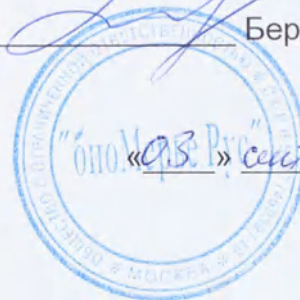


УТВЕРЖДАЮ

Генеральный директор

ООО «Биомерье Рус»

Бердникова Н.В.

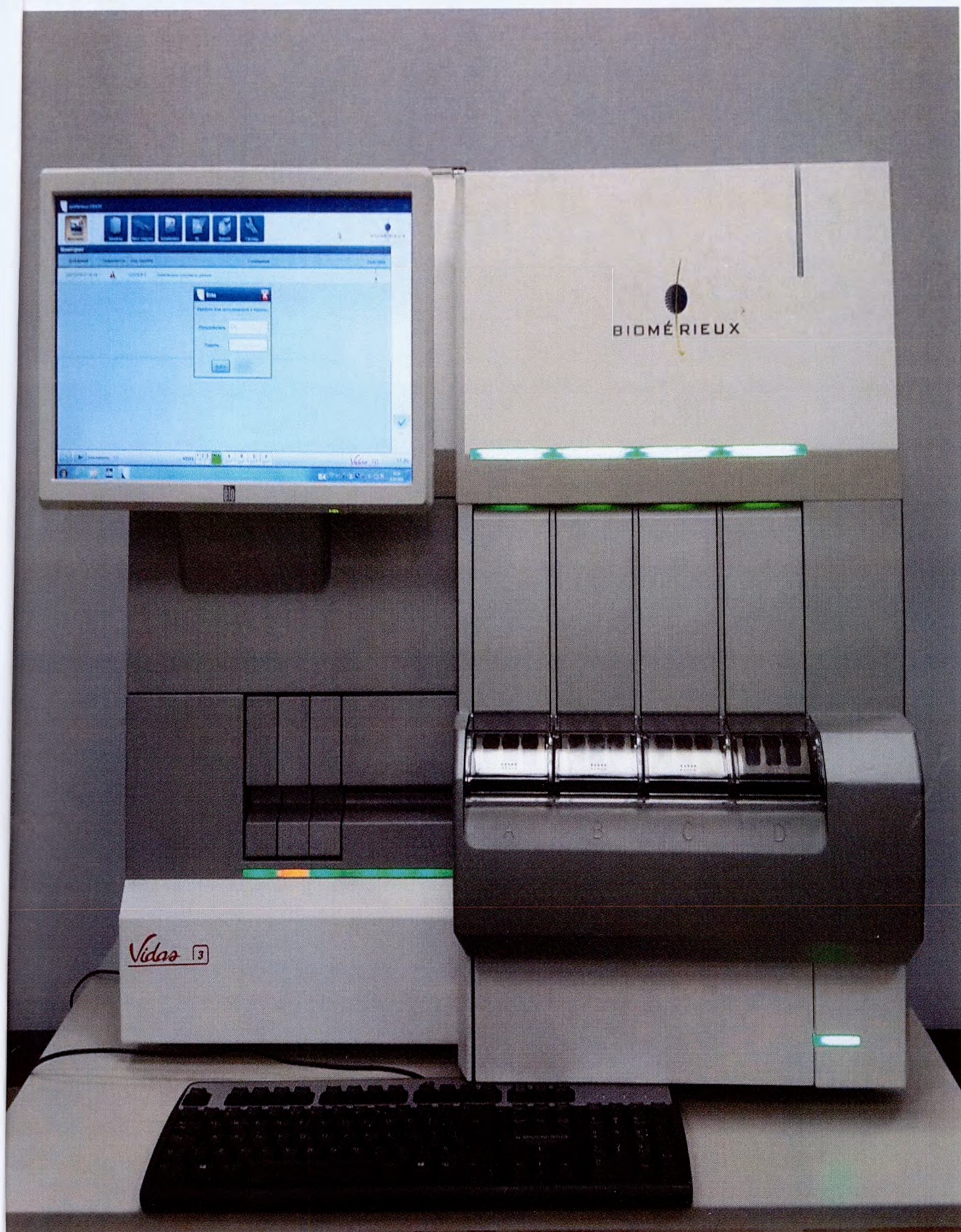


«03» сентября 2018 г.

## ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ МЕДИЦИНСКОГО ИЗДЕЛИЯ

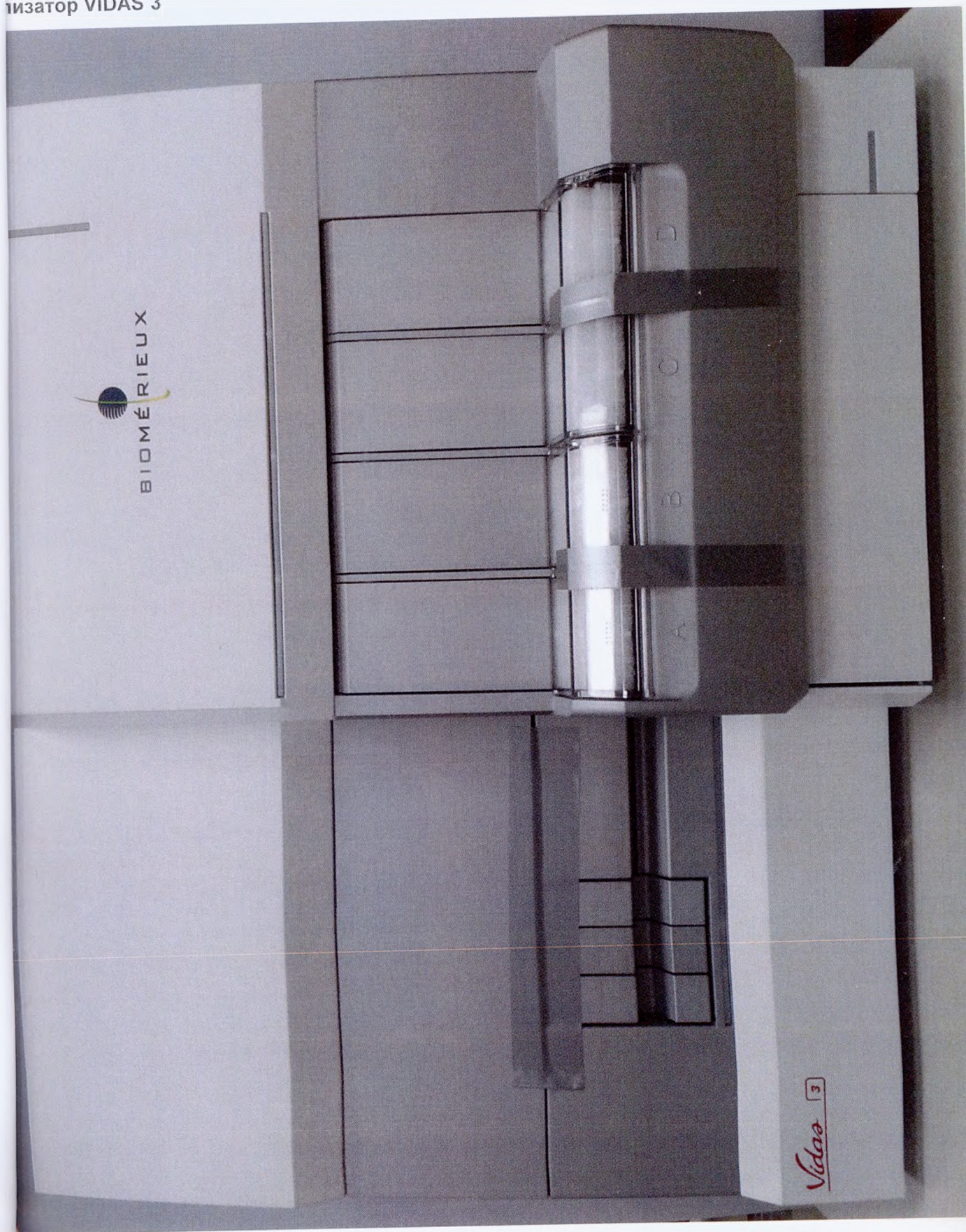
«Анализатор иммунологический VIDAS 3 для диагностики in vitro клинических образцов  
методом иммуноферментного флуоресцентного анализа»  
с принадлежностями





