МАРКИРОВКА МЕДИЦИНСКОГО ИЗДЕЛИЯ

Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ) TEST1 с принадлежностями модели TEST1 THL/BCL/SDL/YDL/MDL

ВНУТРЕННЯЯ МАРКИРОВКА АНАЛИЗАТОРА

Модель, местоположение	Образец маркировки (оригинал)	Образец маркировки (русский язык)
a) Маркировка **модели TEST1 THL** на задней панели анализатора		
b) Маркировка **модели TEST1 BCL** на задней панели анализатора		

ЭЛЕКТРОННАЯ КОПИЯ ОФОРМЛЕНА ЦЕНТРОМ ИСПЫТАНИЙ И РЕГИСТРАЦИИ МЕДИЦИНСКИХ ИЗДЕЛИЙ

c) Маркировка **модели TEST1 SDL** на задней панели анализатора		
d) Маркировка **модели TEST1 YDL** на задней панели анализатора		
e) Маркировка **модели TEST 1 MDL** на задней панели анализатора		

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Передняя этикетка TEST1 THL на лицевой стороне анализатора, на пластиковой крышке		
Передняя этикетка TEST1 BCL на лицевой стороне анализатора, на пластиковой крышке		
Передняя этикетка TEST1 SDL на лицевой стороне анализатора, на пластиковой крышке		
Передняя этикетка TEST1 YDL на лицевой стороне анализатора, на пластиковой крышке		
Передняя этикетка TEST1 MDL на лицевой стороне анализатора, на пластиковой крышке		

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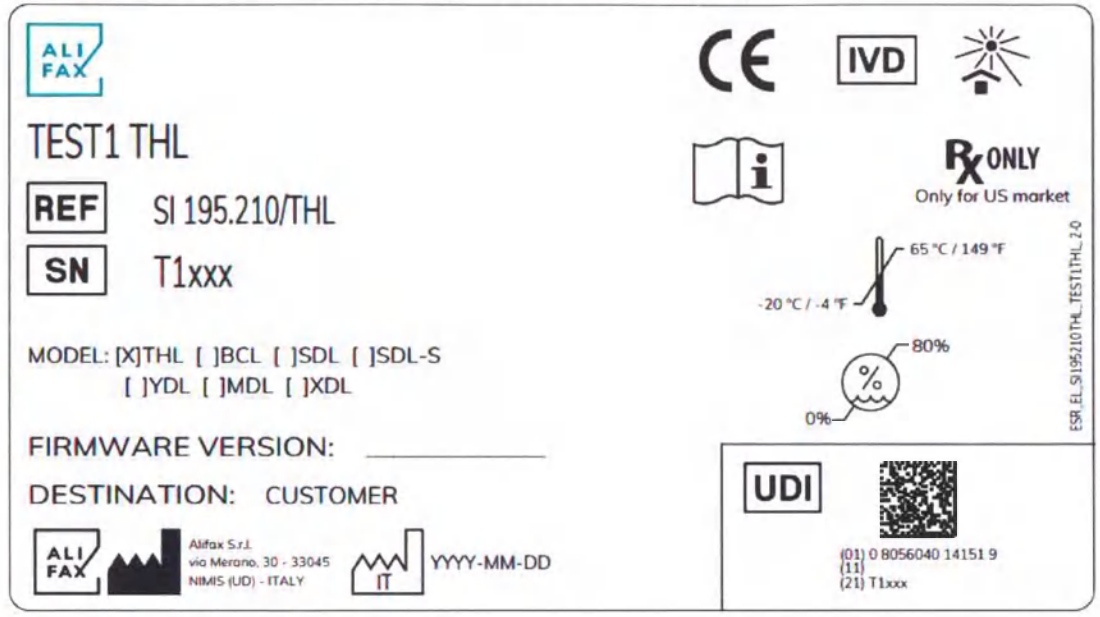
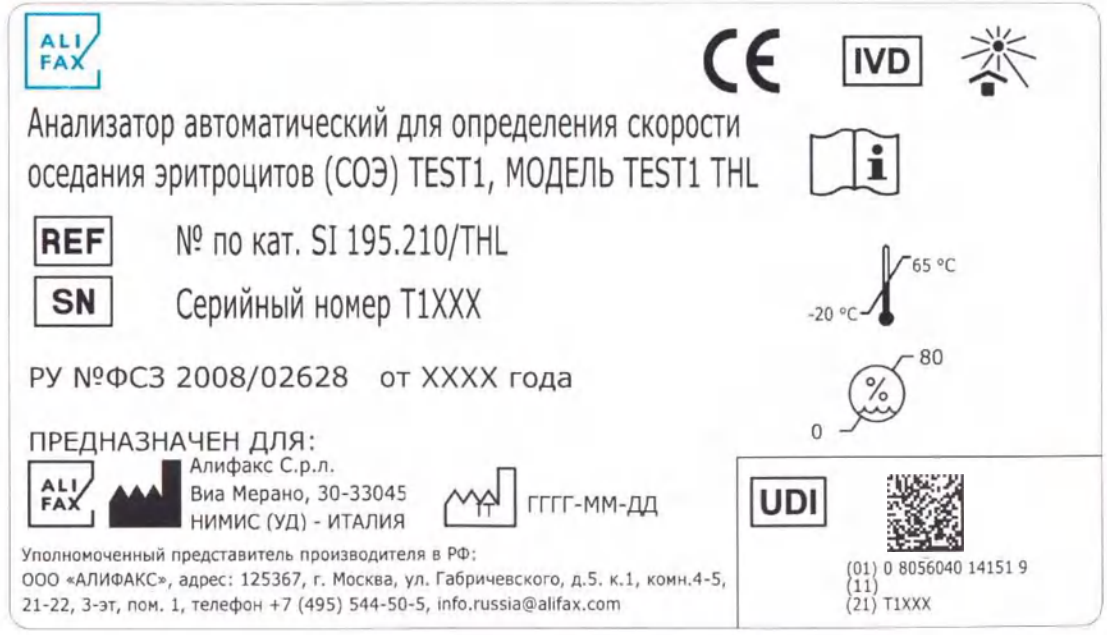
ВНЕШНЯЯ (ТРАНСПОРТНАЯ) МАРКИРОВКА (на примере модели TEST1 THL)





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В данном документе
пронумеровано и прошито

4 (Четыре)
лист(а)ов

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фотографические изображения медицинского изделия

Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ) TEST1 с принадлежностями

(Регистрационное удостоверение № ФСЗ 2008/02628 от 17 июня 2021 года)

ООО «ЛИФАКС»

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 1 Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ) TEST1 THL (общий вид)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 2 Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ) TEST1 THL (фото маркировки)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

ALIFAX

TEST 1

Руководство по эксплуатации

Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ) TEST1 с принадлежностями

Действительно для всех моделей

Применимо к версии 9.00X

Редакция для Российской Федерации

CE RoHS 2

Прибор для профессионального использования в области In Vitro диагностики

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Торговая марка TEST 1 является собственностью Alifax S.r.l.

