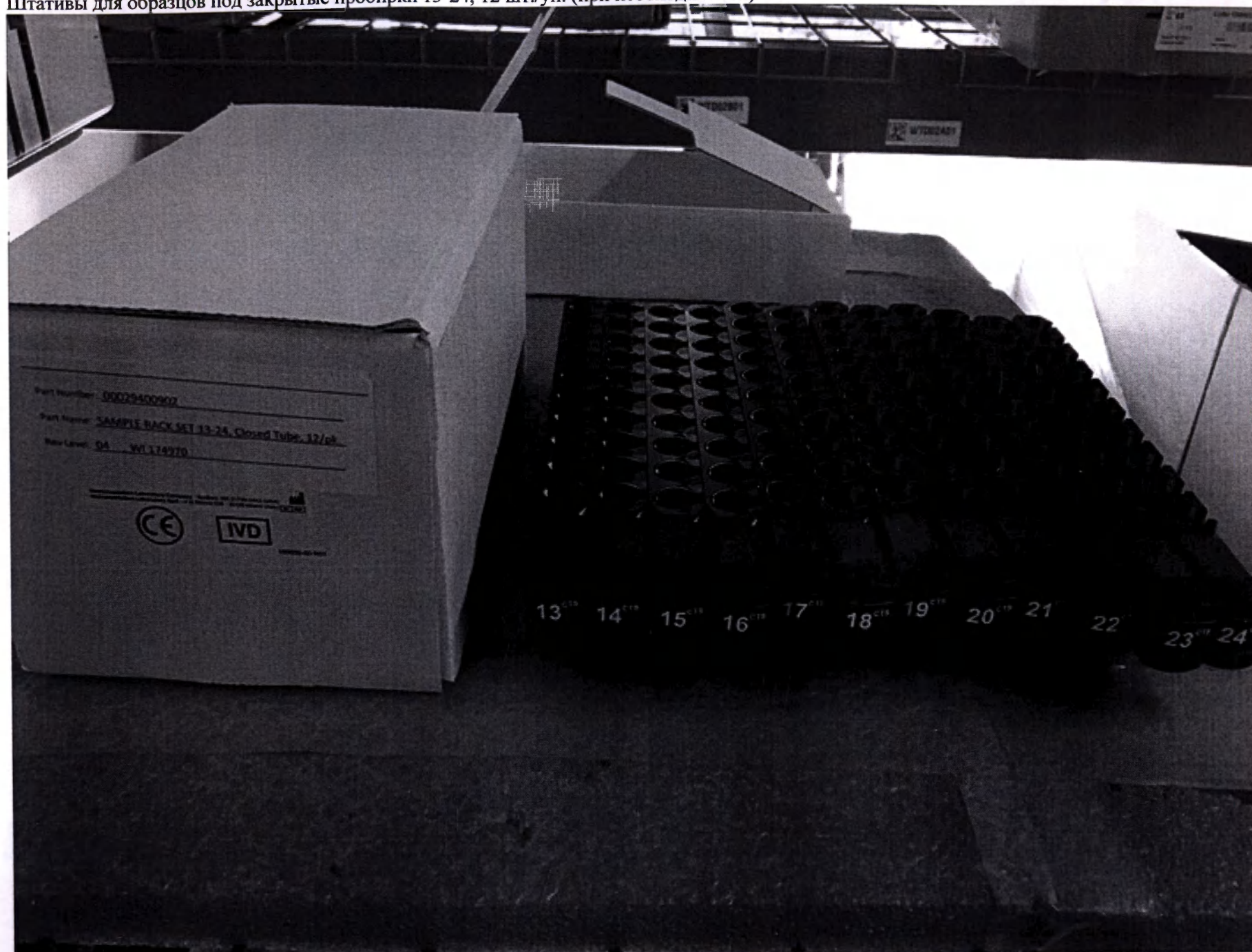
Адаптеры для CTS штативов, голубые (48 шт.) (при необходимости)



Адаптеры для CTS штативов, голубые (96 шт.) (при необходимости)



Штативы для образцов под закрытые пробирки 13-24, 12 шт./уп. (при необходимости)



