

ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ
МЕДИЦИНСКОГО ИЗДЕЛИЯ

АНАЛИЗАТОР АВТОМАТИЧЕСКИЙ ДЛЯ ОПРЕДЕЛЕНИЯ
СКОРОСТИ ОСЕДАНИЯ ЭРИТРОЦИТОВ (СОЭ) ROLLER 20,
МОДЕЛЬ ROLLER 20 PN С ПРИНАДЛЕЖНОСТЯМИ



Фото 1. Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ) ROLLER 20, модель ROLLER 20 PN с принадлежностями (нумерация принадлежностей согласно перечню).

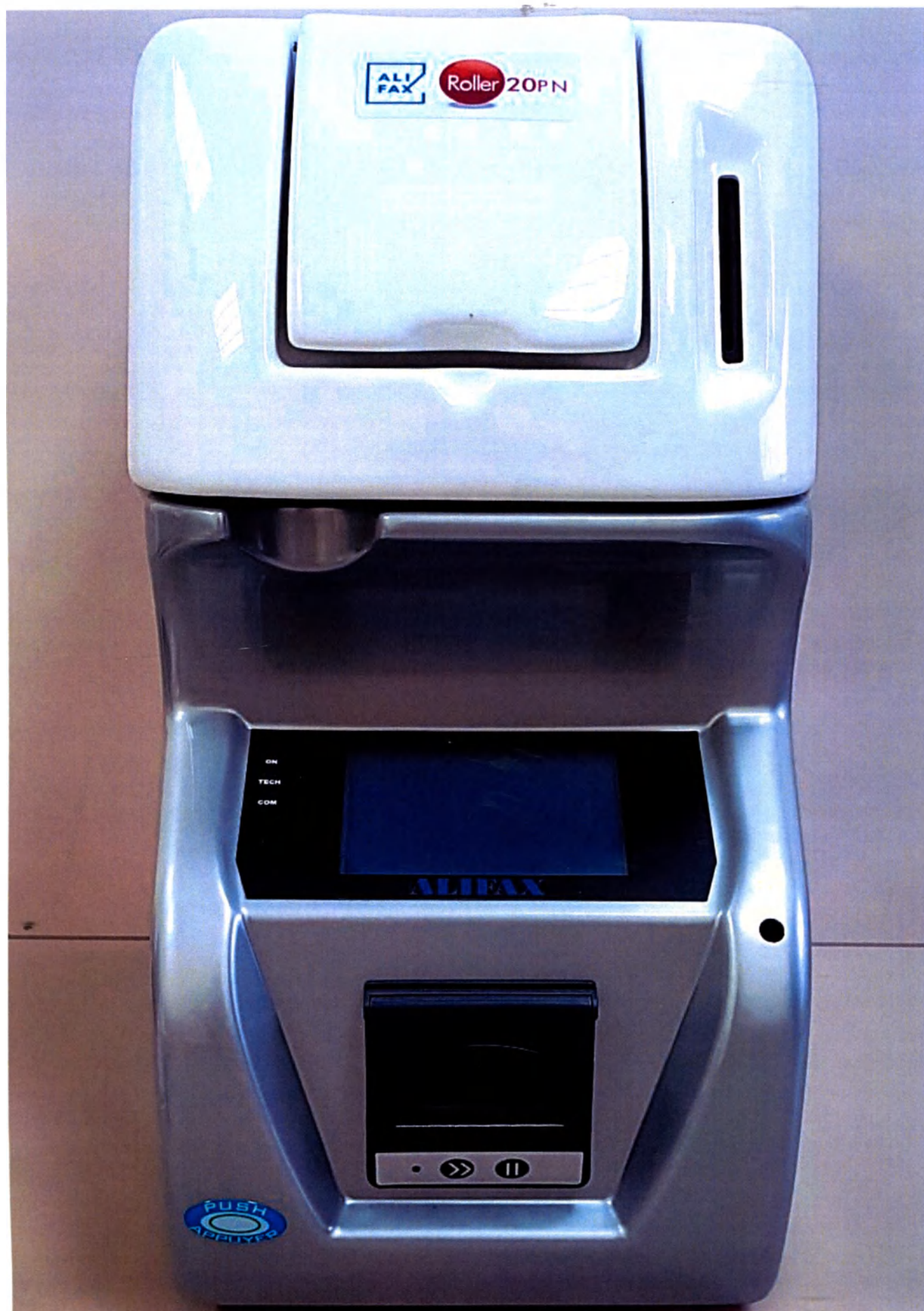


Фото 2 Анализатор автоматический для определения скорости оседания
субстратов (СОЗ) ROLLER 20, модель ROLLER 20 PN. Вид спереди.