Фото 3 Руководство по эксплуатации на русском языке

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 4 Руководство по эксплуатации на электронном носителе (CD-диск)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 5 Руководство по эксплуатации на электронном носителе (флеш-карта)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

ALIFAX

FASCICOLO APPARECCHIO D155.05.03.02 Rev 1.9
DEVICE HISTORY RECORD
TEST1 THL / BCL / SDL / YDL / MDL / XDL / HDL (SI 195.2XX)
s.n. T172332 commessa (Job Order) 2023-2-12580 Data PRD 22/2/23

CORREDO DI SERIE / PACKING LIST

STRUMENTO INSTRUMENT	MODELLO MODEL						LINGUA LANGUAGE	
☒ TEST1 SI 195.2XX	THL	BCL	SDL	YDL	MDL	XDL	EN	IT
	☒	☐	☐	☐	☐	☐	☒	☐

Corredo di serie / Packing list

- ☒ N.° 2 SI195800 Rotoli Carta termica / Thermal Paper rolls
- ☒ N.° 2 SI205801 Tanica di lavaggio / Wash Tank
- ☒ N.° 2 SI205801 Tanica di scarico / Waste Tank
- ☒ N.° 2 Fusibili di alimentazione T5A / Main fuses T5A
- ☒ N.° 1 Cavo Alimentazione / Main cable plug
- ☐ Cavo alimentazione personalizzato/Personalized main cable _____
- ☒ N.° 1 Ago a vite / Needle
- ☒ N.° 1 CD Manuale operativo multilingua / CD Multi-Language Operative manual (Language and version)
  ESR_UM_SI195_TEST1_SW 11-00A-1-0-EN-ES-IT-PT-FR-DE-FI ESR-CD-SI195-TEST1-SWM-004-1-1
- ☒ ESR_IQOQ_SI195_TEST1: Modulo di installazione / Installation Report

SOLO STRUMENTI SDL / SDL INSTRUMENTS ONLY:

- ☐ N.°4 Pettine rack Sysmex XN / Sysmex XN rack scallop
- ☐ Nota tecnica n.° 2004 EN / Technical note n.° 2004 EN

SOLO STRUMENTI SDL PER PROVETTE SARSTEDT / SDL INSTRUMENTS FOR SARSTEDT TUBES ONLY:

- ☐ N.° 4 Pettine x Sarstedt 11X66 / Sarstedt 11x66 scallop
- ☐ Nota tecnica n.° 2006 EN / Technical note n.° 2006 EN

- ☒ Dichiarazione di conformità CE / EC declaration of conformity
- ☒ DPRD0105: Prove elettriche di routine / Electrical routine tests
- ☒ Pag 8/9: Certificato di Collaudo / Final Test report
- ☒ Pag 9/9: Packing List / This document

Compilatore/Signature Cassetti Data/Date 16/03/2023

Approvato dal Responsabile Produzione Strumenti per rilascio finale / Manufacturer Manager Approval

DATA/Date 16/03/2023 FIRMA/Signature

Approvato da Assicurazione Qualità (Approved by Quality Assurance)

Data 16.03.2023 (Date) Firma (Signature)

ALIFAX S.r.l.
via Petrarca 2/1 – 35020 POLVERARA (PD) – ITALY
Tel. +39 0498992000 e-mail: info@alifax.com
PI 04337640280

ALIFAX S.r.l.
via Morano 30 – 33045 NIMIS (UD) – ITALY
Documents available on: www.alifax.com

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Фото 6 Упаковочный лист (анализатор TEST1 модель THL)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

INSTALLATION REPORT
for TEST1 Instruments

Rev. 3.0 – Valid since 2022 May 25

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. +39-0432-197900
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: ☐ TEST1 Model: _____	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 7 Инсталляционная форма

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

EU DECLARATION OF CONFORMITY

Code: ESR_DECO_SI1952XX_TEST1_3-0_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 devices:

Product Name and Product Code	TEST1 THL	SI 195.210/THL
	TEST1 BCL	SI 195.220/BCL
	TEST1 SDL	SI 195.230/SDL
	TEST1 YDL	SI 195.240/YDL
	TEST1 MDL	SI 195.250/MDL
	TEST1 XDL	SI 195.260/XDL
Intended Purpose	TEST1 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. TEST1 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.	

comply 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 devices have 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 Electrical equipment for measurement, control and laboratory use - EMC requirements IEC 61326-2-6:2012: Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

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.pA
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Фото 8 Декларация соответствия

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

ALI FAX

FASCICOLO APPARECCHIO D195.05.03.02 Rev 1.9 Pag 8 di 9
DEVICE HISTORY RECORD
TEST1 THL / BCL / SDL / YDL / MDL / XDL / HDL (SI 195.2XX)
s.n. T17232 commessa (Job Order) 2023-2/1260 Data PRD 22/2/23

CERTIFICATO DI COLLAUDO *TEST1*		*TEST1* – FINAL TEST REPORT	
MATRICOLA COMPONENTI - INTERNAL PARTS SERIAL NUMBERS			
DESCRIZIONE BOARD NAME	CODICE PART CODE	MATRICOLA SERIAL NUMBER	Sigla Operat. Oporator
Lotto TELAIO	M195.11.13	124/2022	RM
Lotto PANNELLO COMANDI	195.042	18/2022	
Lotto KIT FAST	195.032	01/2023	
Lotto ROTORE	195.031	103/2022	
Lotto TRASFORMATORE	195.046	1198/22	
SCHEDA ALIMENTATORE Power supply board	195.005	195005*8865	RM
SCHEDA CPU CPU Board	195.052	195052*01324	RM
SCHEDA CPS-MC CPS-MC Board	G1102.004	G1102004*429	RM
SCHEDA SENS. RACK E HOME Rack and Home Sensor Board	195.009	003822007-1	RM
SCHEDA SERIALE Serial Connectors Board	195.011	195011*6066	RM
CARRELLO Carriage	G195.001	G195001*1675	RM
LETTORE INTERNO DI CODICI A BARRE Internal barcode reader	ORTC1200-1000	Serial Number G22M43586	RM