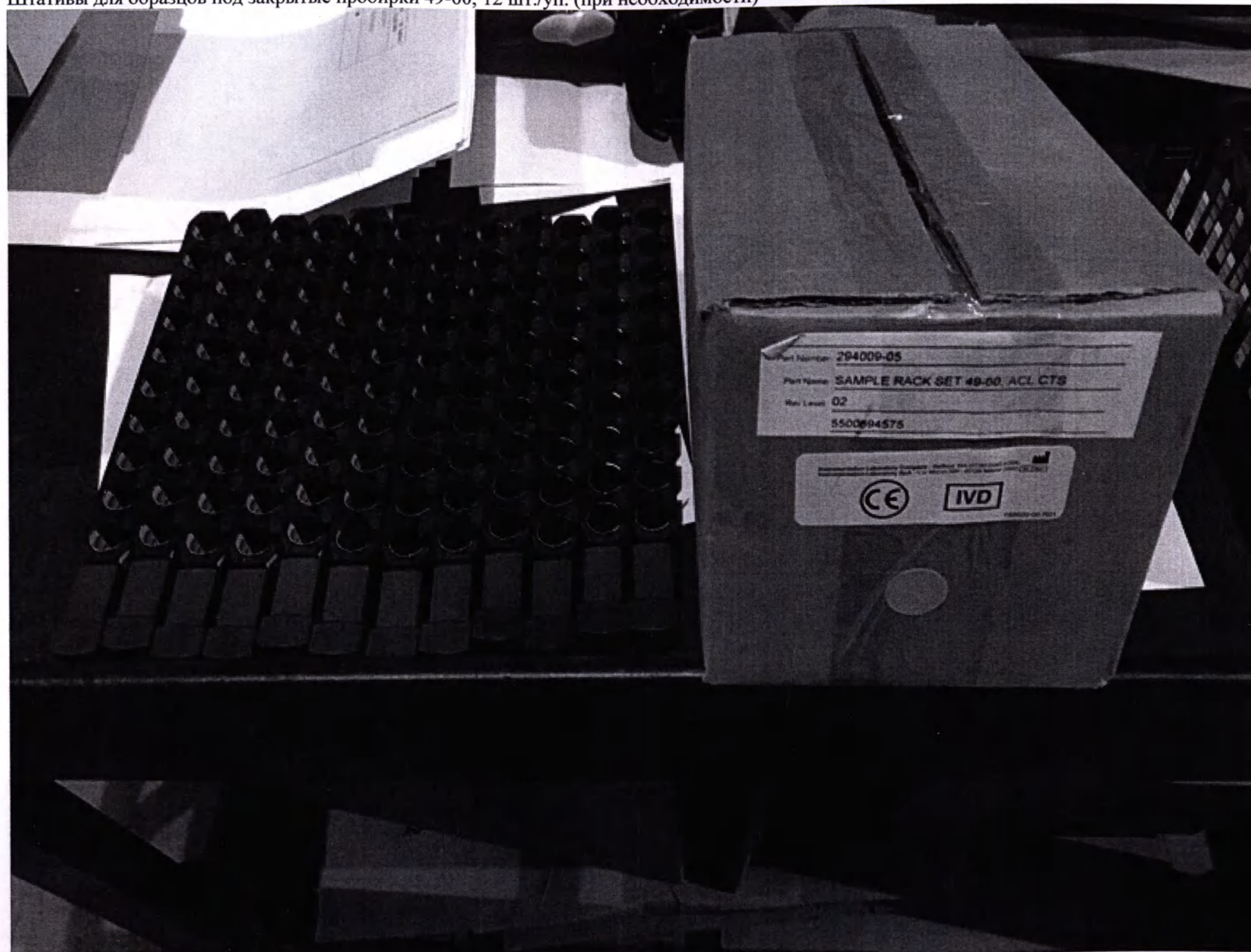
Штативы для образцов под закрытые пробирки 25-36, 12 шт./уп. (при необходимости)



Штативы для образцов под закрытые пробирки 37-48, 12 шт./уп. (при необходимости)



Штативы для образцов под закрытые пробирки 49-60, 12 шт./уп. (при необходимости)