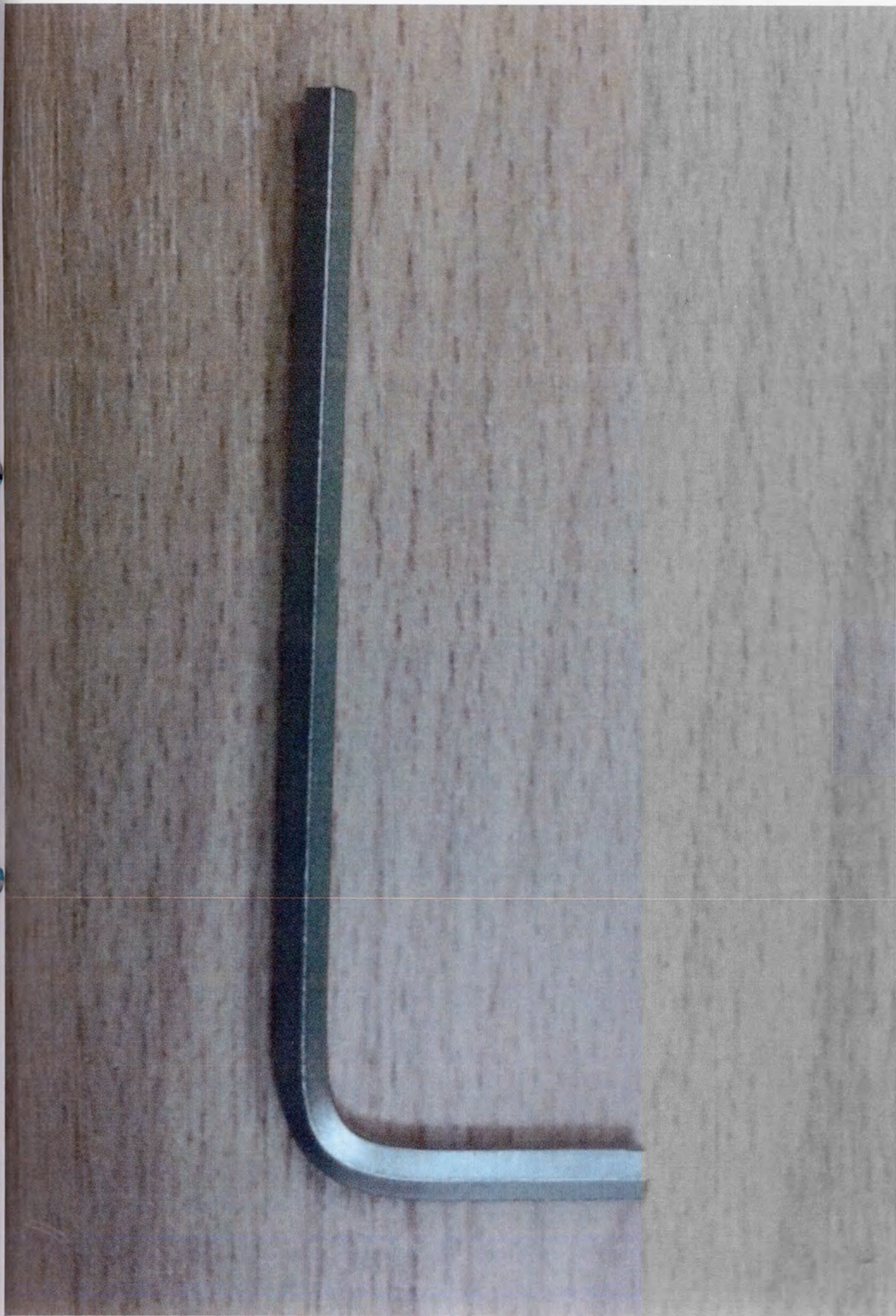












BIOMÉRIEUX

| PRODUCT CERTIFICATE / CERTIFICAT PRODUIT |                                                                    |
|------------------------------------------|--------------------------------------------------------------------|
| Manufacturer /<br>Fabricant:             | BioMérieux SA<br>Chemin de l'Orme<br>69280 Marcy l'Etoile - France |
| Product name /<br>Nom du produit:        | VIDAS® 3                                                           |
| Reference /<br>Référence:                | 412590                                                             |
| Numéro de série /<br>Serial number:      | VN04390                                                            |

This product has been developed and is manufactured in accordance with the provisions of ISO 9001 and ISO 13485 certified Quality System and with Quality System Regulation requirements (21 CFR 820 - US FDA).  
 This product is CE marked according to Directive 98/79/EC on in vitro diagnostic medical devices.  
 This product has been tested by an independent testing agency with regards to safety and electromagnetic compatibility requirements and shows compliance with the standards mentioned below:  
 Ce produit a été développé et est fabriqué conformément à notre Système Qualité certifié ISO 9001 et ISO 13485, et conformément aux exigences du Quality System Regulation (21 CFR 820 - US FDA).  
 Ce produit est marqué CE selon la directive 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.  
 Ce produit a été contrôlé aux exigences de sécurité et de compatibilité électromagnétique par un organisme de test indépendant, et est conforme aux normes mentionnées ci-après:

| Safety/EMC European Standards<br>Normes européennes de Sécurité et de CEM                                                                                                                                                                                                                                                                                                                                                                                                 | Testing Agency<br>Organisme de test |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| EN 61010-1:2001; EN 61010-2-10: 2003 EN 61010-2-081:2002; EN 61010-2-101:2002;<br>EN 60825-1:2007; EN 62471:2008<br>EN 61326-1: 2006; EN 61326-2-6: 2006<br>(including / comprenant: EN 55011:1998+A1:1999+A2:2002 Class/Classe A; EN 61000-4-2:1995+A1:1999+A2:2001;<br>EN 61000-4-3: 2002; EN 61000-4-4: 2004; EN 61000-4-5:1995+A1:2001; EN 61000-4-6:1995+A1:2001;<br>EN 61000-4-8: 1993+A1: 2001; EN 61000-4-11: 2004; EN 61000-3-2:2006; EN 61000-3-3:1995+A1:2001) | IMQ - ITALY                         |
| Other International Standards<br>Autres normes internationales                                                                                                                                                                                                                                                                                                                                                                                                            | Testing Agency<br>Organisme de test |
| IEC 61010-1:2001; IEC 61010-2-10: 2003; IEC 61010-2-081:2001+A1:2003; IEC 61010-2-101:2002;<br>IEC 60825-1:2007; IEC 62471:2006<br>UL 61010-1 (2nd Edition);<br>CSA C22.2 No 61010-1 (2nd Edition); CSA C22.2 No 61010-2-010-04; CSA C22.2 No 61010-2-081-04;<br>CSA C22.2 No 61010-2-101-04<br>CFR 47 part 15 :2009 subpart B; IEC 61326-1: 2005; IEC 61326-2-6: 2005; IEC 61326-1: 2012; IEC<br>61326-2-6: 2012                                                         | IMQ - ITALY                         |



This product bears the mark / Ce produit porte la marque :

| QA/RA Departement/Aff. Règlement. & Ass. Qualité: | Site           | Date       |
|---------------------------------------------------|----------------|------------|
|                                                   | Florence-Italy | 2015-10-26 |
| Name/Nom: Massimo Baroncelli                      | Signature:     |            |

After the final stage of production, this product was controlled using the protocols mentioned below and meets bioMérieux specifications.