COLLAUDI / FINAL TEST REPORT
- TARATURA CPS-MC/ CPS-MC Calibration
- PROVA DI FUNZIONAMENTO OPERATIVO / Final Test
- INSERIMENTO E VALUTAZIONE DEI CORRETTI PARAMETRI DI SETUP / Setup default parameters check

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

Approvato dal Responsabile Produzione Strumenti / Manufacturer Manager Approval

DATA/Date 16/1/2023 FIRMA/Signature

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Фото 9 Сертификат выходного контроля качества (анализатор TEST1 модель THL)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 10 Подставка под штативы

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 11 Резервуар для отходов

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 12 Смарт-карты TEST1 на 1000/4000/10000/20000 тестов

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

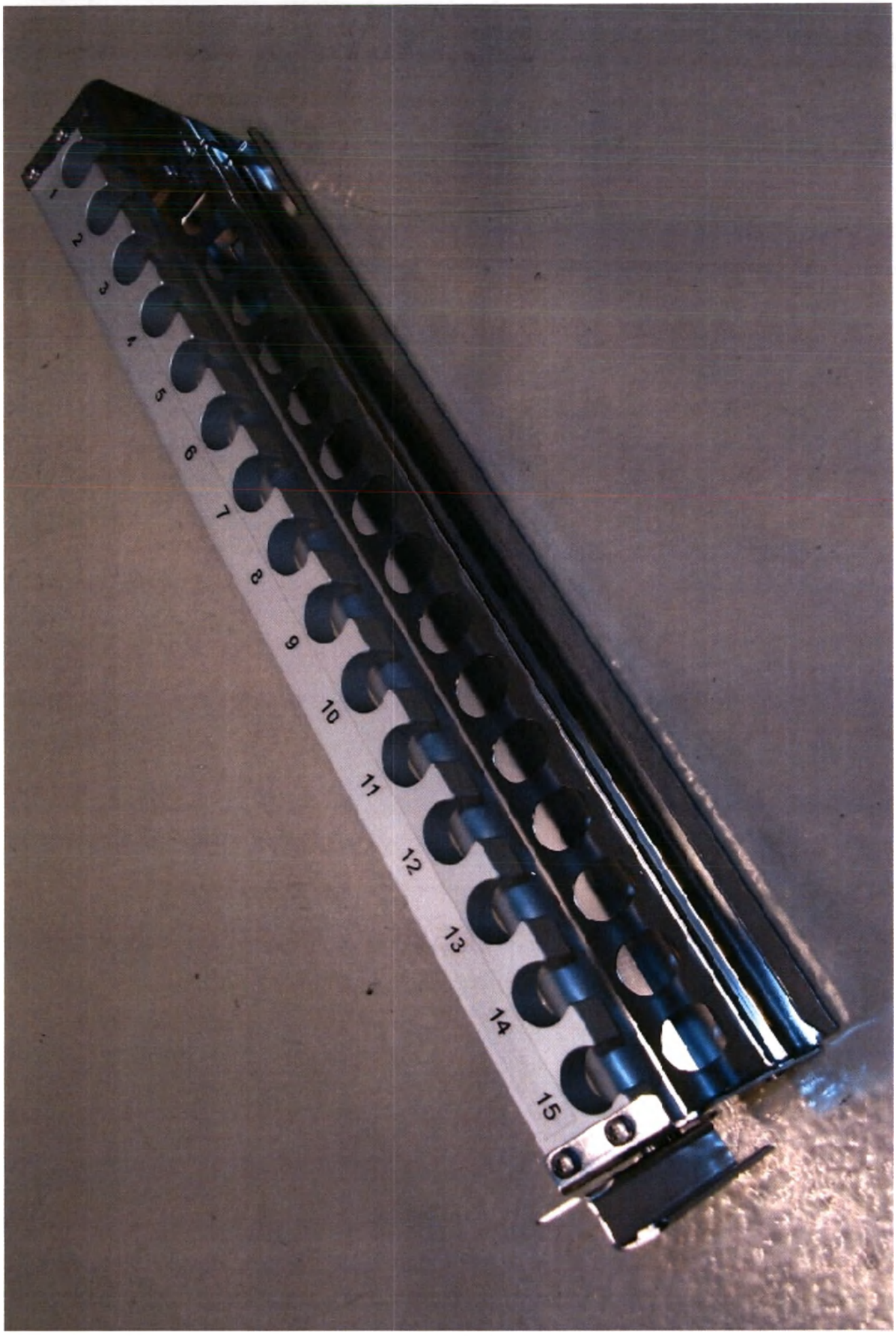

Фото 13 Штатив металлический Alifax (только для TEST1 THL)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 14 Внешний сканер штрих-кодов (только для TEST1 THL)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 15 Крышка-адаптер для пробирок Sarstedt Monovette (только для TEST1 THL)

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Фото 16 Предохранители

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 17 Кабель питания

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 18 Стартовый набор термобумаги в рулонах

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 19 Резервуар для промывки

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 20 Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ) TEST1 BCL (общий вид)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 21 Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ) TEST1 BCL (фото маркировки)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

ALI FAX

TEST 1

Руководство по эксплуатации

Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ) TEST1 с принадлежностями

Действительно для всех моделей

Применимо к версии 9.00X

Редакция для Российской Федерации

CE RoHS 2

Прибор для профессионального использования в области In Vitro диагностики

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Фото 22 Руководство по эксплуатации на русском языке

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 23 Руководство по эксплуатации на электронном носителе (CD-диск)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 24 Руководство по эксплуатации на электронном носителе (флеш-карта)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

FASCICOLO APPARECCHIO D195.05.03.02 Rev 1.9
DEVICE HISTORY RECORD
TEST1 THL / BCL / SDL / YDL / MDL / XDL / HDL (SI 195.2XX)
Pag. 9 di 9

s.n. 117236 commessa (Job Order) 2023-211532 Data PRD 28/12/23

CORREDO DI SERIE / PACKING LIST

STRUMENTO INSTRUMENT	MODELLO MODEL						LINGUA LANGUAGE	
	THL	BCL	SDL	YDL	MDL	XDL	EN	IT
☒ TEST1 SI 195.2XX	☐	☒	☐	☐	☐	☐	☒	☐