Фото 3 Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ) ROLLER 20, модель ROLLER 20 PN. Вид сзади.



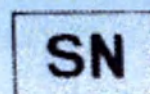
ROLLER 20



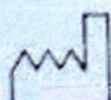
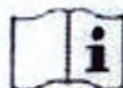
(01) 0 8056040 14034 5



SI R20-PN



R202278PN2



2022-04-20



115/230 V~ 50/60 Hz 115/150 VA

(x2) T2A L 250V 5x20mm



16 kg

(for USA and Canada 115 VAC only)

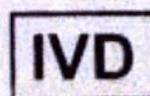
(pour USA et Canada seulement à 115CAV)



Dimensions (LxWxH):
24x39x46 cm



Alifax S.r.l.
via Merano, 30 - 33046
NIMIS (UD) - ITALY



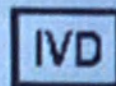
Rx ONLY (USA)
Made in ITALY

ESR IL SIR20PN ROLLER20PN 2-1

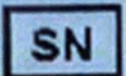
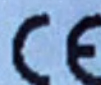
Фото 4. Оригинальная этикетка на анализаторе.



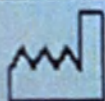
Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ)
ROLLER 20, модель ROLLER 20 PN



№ по каталогу SI R20-PN



Серийный номер: R202278PN2



2022-04-22

Сделано в Италии

РУ №ФСЗ 2010/06240 от XXXXX



Электропитание ~115/230 В, 50/60 Гц, 115/160 ВА

Алифакс С.р.л.

Юр.адрес Алифакс С.р.л.:

Виа Мерано, 30, 33045 Виа Петрарка, 2/1, 35020

Нимис (УД), Италия Польверара (ПД), Италия

Уполномоченный представитель изготовителя в РФ - ООО "Алифакс"
125367, г. Москва, ул. Габричевского, д.5. к. 1, комната 4-5, 21-22, 3-эт,
пом. 1 +7(495)-544-50-55, info.russia@alifax.com

Фото 5. Дополнительная русскоязычная этикетка на анализаторе.