Штативы для образцов под закрытые пробирки 61-72, 12 шт./уп. (при необходимости)



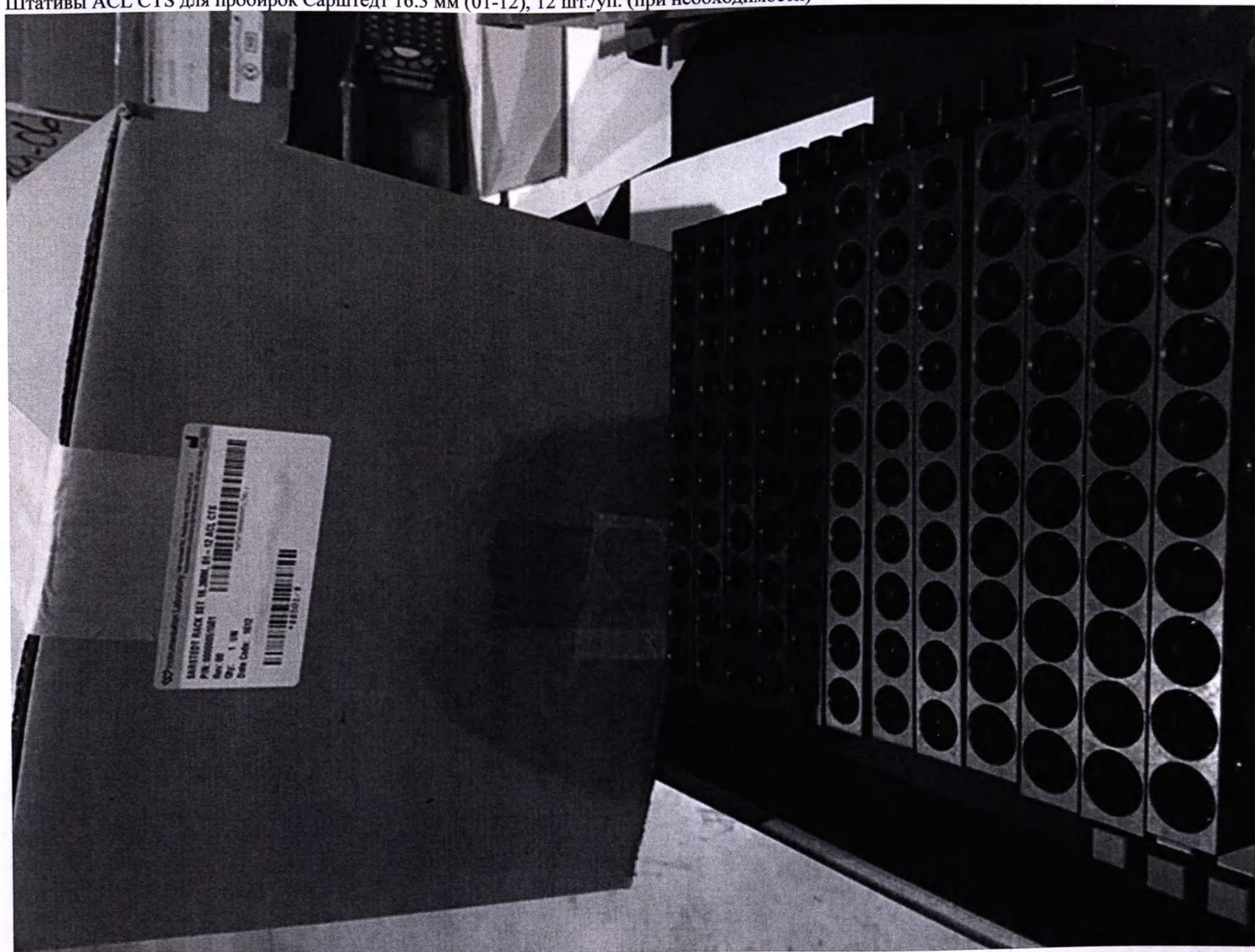
Штативы для образцов под закрытые пробирки 73-84, 12 шт./уп. (при необходимости)