En fin de production, ce produit a été contrôlé selon les protocoles mentionnés ci-après et satisfait aux spécifications de bioMérieux.

| Protocol reference<br>Référence du protocole | Protocol version<br>Version du protocole | Approved on<br>Date d'approbation |
|----------------------------------------------|------------------------------------------|-----------------------------------|
| VN0304                                       | G                                        | 2015-01-13                        |

All information, protocols and tests results are bioMérieux property and must not be diffused. They are recorded and kept on file at bioMérieux and are available for review by regulatory and legal authorities.

This product is therefore suitable for use as defined in the appropriate manual(s).

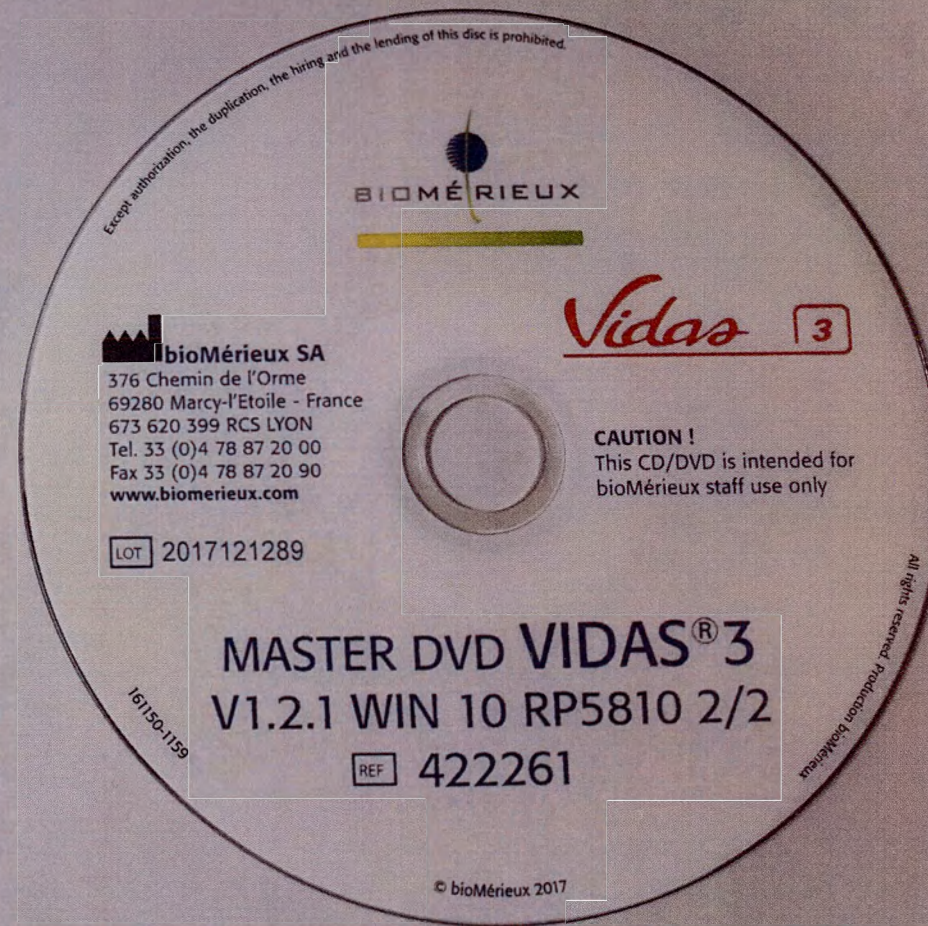
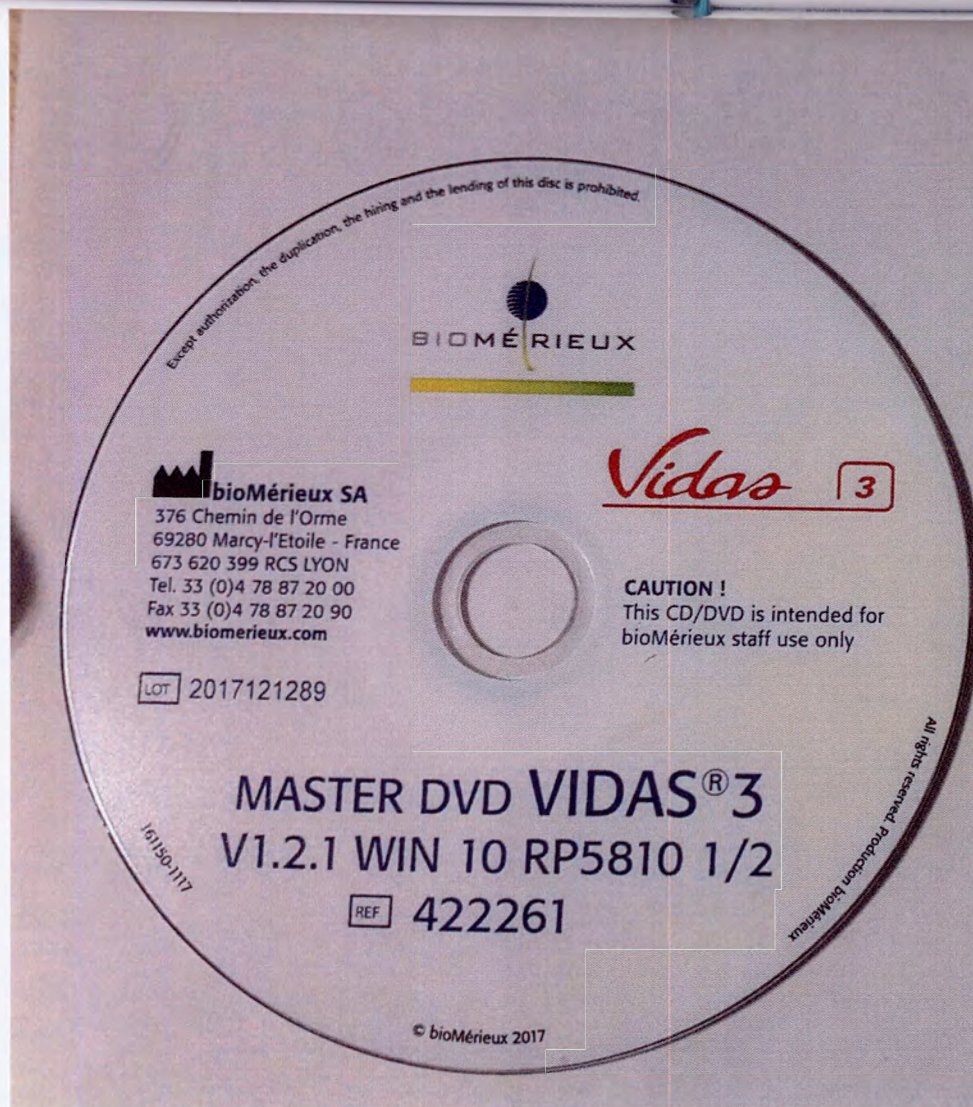
Les informations, protocoles et résultats de tests sont la propriété de bioMérieux et ne sont pas destinés à être diffusés. Ils sont enregistrés et conservés chez bioMérieux et sont disponibles en cas d'inspection par les autorités légales et réglementaires. Ce produit est donc conforme pour une utilisation telle que définie dans le(s) manuel(s) le concernant.