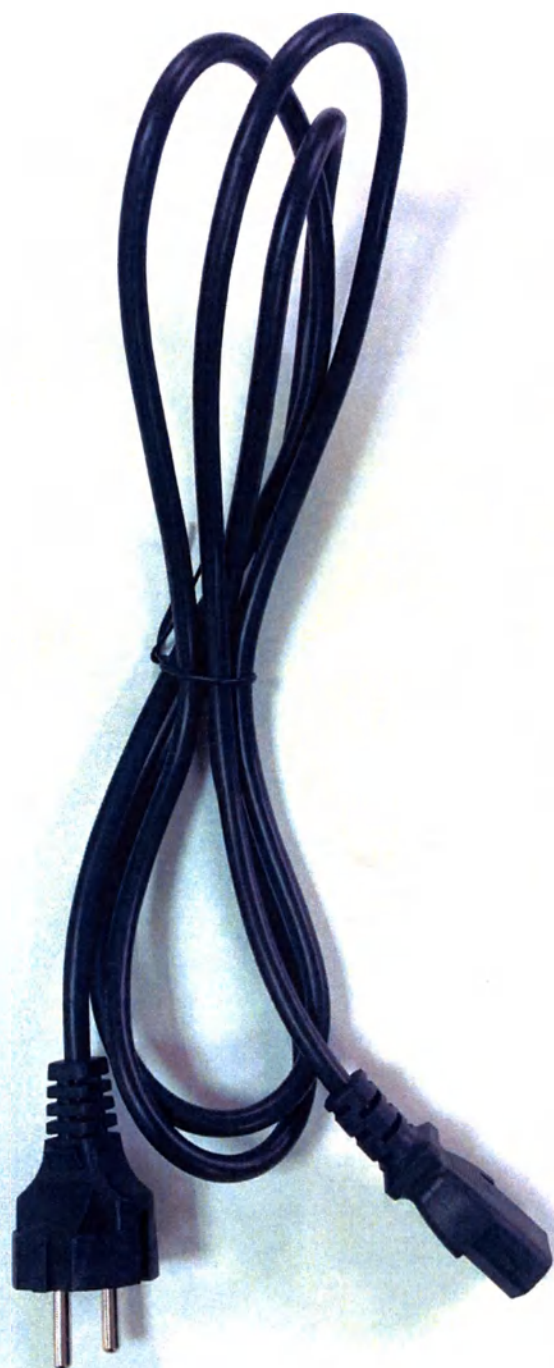


Фото 6. Кабель питания.



Фото 7. Резервуар для промывки.



Фото 8. Резервуар для отходов.



Фото 9. Термобумага в рулоне.