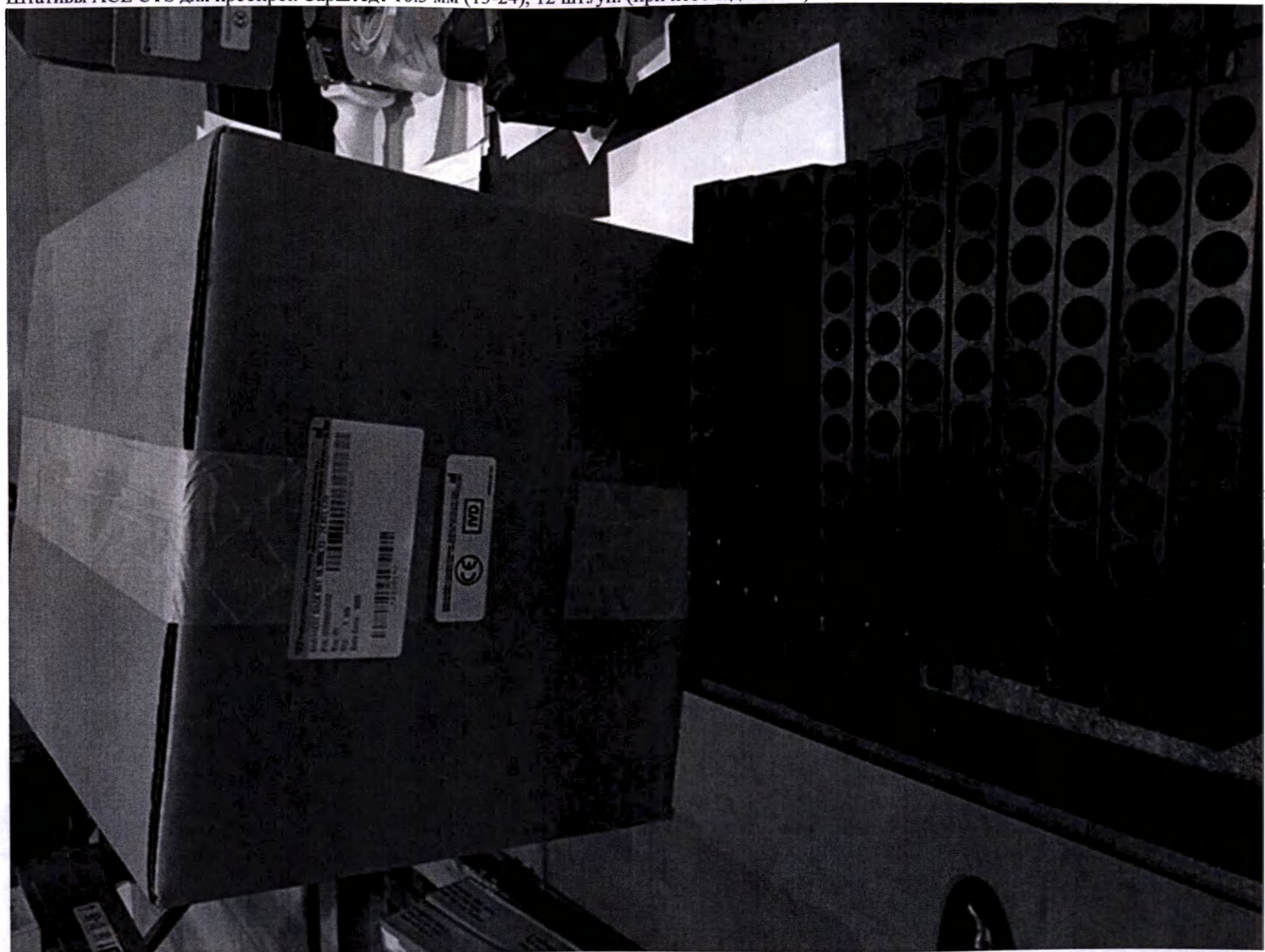
Штативы для образцов под закрытые пробирки 85-96, 12 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 16.3 мм (01-12), 12 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 16.3 мм (13-24), 12 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Саршедт 16.3 мм (25-36), 12 шт./уп. (при необходимости)