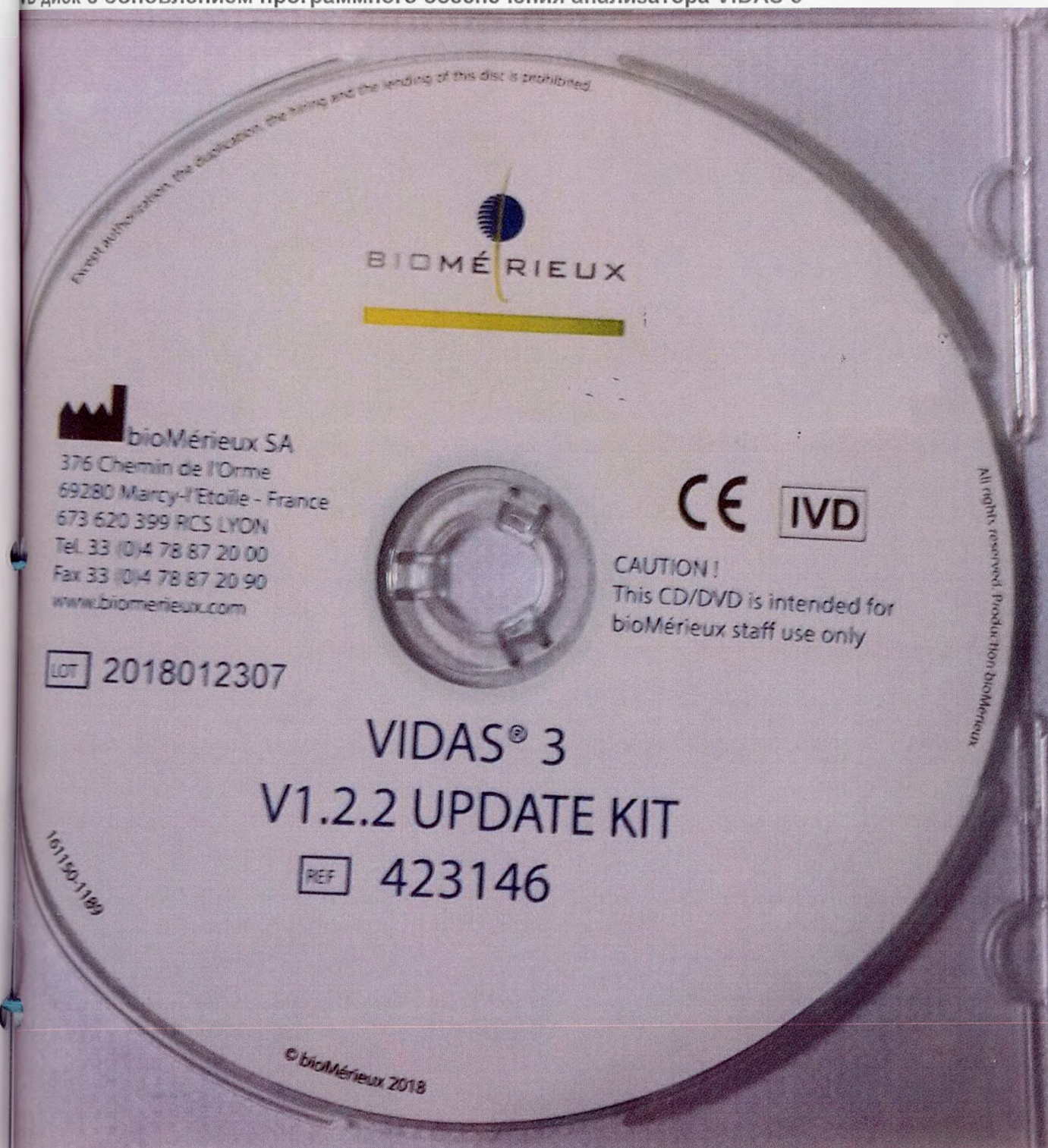
| Manufacturing Department/Unité de production: | Site           | Date       |
|-----------------------------------------------|----------------|------------|
| On behalf of/Au nom de: bioMérieux SA         | Florence-Italy | 2016-02-09 |
| Name/Nom: Paolo Labrini                       | Signature:     |            |

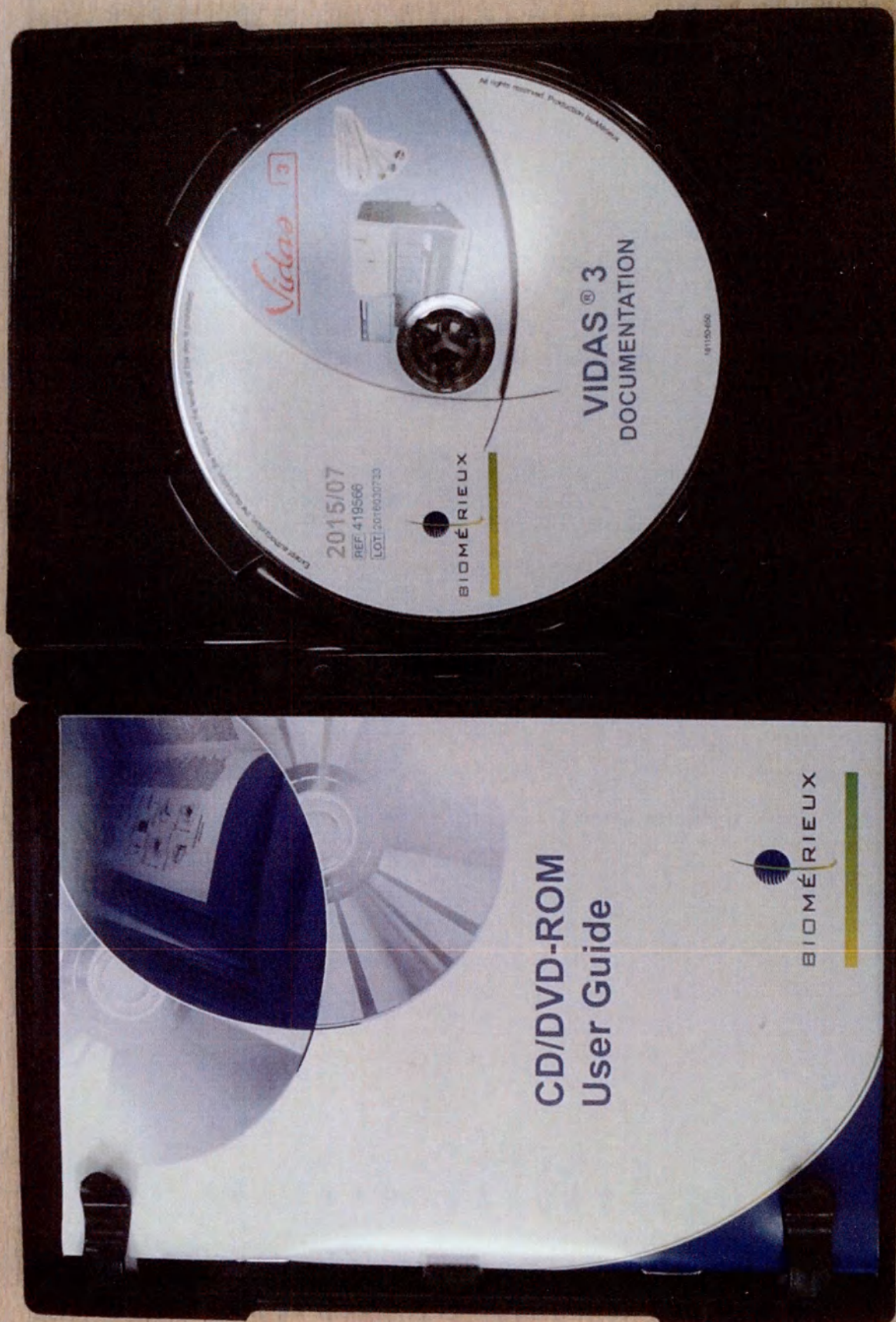
MM/VN0303 Rev.F

bioMérieux Italia S.p.A.