Corredo di serie / Packing list

- ☒ N.° 2 SI195800 Rotoli Carta termica / Thermal Paper rolls
- ☒ N.° 2 SI205801 Tanica di lavaggio / Wash Tank
- ☒ N.° 2 SI205801 Tanica di scarico / Waste Tank
- ☒ N.° 2 Fusibili di alimentazione T5A / Main fuses T5A
- ☒ N.° 1 Cavo Alimentazione / Main cable plug
- ☐ Cavo alimentazione personalizzato/Personalized main cable _____
- ☒ N.° 1 Ago a vite / Needle
- ☒ N.° 1 CD Manuale operativo multilingua / CD Multi-Language Operative manual (Language and version)
  ESR_UM_SI195_TEST1_SW 11-01A-1-1-EN-ES-IT-PT-FR-DE-FI-LT ESR-CD-SI195-TEST1-SW11-00X-1-2
- ☒ ESR_IQOQ_SI195_TEST1: Modulo di installazione / Installation Report

SOLO STRUMENTI SDL / SDL INSTRUMENTS ONLY:

- ☐ N.°4 Pettine rack Sysmex XN / Sysmex XN rack scallop
- ☐ Nota tecnica n.° 2004 EN / Technical note n.° 2004 EN

SOLO STRUMENTI SDL PER PROVETTE SARSTEDT / SDL INSTRUMENTS FOR SARSTEDT TUBES ONLY:

- ☐ N.° 4 Pettine x Sarstedt 11X66 / Sarstedt 11x66 scallop
- ☐ Nota tecnica n.° 2006 EN / Technical note n.° 2006 EN

- ☒ Dichiarazione di conformità CE / EC declaration of conformity
- ☒ DPRD0105: Prove elettriche di routine / Electrical routine tests
- ☒ Pag 8/9: Certificato di Collaudo / Final Test report
- ☒ Pag 9/9: Packing List / This document

Compilatore/Signature CUSSIGH **Data/Date** 21/3/2023

Approvato dal Responsabile Produzione Strumenti per rilascio finale / Manufacturer Manager Approval

DATA/Date 24/03/2023 **FIRMA/Signature** _____

Approvato da Assicurazione Qualità (Approved by Quality Assurance)

Data 21/03/2023 **Firma** _____
(Date) (Signature)

ALIFAX S.r.l.
via Petrarca 2/1 – 35020 POLVERARA (PD) – ITALY
Tel. +39 0490992000 e-mail: info@alifax.com
PI 04337640280

ALIFAX S.r.l.
via Merano 30 – 33045 NIMIS (UD) – ITALY
Documents available on: www.alifax.com

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Фото 25 Упаковочный лист (анализатор TEST1 модель BCL)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

INSTALLATION REPORT
for TEST1 Instruments

Rev. 3.0 – Valid since 2022 May 25

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. +39-0432-197900
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: ☐ TEST1 Model: _____	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 26 Инсталляционная форма

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

EU DECLARATION OF CONFORMITY

Code: ESR_DECO_SI1952XX_TEST1_3-0_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 devices:

Product Name and Product Code	TEST1 THL	SI 195.210/THL
	TEST1 BCL	SI 195.220/BCL
	TEST1 SDL	SI 195.230/SDL
	TEST1 YDL	SI 195.240/YDL
	TEST1 MDL	SI 195.250/MDL
	TEST1 XDL	SI 195.260/XDL
Intended Purpose	TEST1 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. TEST1 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.	

comply 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 devices have 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 Electrical equipment for measurement, control and laboratory use - EMC requirements IEC 61326-2-6:2012: Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

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.pA
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Фото 27 Декларация соответствия

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

FASCICOLO APPARECCHIO D195.05.03.02 Rev 1.9
DEVICE HISTORY RECORD
TEST1 THL / BCL / SDL / YDL / MDL / XDL / HDL (SI 195.2XX)
s.n. I12236 commessa (Job Order) 2023-211532 Data PRD 28/12/2023

CERTIFICATO DI COLLAUDO *TEST1* — *TEST1* – FINAL TEST REPORT

MATRICOLA COMPONENTI - INTERNAL PARTS SERIAL NUMBERS

DESCRIZIONE BOARD NAME	CODICE PART CODE	MATRICOLA SERIAL NUMBER	Sigla Operat. Operator
Lotto **TELAIO**	M195.11.13	12/2022	
Lotto **PANNELLO COMANDI**	195.042	02/2023	
Lotto **KIT FAST**	195.032	02/2023	
Lotto **ROTORE**	195.031	103/2022	
Lotto **TRASFORMATORE**	195.046	1138/24	
SCHEDA ALIMENTATORE Power supply board	195.005	195005*8942	
SCHEDA CPU CPU Board	195.052	195052*01423	
SCHEDA CPS-MC CPS-MC Board	G1102.004	G1102004*457	
SCHEDA SENS. RACK E HOME Rack and Home Sensor Board	195.009	009032301 77	
SCHEDA SERIALE Serial Connectors Board	195.011	195011*6111	
CARRELLO Carriage	G195.001	G195001*1687	
LETTORE INTERNO DI CODICI A BARRE Internal barcode reader	ORTC1200-1000	Serial Number G22M43556	

COLLAUDI / FINAL TEST REPORT

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

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

Approvato dal Responsabile Produzione Strumenti / Manufacturer Manager Approval

DATA/Date 21/05/2023 FIRMA/Signature

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Фото 28 Сертификат выходного контроля качества (анализатор СОЭ TEST1 модель BCL)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 29 Подставка под штативы

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 30 Резервуар для отходов

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 31 Смарт-карты TEST1 на 1000/4000/10000/20000 тестов