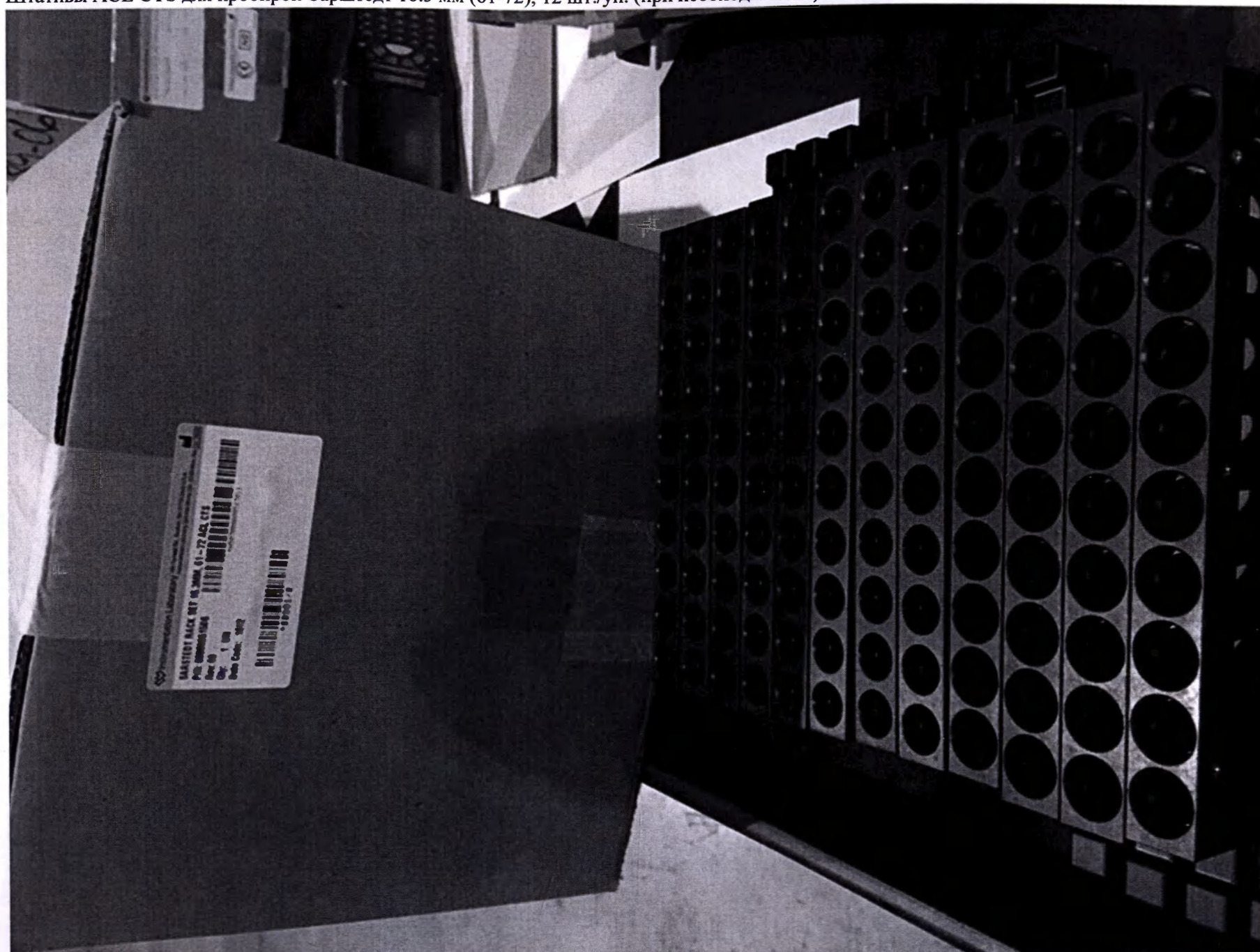
Штативы ACL CTS для пробирок Сарштедт 16.3 мм (37-48), 12 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 16.3 мм (49-60), 12 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 16.3 мм (61-72), 12 шт./уп. (при необходимости)