Sede Legale Via di Campighiano, 5B Loc. Ponte a Ema - 50012 Bagno a Ripoli (FI) Italia  
 Tel. +39 055 64497 / Fax +39 055 643025 / www.biomérieux.it  
 Capitale Sociale € 9.000.000 i.v. Socio Unico / n. REA FI 443558 / C.F. 07146020586 / P.IVA 01695821006  
 Iscrizione Registro AEE n° IT0802000001774

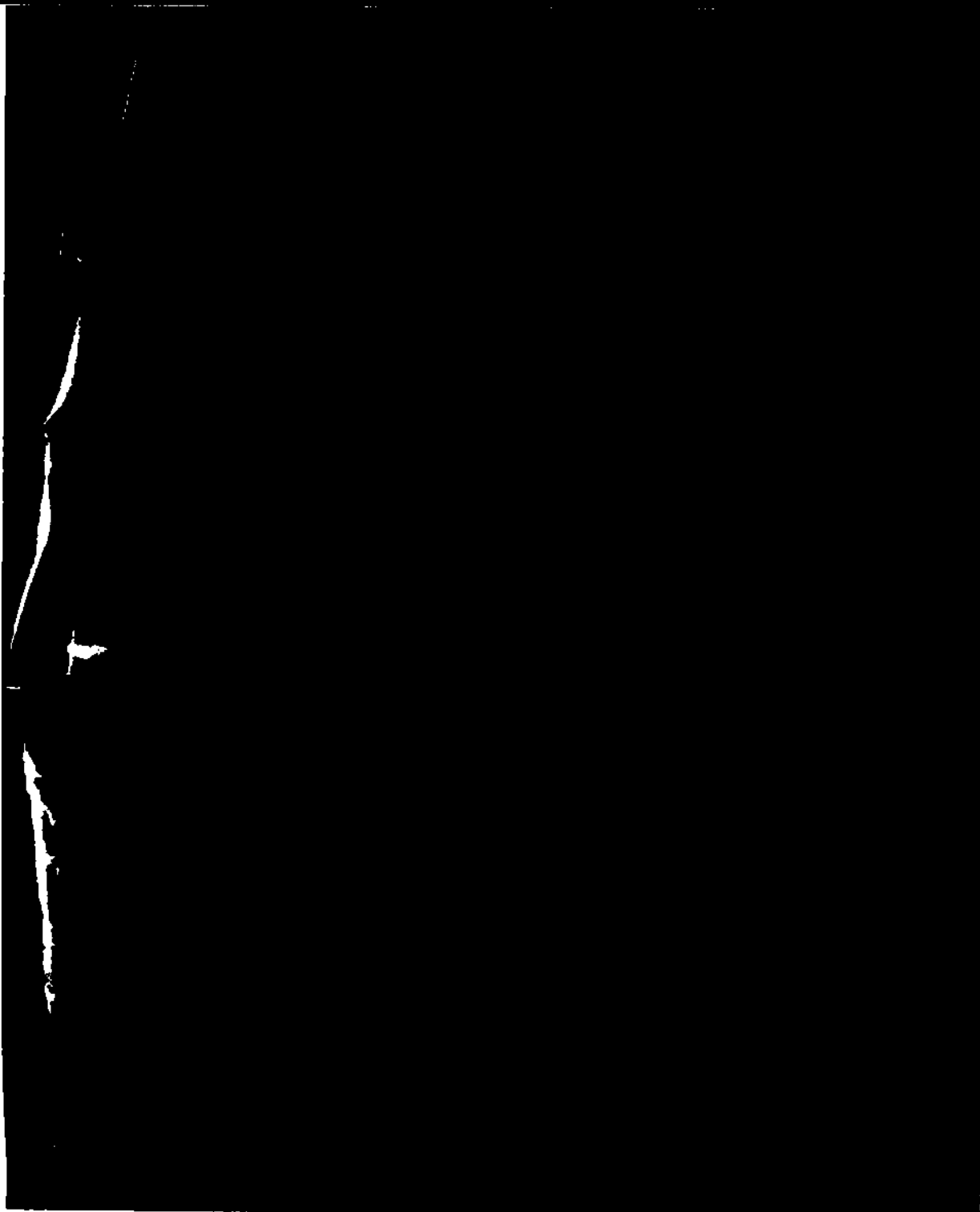
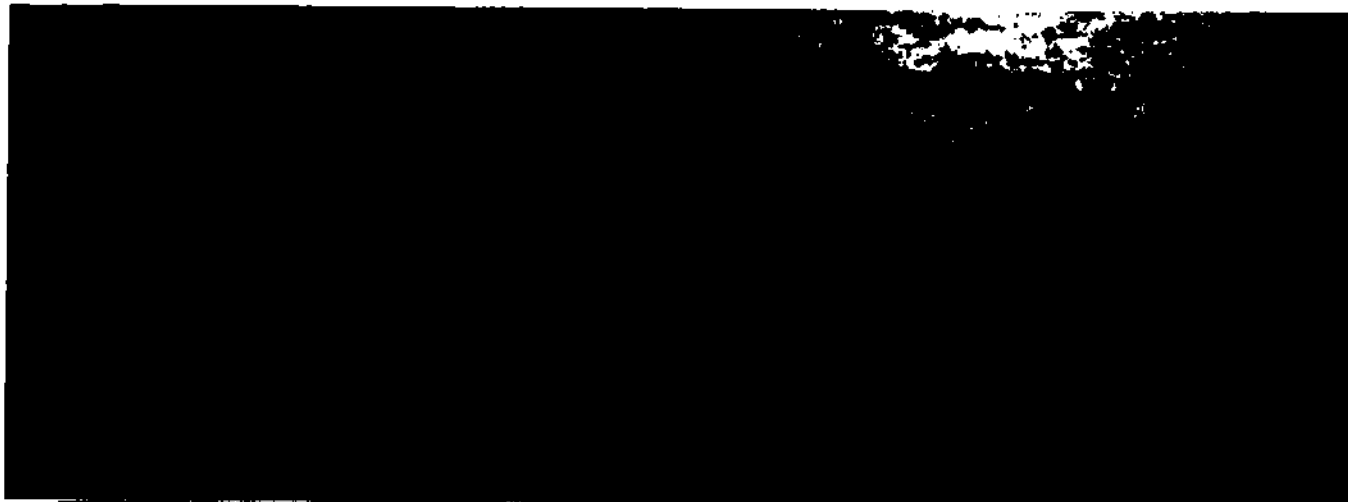