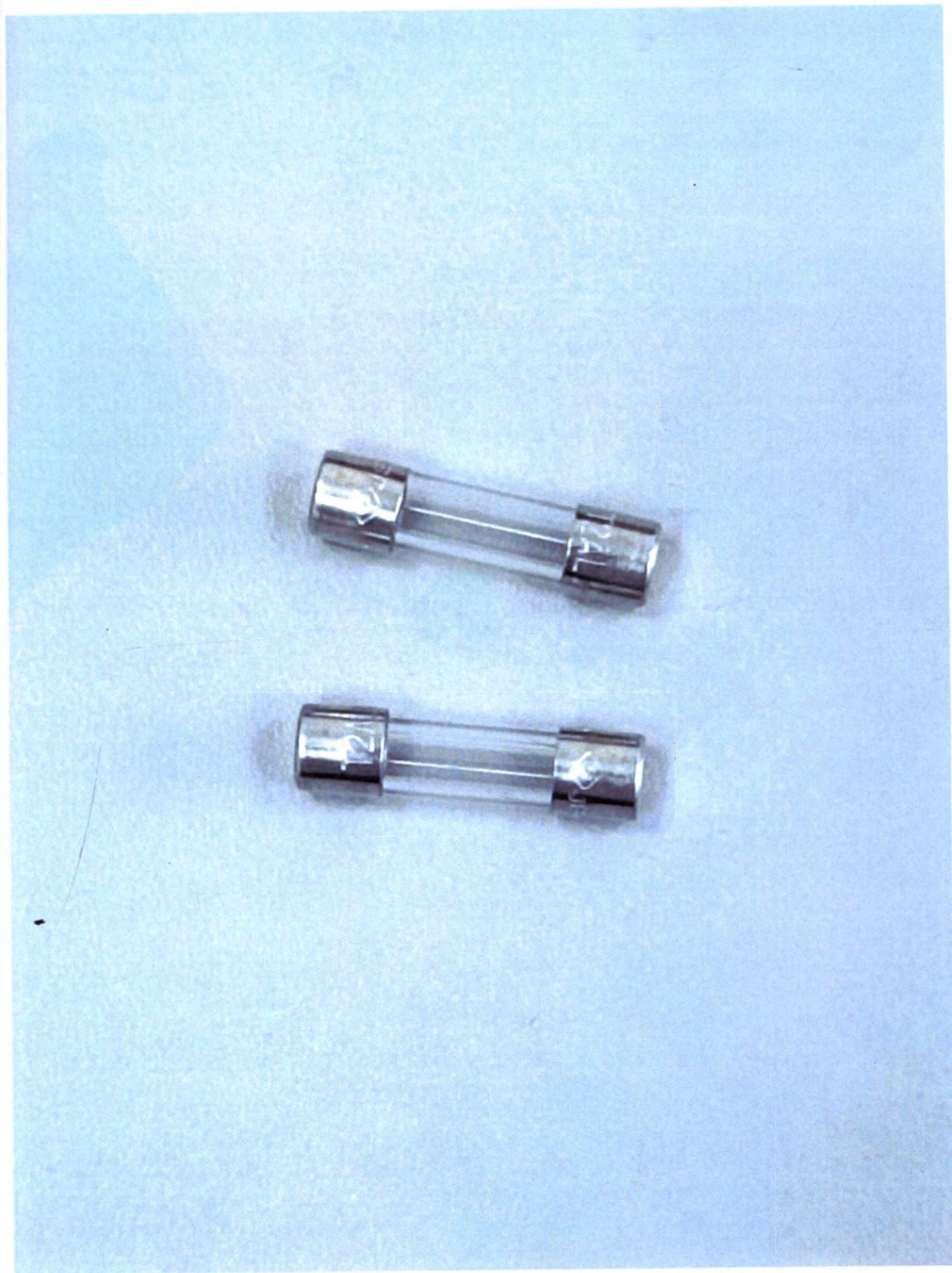


Фото 10. Предохранители.



Фото 11. Универсальная смарт-карта на 1000 тестов.



Фото 12. Универсальная смарт-карта на 4000 тестов.



Фото 13. Универсальная смарт-карта на 10000 тестов.



Фото 14. Универсальная смарт-карта на 20000 тестов.