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

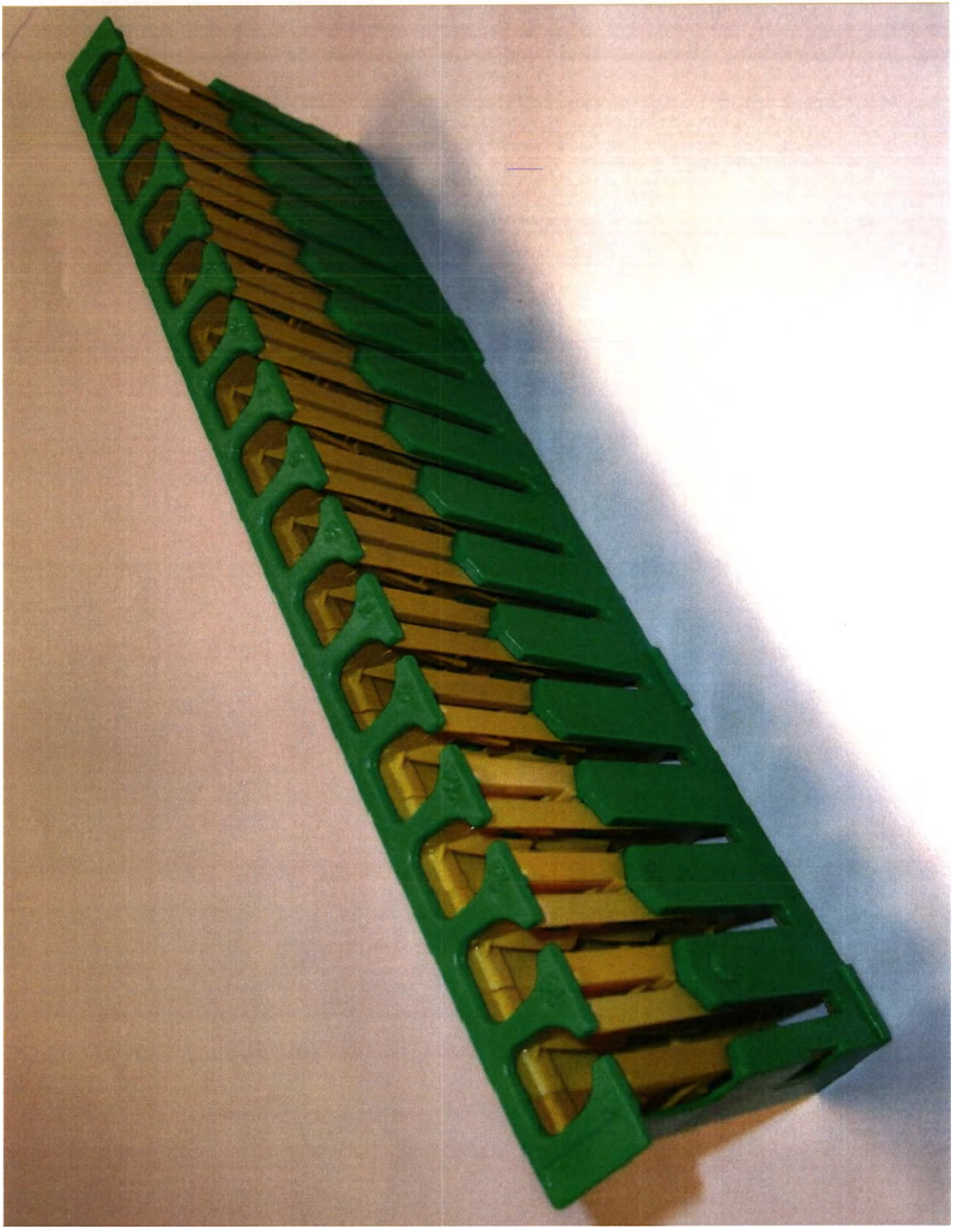

Фото 32 Штатив Alifax для TEST1 BCL (зеленый)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 33 Кабель питания

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 34 Стартовый набор термобумаги в рулонах

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 35 Предохранители

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 36 Резервуар для промывки

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 37 Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ) TEST1 SDL (общий вид)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 38 Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ) TEST1 SDL (фото маркировки)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

ALIFAX

TEST 1

Руководство по эксплуатации

Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ) TEST1 с принадлежностями

Действительно для всех моделей

Применимо к версии 9.00X

Редакция для Российской Федерации

CE RoHS2

Прибор для профессионального использования в области In Vitro диагностики

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Торговая марка TEST 1 является собственностью Alifax S.r.l.

Фото 39 Руководство по эксплуатации на русском языке

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

40

Фото 40 Руководство по эксплуатации на электронном носителе (CD-диск)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 41 Руководство по эксплуатации на электронном носителе (флеш-карта)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

ALIFAX

FASCICOLO APPARECCHIO D195.05.03.02 Rev 1.9 — Pag. 9 di 9
DEVICE HISTORY RECORD
TEST1 THL / BCL / SDL / YDL / MDL / XDL / HDL (SI 195.2XX)
s.n. 717235 commessa (Job Order) 2023 2/1050 Data PRD 16/12/2023

CORREDO DI SERIE / PACKING LIST

STRUMENTO INSTRUMENT	MODELLO MODEL						LINGUA LANGUAGE	
	THL	BCL	SDL	YDL	MDL	XDL	EN	IT
☒ TEST1 SI 195.2XX	☐	☐	☒	☐	☐	☐	☒	☐

Corredo di serie / Packing list

- ☒ N.° 2 SI195800 Rotoli Carta termica / Thermal Paper rolls
- ☒ N.° 2 SI205801 Tanica di lavaggio / Wash Tank
- ☒ N.° 2 SI205801 Tanica di scarico / Waste Tank
- ☒ N.° 2 Fusibili di alimentazione T5A / Main fuses T5A
- ☒ N.° 1 Cavo Alimentazione / Main cable plug
- ☐ Cavo alimentazione personalizzato/Personalized main cable _____
- ☒ N.° 1 Ago a vite / Needle
- ☒ N.° 1 CD Manuale operativo multilingua / CD Multi-Language Operative manual (Language and version)
  ESR_UM_SI195_TEST1_SW 11-00A-1-0-EN-ES-IT-PT-FR-DE-FI ESR-CD-SI195-TEST1-SW11-00X-1-1
- ☒ ESR_IQOQ_SI195_TEST1: Modulo di installazione / Installation Report

SOLO STRUMENTI SDL / SDL INSTRUMENTS ONLY:

- ☒ N.°4 Pettine rack Sysmex XN / Sysmex XN rack scallop
- ☒ Nota tecnica n.° 2004 EN / Technical note n.° 2004 EN

SOLO STRUMENTI SDL PER PROVETTE SARSTEDT / SDL INSTRUMENTS FOR SARSTEDT TUBES ONLY:

- ☐ N.° 4 Pettine x Sarstedt 11X66 / Sarstedt 11x66 scallop
- ☐ Nota tecnica n.° 2006 EN / Technical note n.° 2006 EN

- ☒ Dichiarazione di conformità CE / EC declaration of conformity
- ☒ DPRD0105: Prove elettriche di routine / Electrical routine tests
- ☒ Pag 8/9: Certificato di Collaudo / Final Test report
- ☒ Pag 9/9: Packing List / This document