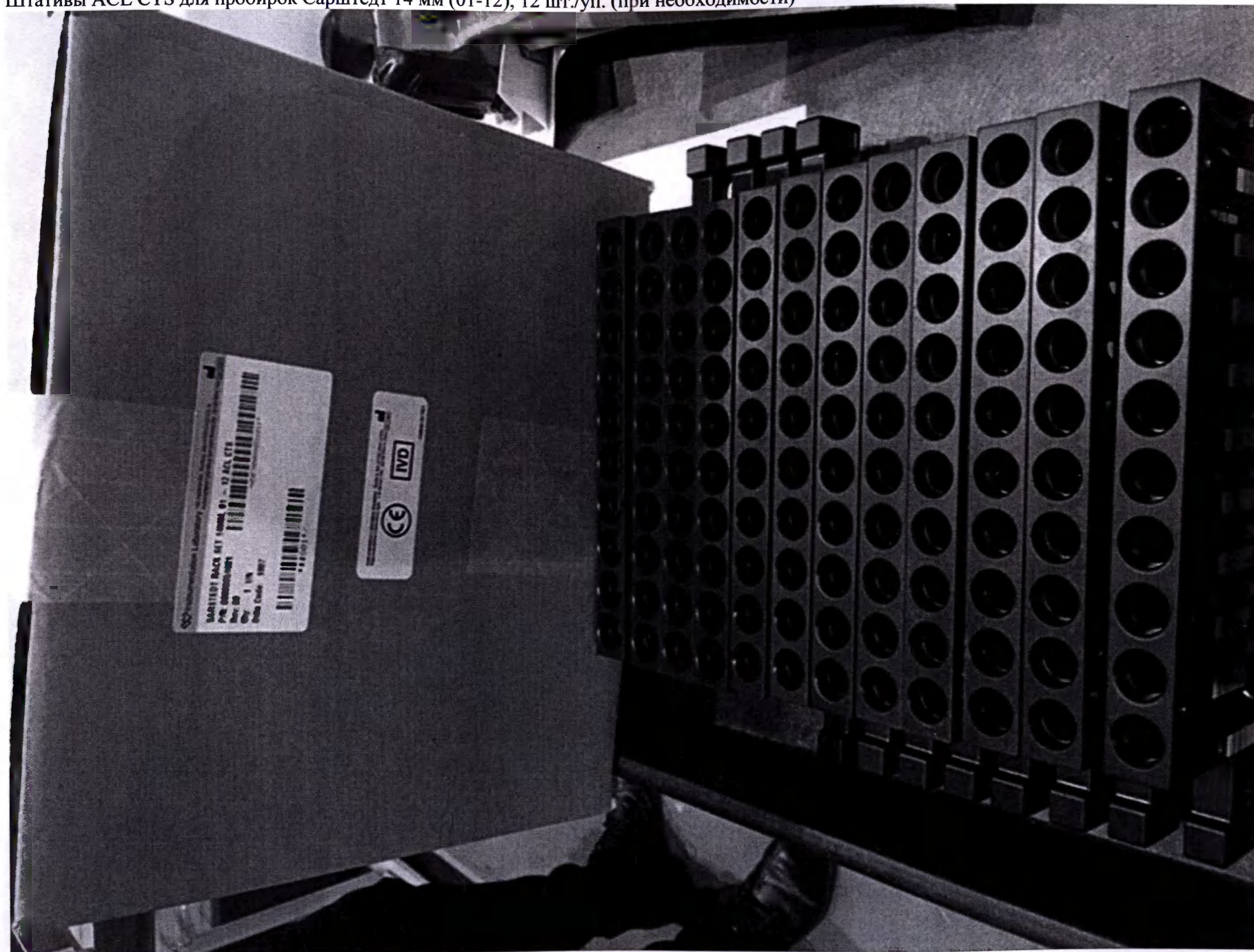
Штативы ACL CTS для пробирок Сарштедт 16.3 мм (73-84), 12 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 16.3 мм (85-96), 12 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Саршедт 14 мм (01-12), 12 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 14 мм (13-24), 12 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 14 мм (25-36), 12 шт./уп. (при необходимости)