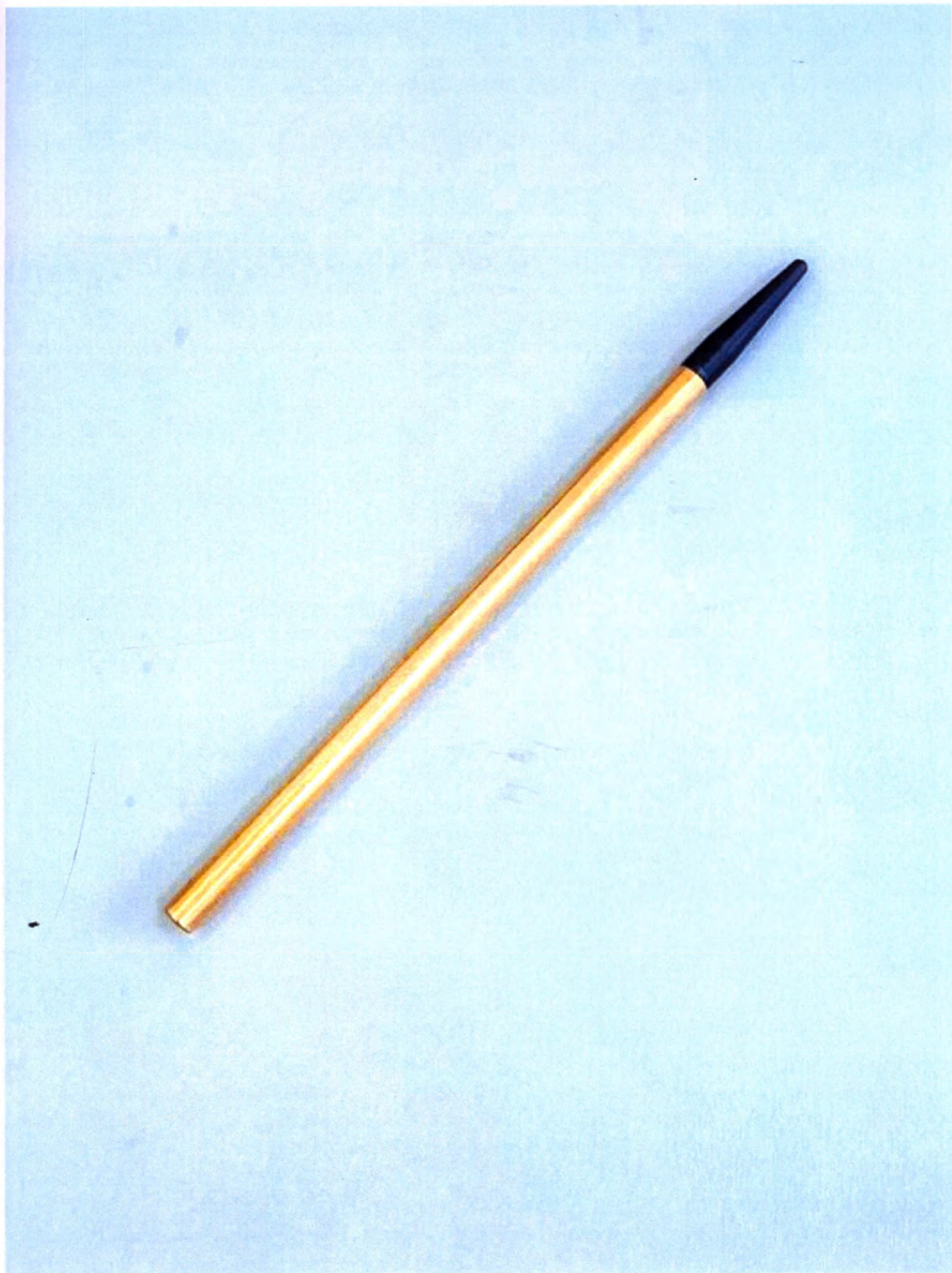


Фото 15. Стилус.



Фото 16. Адаптер для педиатрических пробирок



Фото 17. Руководство по эксплуатации на электронном носителе (CD-диске)



EU DECLARATION OF CONFORMITY

Code: ESR_DECO_SIR20PN_ROLLER20_2-0_EN

Date: 2022-05-25

The Manufacturer:

Manufacturer Name/Registered trade Name	ALIFAX S.R.L.
Address	Via Merano 30 33045 NIMIS (UD) ITALY

declares on his own responsibility that the following device:

Product Name and Product Code	ROLLER 20	SIR20-PN
Intended Purpose	ROLLER 20 is an in vitro diagnostic automatic analyzer for the quantitative determination of Erythrocyte Sedimentation Rate (ESR) in human blood samples with EDTA from adult and pediatric patients with suspected inflammation. ROLLER 20 provides results to inform clinical management for serious and non-serious conditions that require further diagnostic investigations and evaluation of the clinical status. The physician performs his/her expert evaluation on the information provided by the analyzer thanks to his/ her professional knowledge, competence and skills as per the local law.	
Basic UDI-DI	805604014SIR20.195.804DA	
Risk Class	Class A, according to IVDR 746/2017.	

complies with the General Safety and Performance Requirements of the Regulation 746/2017 related to the In Vitro Diagnostic Medical Devices (IVDR).

We declare also that the device has been designed and manufactured in conformity to the below:

Harmonised Standards	EN ISO 13485:2016 A11:2021: Medical devices - Quality management systems - Requirements for regulatory purposes EN ISO 14971:2019: Medical devices - Application of risk management to medical devices EN ISO 15223-1:2021: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied EN ISO 18113 -1:2011: In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) EN ISO 18113 -3:2011: Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use EN 62304:2006+A1:2015: Medical device software - Software life cycle processes
Technical Standards	IEC 62366-1:2015: Application of usability engineering to medical devices IEC TR 62366-2:2016: Guidance on the application of usability engineering to medical device IEC 61326-1:2012; IEC 61326-2-6:2012: Electrical equipment for measurement, control and laboratory use - EMC requirements IEC 61010-1:2001; IEC 61010-2-101:2002: Safety requirements for electrical equipment for measurement, control, and laboratory use
Other	Directive 2015/863/EU (RoHS3)

The device has been CE Marked as IVD Medical Device according to Article 48 (10) of Reg. 746/2017 (IVDR).

DPGT0130 - Ed. 1 Rev. 1 - 2022-03-30

Pag. 1 di 2

Entered in Padova companies register at the n. 04337640280. Company stock 10.000.000 entirely deposited.

Company with single partner and subjected to direction and coordination of Alifax Holding S.p.A.