Compilatore/Signature [signature] Data/Date 08/03/2023

Approvato dal Responsabile Produzione Strumenti per rilascio finale / Manufacturer Manager Approval

DATA/Date 08/03/2023 FIRMA/Signature [signature]

Approvato da Assicurazione Qualità (Approved by Quality Assurance)

Data 08/03/2023 (Date) Firma [signature] (Signature)

ALIFAX S.r.l.
via Petrarca 2/1 – 35020 POLVERARA (PD) – ITALY
Tel. +39 0490992000 e-mail: info@alifax.com
PI 04337640280

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via Merano 30 – 33045 NIMIS (UD) – ITALY
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Фото 42 Упаковочный лист (анализатор TEST1 модель SDL)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

INSTALLATION REPORT
for TEST1 Instruments

Rev. 3.0 – Valid since 2022 May 25

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. +39-0432-197900
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: ☐ TEST1 Model: _____	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 43 Инсталляционная форма

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

EU DECLARATION OF CONFORMITY

Code: ESR_DECO_SI1952XX_TEST1_3-0_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 devices:

Product Name and Product Code	TEST1 THL	SI 195.210/THL
	TEST1 BCL	SI 195.220/BCL
	TEST1 SDL	SI 195.230/SDL
	TEST1 YDL	SI 195.240/YDL
	TEST1 MDL	SI 195.250/MDL
	TEST1 XDL	SI 195.260/XDL
Intended Purpose	TEST1 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. TEST1 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.	

comply 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 devices have 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 Electrical equipment for measurement, control and laboratory use - EMC requirements IEC 61326-2-6:2012: Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

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.pA
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Фото 44 Декларация соответствия

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

ALI FAX

FASCICOLO APPARECCHIO D195.05.03.02 Rev 1.9 Pag. 8 di 9
DEVICE HISTORY RECORD
TEST1 THL / BCL / SDL / YDL / MDL / XDL / HDL (SI 195.2XX)
s.n. 717220 commessa (Job Order) 2023-21990 Data PRD 16/12/2023

CERTIFICATO DI COLLAUDO *TEST1* — *TEST1* – FINAL TEST REPORT			
MATRICOLA COMPONENTI - INTERNAL PARTS SERIAL NUMBERS			
DESCRIZIONE BOARD NAME	CODICE PART CODE	MATRICOLA SERIAL NUMBER	Sigla Operat. Operator
Lotto TELAIO	M195.11.13	12/2022	
Lotto PANNELLO COMANDI	195.042	17/2022	
Lotto KIT FAST	195.032	20/2022	
Lotto ROTORE	195.031	103/2022	
Lotto TRASFORMATORE	195.046	1198/22	
SCHEDA ALIMENTATORE Power supply board	195.005	195005*8869	
SCHEDA CPU CPU Board	195.052	195052*01218	
SCHEDA CPS-MC CPS-MC Board	G1102.004	G1102004*406	
SCHEDA SENS. RACK E HOME Rack and Home Sensor Board	195.009	0903230161	
SCHEDA SERIALE Serial Connectors Board	195.011	195011*5744	
CARRELLO Carriage	G195.001	G195001*1680	
LETTORE INTERNO DI CODICI A BARRE Internal barcode reader	ORTC1200-1000	Serial Number G22M43598	

COLLAUDI / FINAL TEST REPORT

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

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

Approvato dal Responsabile Produzione Strumenti / Manufacturer Manager Approval

DATA/Date 03/03/2023 FIRMA/Signature

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ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 45 Сертификат выходного контроля качества (анализатор TEST1 модель SDL) 46

Фото 46 Подставка под штативы

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 47 Резервуар для отходов

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 48 Смарт-карты TEST1 на 1000/4000/10000/20000 тестов