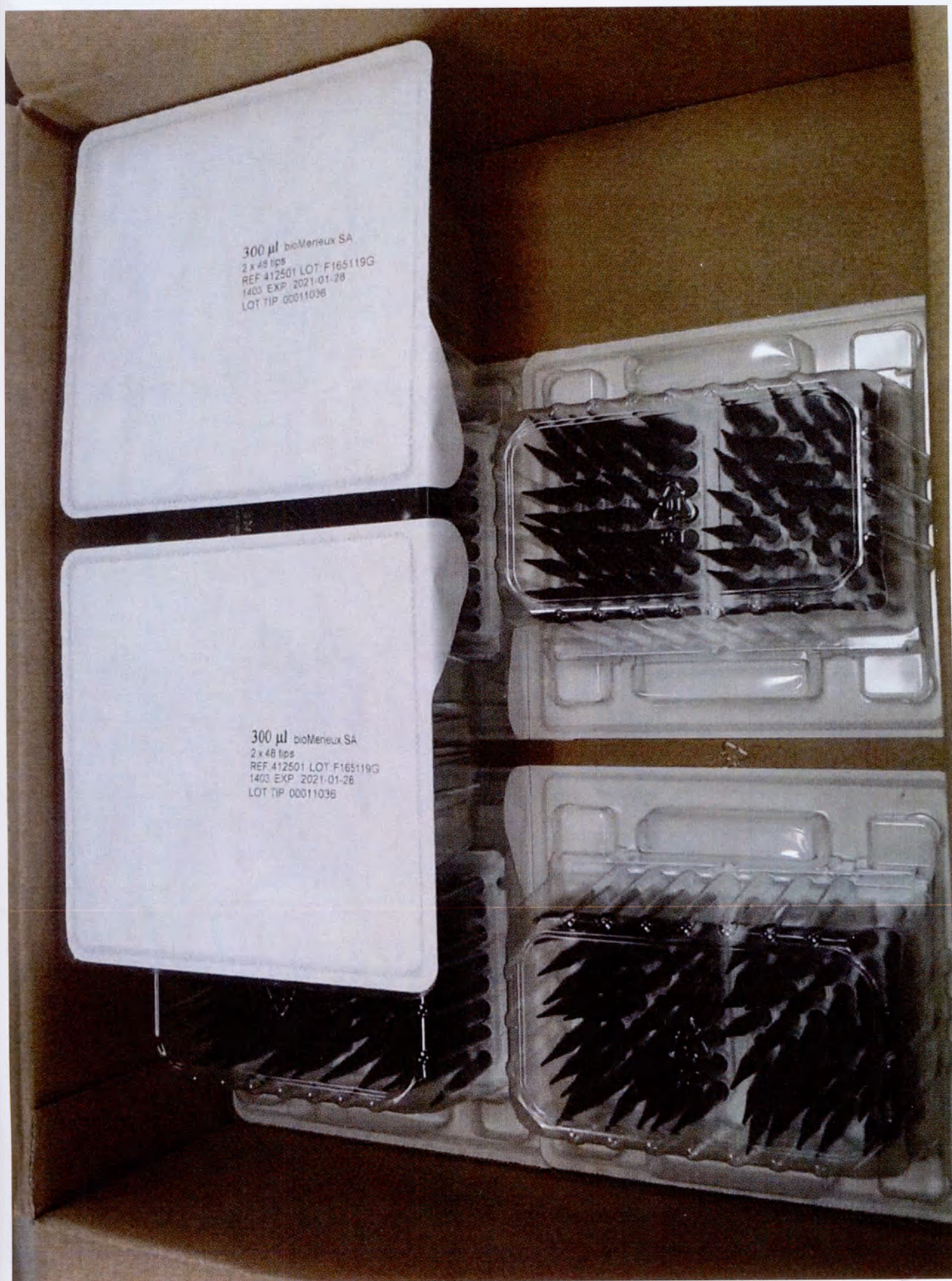






Лопатки на 16 лунок для разведения образцов, 44 шт./уп.;





Контейнер для сбора отходов, 50 шт./уп.;



емкости для реагентов (пустые);



Источник бесперебойного питания, с кабелями для подключения и сопроводительной документацией;



### Safety and General Information

- Inspect the package contents upon receipt. Notify the carrier and dealer if there is any damage.
- Read the Safety Guide supplied with this unit before installing the UPS.
- Pathways to all national and local electrical codes.
  - This UPS is intended for indoor use only.
  - Do not operate the UPS in areas subject to dust, dirt, or other contaminants.
  - Do not use the unit as the UPS will not be damaged. Allow adequate space for proper ventilation.
  - The battery typically lasts for two to four years. Improper use may reduce battery life. Use and follow all instructions, proper quality safety procedures and keep the unit away from children.
  - Connect the UPS power cable directly to a wall outlet. Do not use surge protectors or extension cords.
  - The equipment is heavy. Always practice safe lifting techniques to avoid injury to the weight of the equipment.
  - The model and serial numbers are printed on a name plate on the front. The name plate is attached to the front of the unit.
  - Always use proper safety procedures.
  - Retain the package materials in case they are needed.

### Certificate of Compliance / Certificat de Conformite

Name: APC 1500-VA (1.5kVA)

|                           |                           |
|---------------------------|---------------------------|
| Compliance EN: EN 60950-1 | Product Name: UPS 1500-VA |
| Manufacturer Ref: 1500-VA | Version: 1.0              |

This product has been manufactured and tested in accordance with the specifications and procedures of compliance with CE 2007 standards for Quality Systems and with the standards of Systeme Qualite ISO 9001 for European manufacturers.

On product is not manufactured or modified under the specifications of compliance with the standards of Systeme Qualite ISO 9001 for European manufacturers.

At the final stage of production, the above referenced product is not 1500-VA.

As the final stage of production, the above referenced product is not 1500-VA.

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Product Ref: 1500-VA (1.5kVA)

Product Name: UPS 1500-VA (1.5kVA)

Product Version: 1.0

Product Name: UPS 1500-VA (1.5kVA)

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Product Name: UPS 1500-VA (1.5kVA)

интер, в комплекте;



шрутизатор, с кабелями для подключения, USB-накопителем и сопроводительной документацией:





AVB Allied Telesis

# China RoHS HS/TS Substances Concentration Chart

中国 RoHS 有害 / 有害物质浓度表

Information on HS/TS Substances According to Chinese Standards  
In accordance with China's Administrative Measures on the Control of Pollution Caused by Electrical, Electronic Products, also known as China RoHS, the following information is provided regarding the names and concentration levels of Toxic Substances (TSPs) and Heavy Metals (HMs) that may be contained in products from Allied Telesis Inc. relative to EU standards by China's Ministry of Information Industry (MI).

| Substance | Concentration |
|-----------|---------------|
| Cd        | 100ppm        |
| Pb        | 100ppm        |
| Hg        | 100ppm        |
| Cu        | 100ppm        |
| Cr        | 100ppm        |
| Co        | 100ppm        |
| Fe        | 100ppm        |
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| Al        | 100ppm        |
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| Lu        | 100ppm        |
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| Y         | 100ppm        |
| Zr        | 100ppm        |
| Nb        | 100ppm        |
| Mo        | 100ppm        |
| Tc        | 100ppm        |
| Ru        | 100ppm        |
| Rh        | 100ppm        |
| Pd        | 100ppm        |
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| Cu        | 100ppm        |
| Cd        | 100ppm        |
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| Zr        | 100ppm        |
| Nb        | 100ppm        |
| Mo        | 100ppm        |
| Tc        | 100ppm        |
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| Rh        | 100ppm        |
| Pd        | 100ppm        |
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| Hg        | 100ppm        |
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| Pr        | 100ppm        |
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| Pm        | 100ppm        |
| Sm        | 100ppm        |
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| Tm        | 100ppm        |
| Yb        | 100ppm        |