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INSTALLATION REPORT for ROLLER 20 – SI R20-PN

Rev. 2.0 Effective since 2022 May 23

Dear Distributor,

You are kindly requested to fill-in this form during the installation and return a copy within one month since the installation to:

export.tech@alifax.com

Alifax S.r.l.
Via Merano 30 - 33045 Nimis (UD) - Italy
Tel. +39-0432-547454
Fax: +39-0432-547378

IMPORTANT NOTES:

- Warranty expires 12 months after the installation date written on the present Installation Report duly filled in all its parts and returned to Alifax. If a copy of the report is not received back within one month, warranty will be invalidated.
- It is Your responsibility to verify that the device is properly installed and operates correctly and safely by filling this installation report and to keep such installation reports together with the related tests performed.

DISTRIBUTOR:	COUNTRY:
INSTALLATION SITE:	INSTALLATION DATE:
INSTRUMENT: ☐ ROLLER 20 – SI R20-PN	SERIAL NUMBER:
SOFTWARE VERSION (please see the print out):	

This document is divided in two parts: the installation report module (part one) containing **installation qualification** and **operative qualification** checklist and the installation procedure; the first one must be returned to manufacturer.

- Installation module as well as check list MUST be sent back to manufacturer by email

Please register at <http://www.alifax.com/> in order to obtain the latest version of the USER MANUAL and SERVICE MANUAL related to the software version installed on the instrument.

Фото 19. Инсталляционная форма.

ALI
FAX

FASCICOLO APPARECCHIO (DEVICE HISTORY RECORD)

ROLLER20PN2

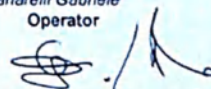
s.n. R202278PN2

DPRD0105 Prove elettriche - Rev 4.2-27-02-2018

PROVE ELETTRICHE INDIVIDUALI SUGLI APPARECCHI ELECTRICAL ROUTINE TESTS ON EQUIPMENTS		NORMA EUROPEA STANDARD: EUROPEAN STANDARD		IEC 61010-1:2010 Annex F	
Stumento utilizzato per le misure: Test instrument id		Altri standard: Other std		CAN/CSA-C22 2 No 61010-1 CAN/CSA-C22 2 No 61010-2-081 UL 61010-1	
TESTS @ 230 Vac	Parametro Parameter	Range di accettazione Accept range	Valore misurato Measured value	Conformita' Compliance	
				SI/Yes	NO/No
A - Condizioni ambientali Environmental conditions	Temperatura Umidita'	15 - 35°C. < 75%	25 °C 41 % Rh	X	
B - Conduttore di protezione PE Continuity test	Ohm at 25 A	< 0.1	46 mOhm	X	
C - Rigidita' dielettrica Dielectric strenght	2220 Vdc for 2 sec.	< 10 mA	N/A	X	
D - Resistenza di isolamento Insulating resistance	Ohm At 500 Vac	> 2 MOhm	40,96 MOhm	X	
			Esito prova Routine Test result	X	

TESTS @ 115 Vac*	Parametro Parameter	Range di accettazione Accept range	Valore misurato Measured value	Conformita' Compliance	
				SI/Yes	NO/No
A - Condizioni ambientali Environmental conditions	Temperatura Umidita'	15 - 35°C. < 75%	25 °C 41 % Rh	X	
B - Conduttore di protezione PE Continuity test	Ohm at 25 A	< 0.1	mOhm		
C - Rigidita' dielettrica Dielectric strenght	2220 Vdc for 2 sec.	< 10 mA	N/A		
D - Resistenza di isolamento Insulating resistance	Ohm At 500 Vac	> 2 MOhm	MOhm		
			Esito prova Routine Test result		

- * Test previsti solo per strumenti dotati di circuito di alimentazione a 115 Vac diverso da quello a 230 Vac e selezionabile tramite cambia-tensione manuale: Test1 (SI 195.2xx) e Roller 20 (SI R20-LC).
 * Test are mandatory only for instruments with 115Vac power supply circuit different from 230 Vac one and selectable by manual power selector: Test1 (SI 195.2xx) and Roller 20 (SI R20-LC).