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

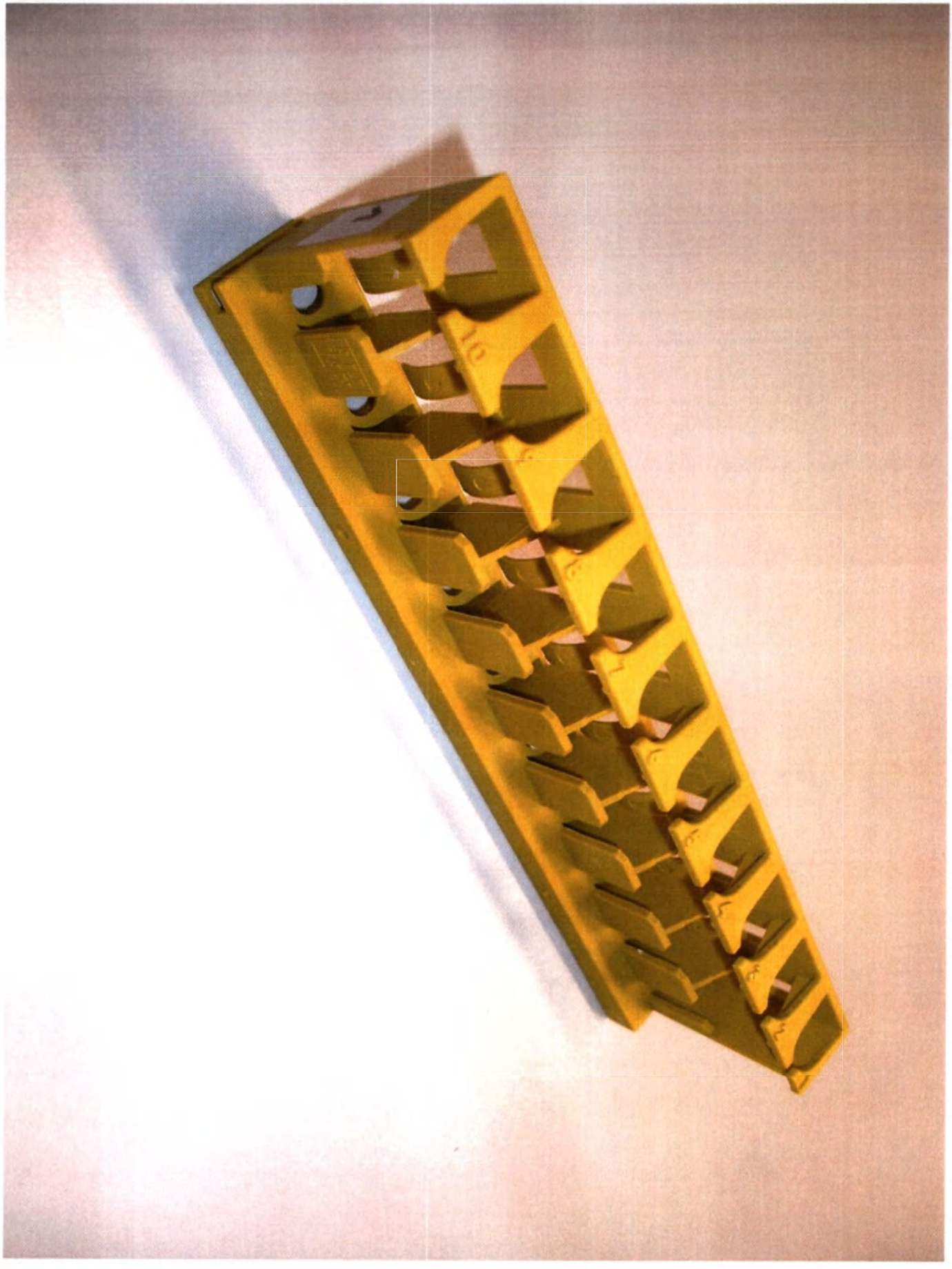

Фото 49 Штатив Alifax для TEST1 SDL (желтый)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 50 Кабель питания

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 51 Стартовый набор термобумаги в рулонах

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 52 Предохранители

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 53 Резервуар для промывки

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 54 Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ) TEST1 YDL (общий вид)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 55 Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ) TEST1 YDL (фото маркировки)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

ALIFAX

TEST 1

Руководство по эксплуатации

Анализатор автоматический для определения скорости оседания эритроцитов (СОЭ) TEST1 с принадлежностями

Действительно для всех моделей

Применимо к версии 9.00X

Редакция для Российской Федерации

CE RoHS 2

Прибор для профессионального использования в области In Vitro диагностики

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Торговая марка TEST 1 является собственностью Alifax S.r.l.

Фото 56 Руководство по эксплуатации на русском языке

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 57 Руководство по эксплуатации на электронном носителе (CD-диск)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

Фото 58 Руководство по эксплуатации на электронном носителе (флеш-карта)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

ALIFAX

FASCICOLO APPARECCHIO D195.05.03.02 Rev 1.7 — Pag. 9 di 9
DEVICE HISTORY RECORD
TEST1 THL / BCL / SDL / YDL / MDL / XDL / HDL (SI 195.2XX)
s.n. T16865 commessa (Job Order) 2022-2/773 Data PRD 16/02/22

CORREDO DI SERIE / PACKING LIST

STRUMENTO INSTRUMENT	MODELLO MODEL						LINGUA LANGUAGE	
	THL	BCL	SDL	YDL	MDL	XDL	EN	IT
☒ TEST1 SI 195.2XX	☐	☐	☐	☒	☐	☐	☒	☐

Corredo di serie / Packing list

- ☒ N.° 2 SI195800 Rotoli Carta termica / Thermal Paper rolls
- ☒ N.° 2 SI205801 Tanica di lavaggio / Wash Tank
- ☒ N.° 2 SI205801 Tanica di scarico / Waste Tank
- ☒ N.° 2 Fusibili di alimentazione T5A / Main fuses T5A
- ☒ N.° 1 Cavo Alimentazione / Main cable plug
- ☐ Cavo alimentazione personalizzato/Personalized main cable _____
- ☒ N.° 1 Ago a vite / Needle
- ☒ N.° 1 CD Manuale operativo multilingua / CD Multi-Language Operative manual (Language and version)
  ESR_UM_SI195_TEST1_SW 9-00C_1-9-EN-ES-IT-PT
- ☒ ESR_IQOQ_SI195_TEST1: Modulo di installazione / Installation Report

SOLO STRUMENTI SDL / SDL INSTRUMENTS ONLY:

- ☐ N.°4 Pettine rack Sysmex XN / Sysmex XN rack scallop
- ☐ Nota tecnica n.° 2004 EN / Technical note n.° 2004 EN

SOLO STRUMENTI SDL PER PROVETTE SARSTEDT / SDL INSTRUMENTS FOR SARSTEDT TUBES ONLY:

- ☐ N.° 4 Pettine x Sarstedt 11X66 / Sarstedt 11x66 scallop
- ☐ Nota tecnica n.° 2006 EN / Technical note n.° 2006 EN

- ☒ Dichiarazione di conformità CE / EC declaration of conformity
- ☒ DPRD0105: Prove Elettriche EN61010-2-101:2002 Allegato F / Electrical routine tests EN61010-2-101:2002 Annex F
- ☒ Pag 8/9: Certificato di Collaudo / Final Test report
- ☒ Pag 9/9: Packing List / This document

Compilatore/Signature _____ **Data/Date** 30/03/2022

Approvato dal Responsabile Produzione Strumenti per rilascio finale / Manufacturer Manager Approval

DATA/Date 30/03/2022 **FIRMA/Signature** _____

Approvato da Assicurazione Qualità (Approved by Quality Assurance)

Data 30/03/2022 **Firma** _____
(Date) (Signature)

ALIFAX S.r.l.
via Petrarca 2/1 – 35020 POLVERARA (PD) – ITALY
Tel. +39 0490992000 e-mail: info@alifax.com
PI 04337640280

ALIFAX S.r.l.
via Merano 30 – 33045 NIMIS (UD) – ITALY
Documents available on: www.alifax.com

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Фото 59 Упаковочный лист (анализатор TEST1 модель YDL)

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

INSTALLATION REPORT
for TEST1 Instruments

Rev. 3.0 – Valid since 2022 May 25

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. +39-0432-197900
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 verity 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: ☐ TEST1 Model: _____	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 60 Инсталляционная форма

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EU DECLARATION OF CONFORMITY

Code: ESR_DECO_SI1952XX_TEST1_3-0_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 devices:

Product Name and Product Code	TEST1 THL	SI 195.210/THL
	TEST1 BCL	SI 195.220/BCL
	TEST1 SDL	SI 195.230/SDL
	TEST1 YDL	SI 195.240/YDL
	TEST1 MDL	SI 195.250/MDL
	TEST1 XDL	SI 195.260/XDL
Intended Purpose	TEST1 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. TEST1 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.	