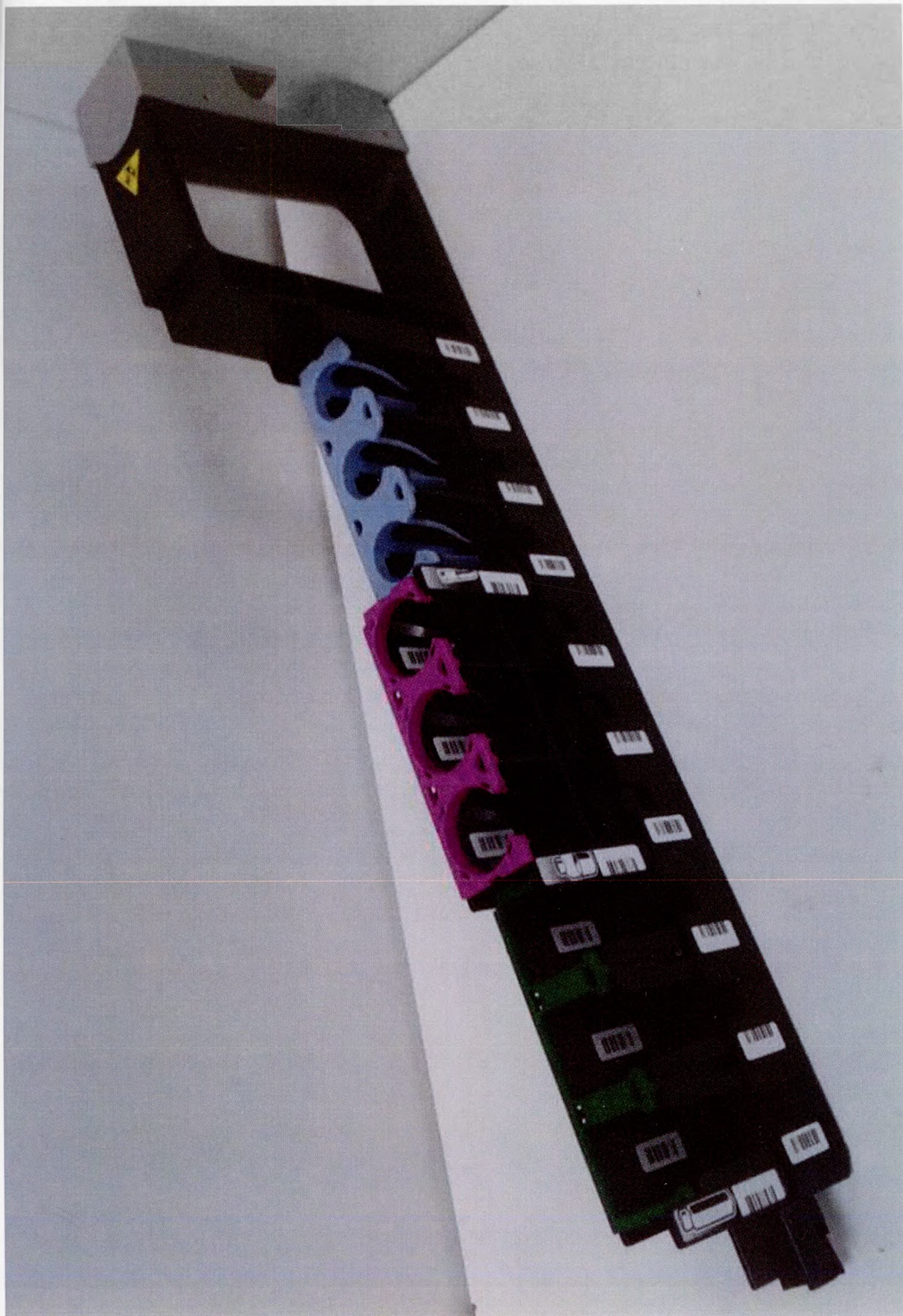


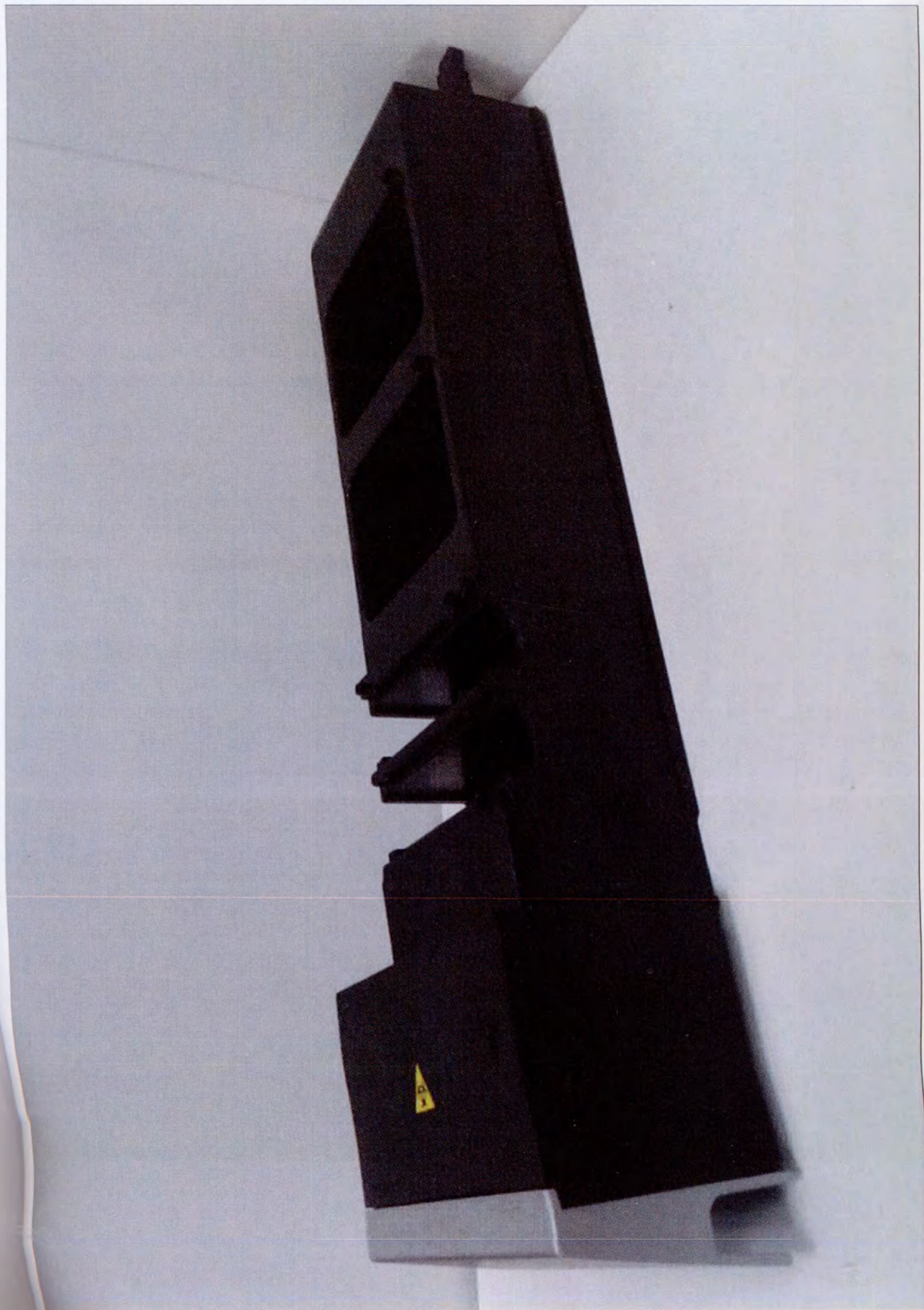




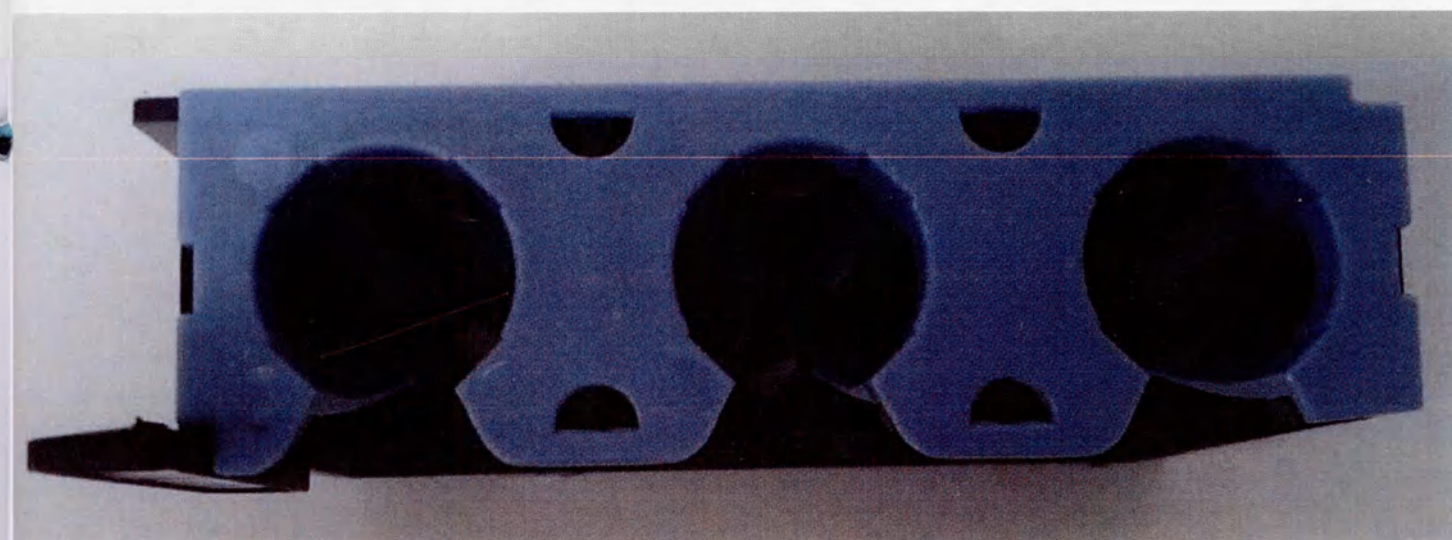
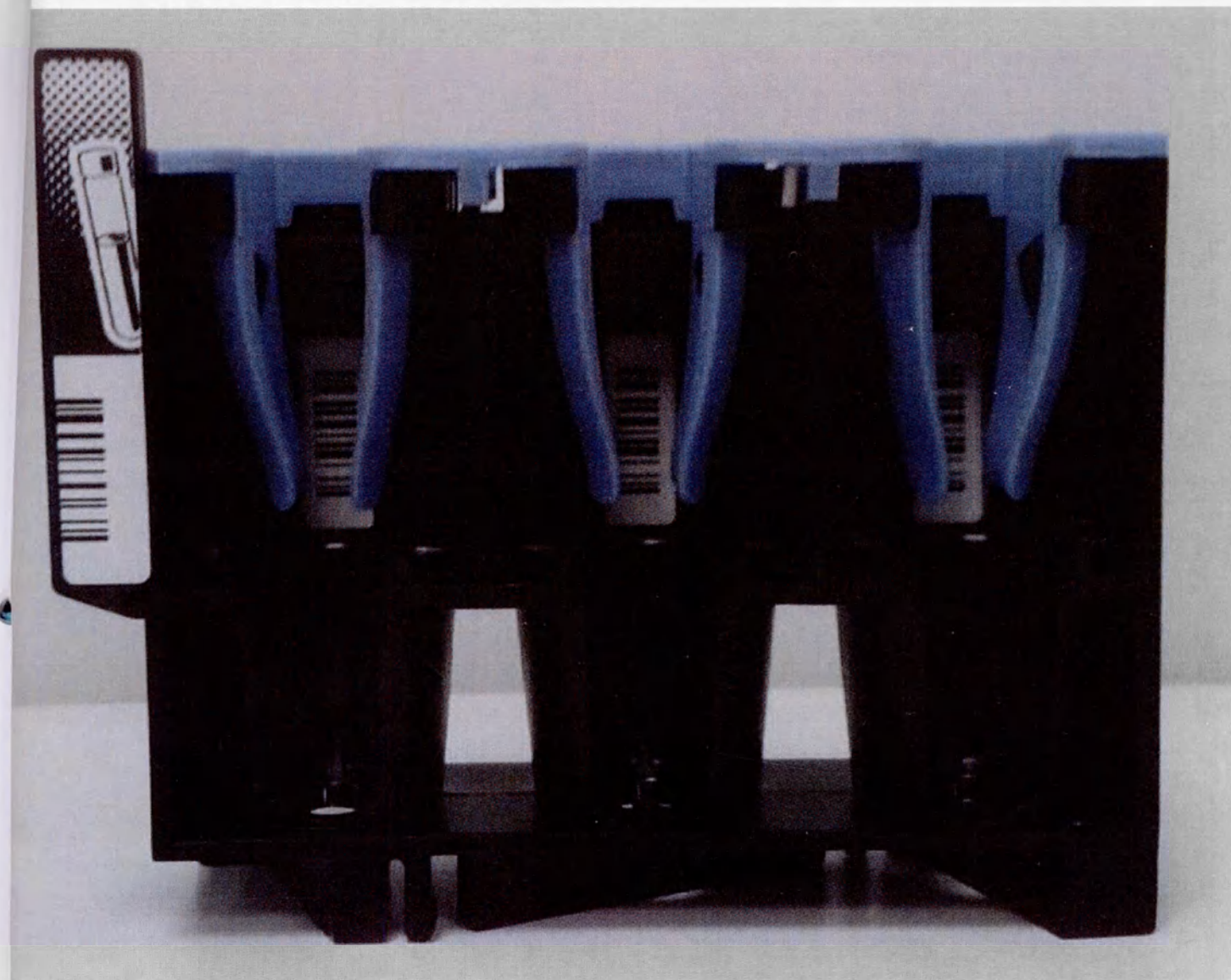


атив для образцов и реагентов:





егмент штатива для пробирок с образцами и пробирок для аликвоты;