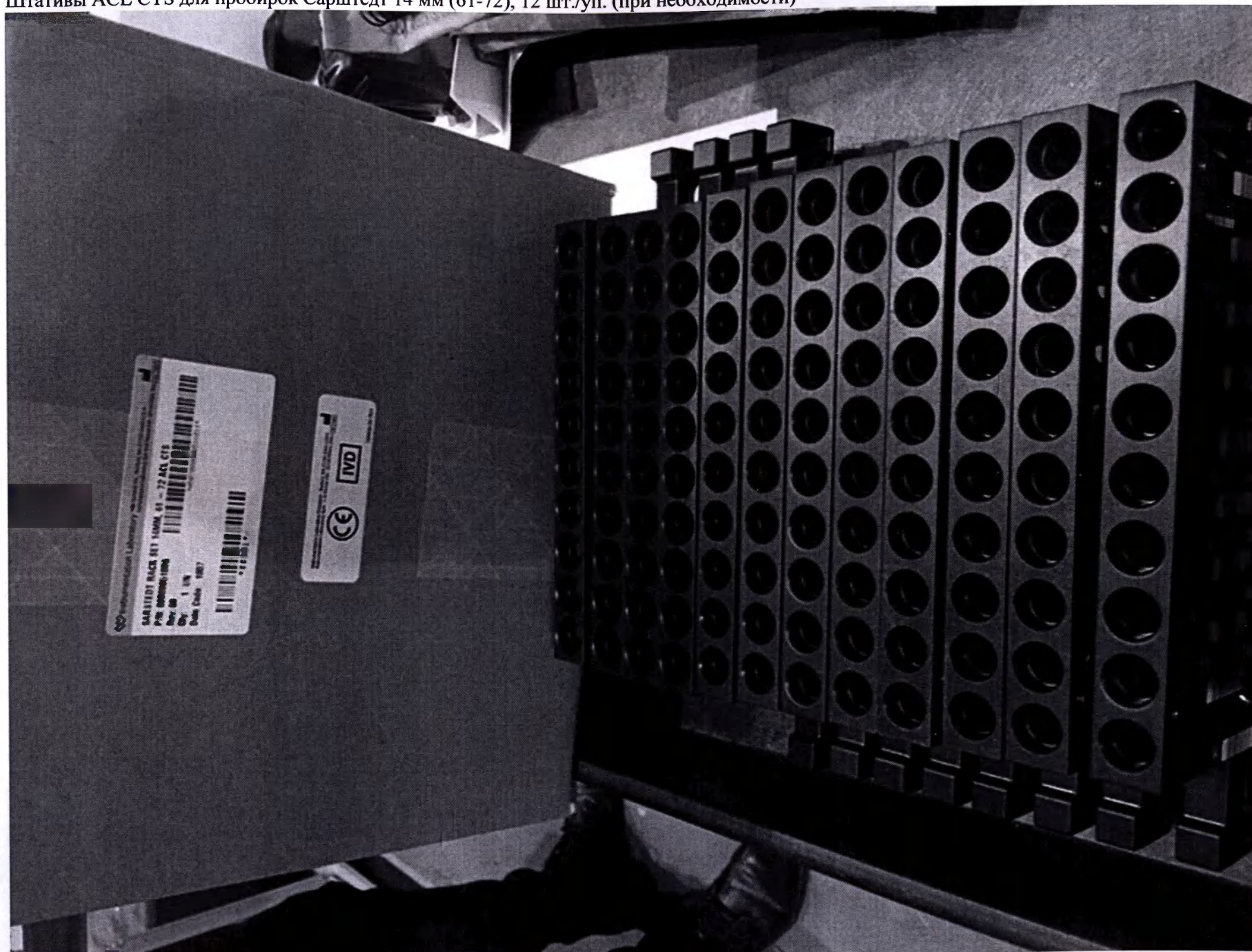
Штативы ACL CTS для пробирок Саршедт 14 мм (37-48), 12 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Саршедт 14 мм (49-60), 12 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 14 мм (61-72), 12 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Сарштедт 14 мм (73-84), 12 шт./уп. (при необходимости)



Штативы ACL CTS для пробирок Саршедт 14 мм (85-96), 12 шт./уп. (при необходимости)



Промышленности и торговли
№ 10

Директор Дорожного
Управления