comply 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 devices have 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 Electrical equipment for measurement, control and laboratory use - EMC requirements IEC 61326-2-6:2012: Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

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.pA
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Фото 61 Декларация соответствия

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ALIFAX

FASCICOLO APPARECCHIO D195.05.03.02 Rev 1.7
DEVICE HISTORY RECORD
Pag. 8 di 9
TEST1 THL / BCL / SDL / YDL / MDL / XDL / HDL (SI 195.2XX)
s.n. T16865 commessa (Job Order) 2022-2/773 Data PRD 14/02/22

CERTIFICATO DI COLLAUDO *TEST1* ***TEST1* – FINAL TEST REPORT**

MATRICOLA COMPONENTI - INTERNAL PARTS SERIAL NUMBERS

DESCRIZIONE BOARD NAME	CODICE PART CODE	MATRICOLA SERIAL NUMBER	Sigla Operat. Operator
Lotto **TELAIO**	M195.11.13	83/22	
Lotto **PANNELLO COMANDI**	195.042	01/22	
Lotto **KIT FAST**	195.032	01/22	
Lotto **ROTORE**	195.031	161/22	
Lotto **TRASFORMATORE**	195.046	1299/20	
SCHEDA ALIMENTATORE Power supply board	195.005	195005*8273	
SCHEDA CPU CPU Board	195.052	195052*01401	
SCHEDA CPS-MC CPS-MC Board	G1102.003	G1102003*1287	
SCHEDA SENS. RACK E HOME Rack and Home Sensor Board	195.009	00926210118	
SCHEDA SERIALE Serial Connectors Board	195.011	195011*5558	
CARRELLO Carriage	G195.001	G195001*1310	
LETTORE INTERNO DI CODICI A BARRE Internal barcode reader	ORTC1200-1000	Serial Number G21M40675	

COLLAUDI / FINAL TEST REPORT

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

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

Approvato dal Responsabile Produzione Strumenti / Manufacturer Manager Approval

DATA/Date 30/03/2022 FIRMA/Signature

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Фото 62 Сертификат выходного контроля качества (анализатор TEST1 модель YDL)

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Фото 63 Подставка под штативы

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Фото 64 Резервуар для отходов

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Фото 65 Смарт-карты TEST1 на 1000/4000/10000/20000 тестов

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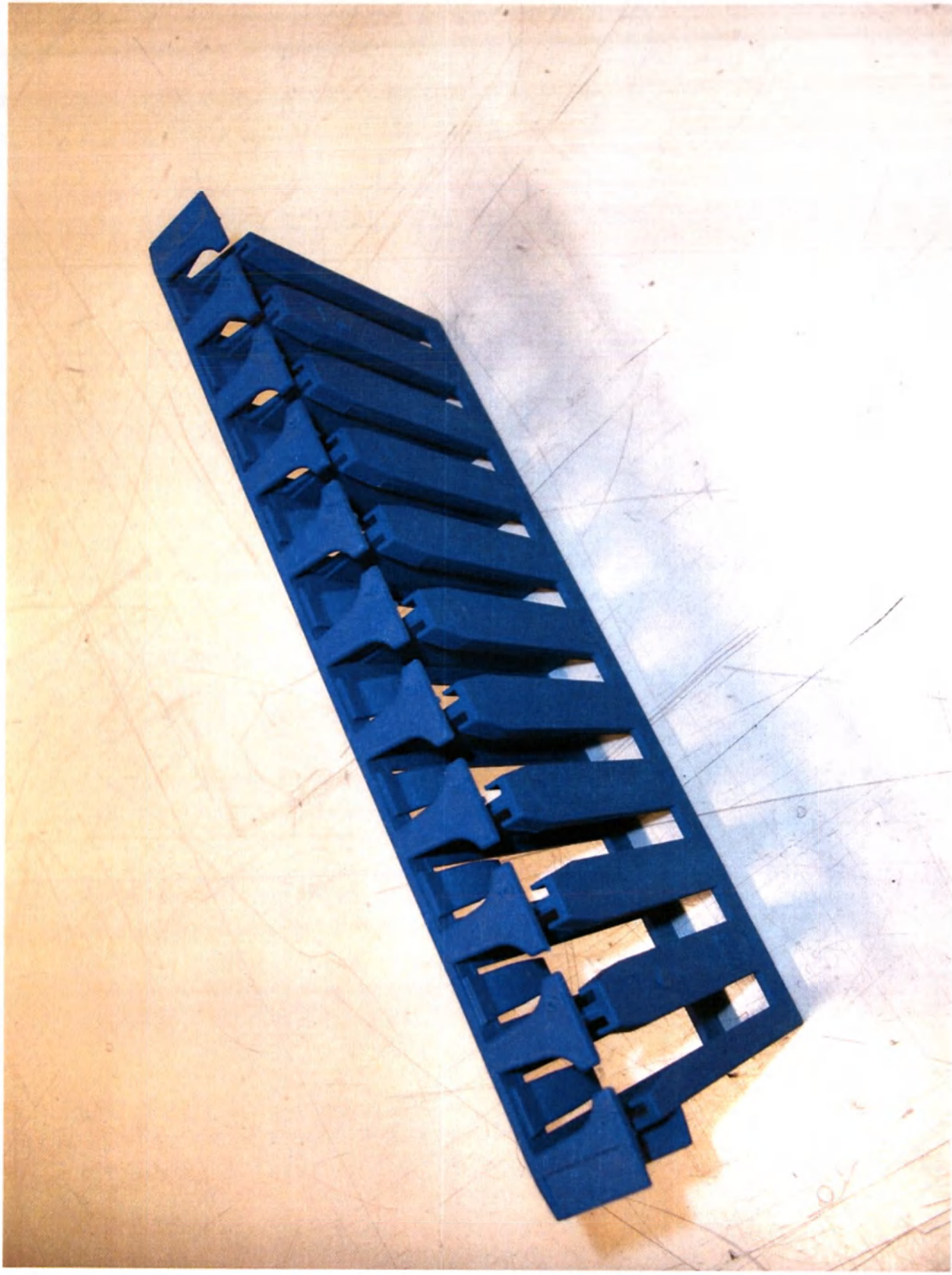

Фото 66 Штатив Alifax для TEST1 YDL (синий)

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Фото 67 Кабель питания

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Фото 68 Стартовый набор термобумаги в рулонах

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Фото 69 Предохранители

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Фото 70 Резервуар для промывки

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В данном документе
пронумеровано и прошито

71

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