мент штатива для флаконов с реагентами объемом 4–8 мл.;



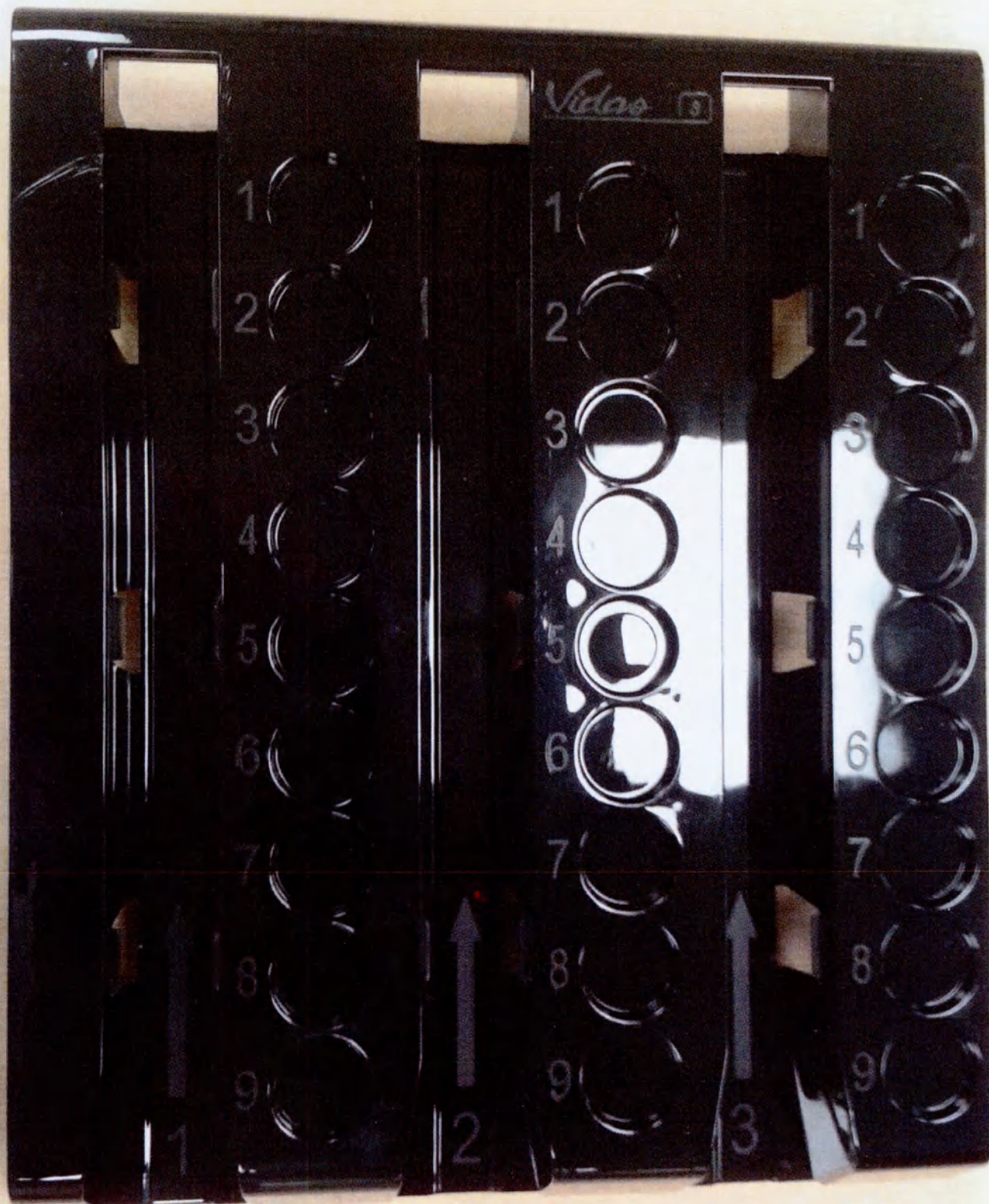
Элемент штатива для флаконов с разбавителями объемом 27 мл.;





РИНАДЛЕЖНОСТИ:

оток держателя штатива;



тилус;



Прошито и пронумеровано  
34 листов

"03" сентября 2018 года

Генеральный директор  
Бердникова Н.В.