Data 28/04/2022
DateMatricola 69
Register no.Operatore Panarelli Gabriele
Operator


ALIFAX S.r.l. - Manufacturing Plant - via Merano 30 - 33045 NIMIS (UD) Italy

ALI
FAXFASCICOLO APPARECCHIO
DEVICE HISTORY RECORD

D205.05.03 Rev2.4

s.n. P202235802 Commessa (Job Order) 223A Data PRD (PrCERTIFICATO DI COLLAUDO ROLLER20PN
Roller20PN FINAL TEST REPORT

MATRICOLA COMPONENTI - INTERNAL PARTS SERIAL NUMBERS

DESCRIZIONE BOARD NAME	CODICE PART CODE	MATRICOLA SERIAL NUMBER	NOTE NOTES
SCHEDA ALIMENTATORE Power Switching board	HSRW-115-4011	/	/
SCHEDA INTERFACCIA UTENTE User Interface Board	205.001	00106220013	Verifica revisi Revision Che
GRUPPO CPS (lato emettitore) CPS Group (emitter side) N° 2 PZ (no. 2 pcs)	M205.50.02	 M2055002*5499  M2055002*5488	Verifica revisi Revision Che
SCHEDA ANALOGICA Analogical Board N° 2 PZ (no. 2 pcs)	205.011	 205011*5503  205011*5508	Verifica revisi Revision Che
SCHEDA CONTROLLO ROBOTICA Motor Control Board	205.002	00204210020	Verifica revisi Revision Che
SCHEDA COMUNICAZIONE Communication Board	205.003	00308220042	Verifica revisi Revision Che
GRUPPO SIRINGA Syringe Group	M205.02.00	18477/2021	Verifica revisi Revision Che
SCHEDA DUAL CPS CONTROLLER Dual CPS Controller Board	205.017	 205017*2244	Verifica revisi Revision Che
SCHEDA SENSORI POSIZIONE SIRINGA MANUALE (10PN/20 PN) Manual Syringe position sensor Board (only 10PN/20 PN)	205.010	 205010*2602	Verifica revisi Revision Che
SMART CARD READER	G205.006	02240210502	Verifica revisi Revision Che

☒ TARATURA CPS
CPS Calibration
☒ PROVA DI FUNZIONAMENTO OPERATIVO
Final Test
☒ INSERIMENTO E VALUTAZIONE DEI CORRETTI PARAMETRI DI SETUP
Setup default parameters check

NOTE / NOTES

SI CERTIFICA CHE TUTTI I CONTROLLI INTERNI SONO STATI SUPERATI CON ESITO POS
WE CERTIFY THAT ALL INTERNAL CHECKS WERE POSITIVELY PASSED

Approvato dal Responsabile Produzione Strumenti (Instruments Manufacturer Man

DATA/Date 03/03/2022 FIRMA/Signature 07/09/2022
16:48:38
ROLLER 20 Plus Needle
R10-05.00C.00R10_U1-05.00C
Apr 27 2021 11:44:22
SN: 2278
DEBUG: OFF
MAINTENANCE
WARNING: 30000
MAINTENANCE COUNTER: 0
washing time: 45
PRINT DURING ANALYSIS: ON
PRINT EXPANDED TEXT: ON
2 CPS On Board: ON
MEC on Board: OFF
Pediatric samples: OFF
Test Mode: OFF# ESR = 200
Global count ESR: 0R10MOT-05.00B
Dec 01 2020 13:00:56
Mixing cycles: 200
Mixing speed: medium
Automatic sample ul: 175
Manual sample ul: 100
Steps UP: 3500
Steps up wash: 4500
Tube offset: -14
Syr fast: OFF
Centrifugation cycles: 30INTERNAL CIRCUIT
R10ANA-03.100
May 31 2013 17:52:25
REFERENCE: EDTA
BY EDTA: 1.4456
MF1: 1.4476
MF2: 1.4435
OFFSET1: -92.32
OFFSET2: -75.59
37.0 (37)
Wash not ok: 2
T.100 SENS1: 3815
T.100 SENS2: 3834
T.100 STOP: 3802
DAC SENS1: 509
DAC SENS2: 476
DAC STOP: 509EXTERNAL CIRCUIT
R10ANA-03.100
May 31 2013 17:52:25
REFERENCE: EDTA
BY EDTA: 1.4335
MF1: 1.4362
MF2: 1.4308
OFFSET1: -94.15
OFFSET2: -71.34
37.1 (37)
Wash not ok: 1
T.100 SENS1: 3795
T.100 SENS2: 3796
T.100 STOP: 3806
DAC SENS1: 506
DAC SENS2: 491
DAC STOP: 412R10COM-04.02B
Aug 08 2018 08:43:53
RS232: NO HUST
Instrument: 1
missingID: ON
ACK: ON
BAYER
PROTOCOL: OFF
TIMEOUT UART: 2
MAX ATTEMPTS: 3
Do on timeout: ON
6 parameters: OFF
Curve parameters: OFF
Send kinetic: OFF000 Alifax Russia
(10000153)
Old code (0x99)
Exp old 31/12/19
SM To Disable: OFF
Credit from Old Card: 200000
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FASCICOLO APPARECCHIO
DEVICE HISTORY RECORD

D205.05.03 Rev2.4

Pag. 10 di 10

s.n. N2227842 Commessa (Job Order) 2235 Data PRD (Production Date) 17/04/22

CORREDO DI SERIE / PACKING LIST

☒ SIR20 PN

Corredo di serie / Packing List

☒ N° 2 - SI205800 Thermal paper rolls (one inside instruments and one spare)

☒ N° 2 - SI205801 (Waste) Tank (one inside instruments and one spare)

☒ N° 2 - SI195145 (Wash) Tank (one inside instruments and one spare)

☒ N° 1 - Touch Screen Pen

☒ N° 1 - CD Multi-language with Operative Manual (Version and languages)

ESR_UM_SIR20_PN_ROLLER20PN_SW S-OOC-L-Q-EN-ES-IT-PT-FR-DE ESR-CD-SIR20-
ROLLER20PN-SW-S-OOC-2-

☒ N° 2 - Spare Mains fuses T2A

☒ N° 1 - Mains Cable

☐ Personalized main cable _____

☒ ~~N° 1 - Needle~~ 13/7/22

☒ N° 1 - DPRD0105: Electrical routine tests EN61010-2-101:2002 Annex F

☒ N° 1 - EC declaration of conformity

☒ N° 1 - ESR_IQOQ_SIR20PN_ROLLER20PN: Installation Report

☒ Pag 9/10 - Final test report

☒ Pag 10/10 - Packing list

Compilatore (Signature) CUSIGHI Data (Date) 08/09/2022

Approvato dal Responsabile Produzione Apparecchi (Manufacturing Manager Approval)

Data 08/09/2022
(Date)

Firma [Signature]
(Signature)

Approvato da Assicurazione Qualità (Approved by Quality Assurance)

Data 08/09/2022
(Date)

Firma [Signature]
(Signature)

A. S. LORENTINO



Фото 23. Внешняя/транспортная упаковка.



ROLLER 20



SI R20-PN



R202278PN2



Rx ONLY

Only for US market



FIRMWARE VERSION: R10.05.00-C (EN)

DESTINATION: 000 ALIFAX



Alifax S.r.l.
via Merano, 30 - 33045
NIMIS (UD) - ITALY



2022-04-20



(01) 0 8056040 14034 5
(11) 220420
(21) R202278PN2

USE EL 5102PN, ROLLER20PN, 2-1P, RU, 1-0



Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ) ROLLER 20, модель ROLLER 20 PN



№ по кат. SI R20-PN



Серийный номер R202278PN2

ПУ №ФСЗ 2010/06240 от XXXX года

ПРЕДНАЗНАЧЕН ДЛЯ:



Алифакс С.р.л.
Виа Мерано, 30-33045
НИМИС (УД) - ИТАЛИЯ



2022-04-20

Уполномоченный представитель производителя в РФ:

ООО «АЛИФАКС», адрес: 125367, г. Москва, ул. Габричевского, д.5. к. 1, комн.4-5,
21-22, 3-эт, пом. 1, телефон +7 (495) 544-50-55, info.russia@alifax.com



(01) 0 8056040 14034 5
(11)
(21) R202278PN2



Фото 24. Маркировка внешней/транспортной упаковки.

В данном документе
пронумеровано и прошито

25 (двадцать пять)

лист(а)ов

