Avantor Performance Materials Poland Spółka Akcyjna
ul. Sowińskiego 11
44-101 Gliwice, Poland
Tel.: +48 32 239 20 00
Fax: +48 32 239 23 70
e-mail: avantor.pl@avantormaterials.com
www.poch.com.pl
www.avantormaterials.com

Declaration of conformity

Avantor Performance Materials Poland S.A. who is an established manufacturer of reagents and products for diagnostic in vitro located at:

Sowińskiego 11 Street
44-101, Gliwice
Poland

Herewith declares the following:
Reagents mentioned in attached list are labeled with J.T.Baker label, comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the requirements of ISO 13485 Standard.
This declaration is the basic for CE marking of the In Vitro Diagnostic Medical Devices.
The products are not part of List A and List B of Annex II of the IVD Directive 98/79/EC but are subject to self registration.
This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking.

Gliwice, Poland.
A. Szuba
June 14, 2016

Digitally signed by Ceaicovschi Tudor
Date: 2024.04.15 14:38:51 EEST
Reason: MoldSign Signature
Location: Moldova

Anna Szuba
Quality Director

NIP: 631-010-13-07
Sąd Rejonowy w Gliwicach, X Wydział Gospodarczy KRS nr 0000010108
Wysokość kapitału zakładowego: 2 360 793,00 zł., w całości opłacony

Avantor Performance Materials Poland Spółka Akcyjna
ul. Sowińskiego 11
44-101 Gliwice, Poland
Tel.: +48 32 239 20 00
Fax: +48 32 239 23 70
e-mail: avantor.pl@avantormaterials.com
www.poch.com.pl
www.avantormaterials.com

Deklaracja zgodności WE

Avantor Performance Materials Poland S.A. producent odczynników do diagnostyki in vitro zlokalizowany:

ul. Sowińskiego 11
44-101, Gliwice
Polska

Deklaruje zgodność odczynników wymienionych w załączonej liście oznakowanych etykietą J.T.Baker z wymaganiami Dyrektywy 98/79/WE Parlamentu Europejskiego i Rady w sprawie wyrobów medycznych używanych do diagnostyki in vitro oraz wymaganiami normy ISO 13485.
Powyższe odczynniki są oznakowane etykietą J.T.Baker i posiadają znaki CE na etykiecie.
Produkty nie są częścią wykazu A i wykazu B załącznika II Dyrektywy dla wyrobów medycznych do diagnostyki in vitro z Dyrektywy 98/79/WE Parlamentu Europejskiego i Rady, ale podlegają rejestracji.
Deklaracja obowiązuje dla wszystkich wyrobów medycznych do diagnostyki in vitro opisanych powyżej oraz wprowadzonych na rynek i posiadających oznakowanie CE.

Gliwice, Polska.
Czerwiec 14, 2016

Anna Szuba
Dyrektor Jakości

NIP: 631-010-13-07
Sąd Rejonowy w Gliwicach, X Wydział Gospodarczy KRS nr 0000010108
Wysokość kapitału zakładowego: 2 360 793,00 zł., w całości opłacony

J.T.Baker product list for CE marked products

Product	Product Number	Pack Size
Hematology Analyzers		
H32 3-Part Differential	2983	1 unit
Diluents		
Diluid™ 100 Plus	3961	20 L
Diluid™ 22	2990.9010PC	10 L
Diluid™ 610	3969	20 L
Diluid™ Abacus	3430,9020	20 L
	3430,9010	10 L
Diluid™ AC 900	3996	20 L
Diluid™ APR	3476.9020PC	20 L
Diluid™ Azide free	3957	20 L
Diluid™ III Diff	3963	20 L
Diluid™ Erma	3459,9020	20 L
Diluid™ Mindray	3439.9020PC	20 L
Diluid™ NR	3483.9020PC	20 L
Diluid™ Ruby	2987.9020PC	20 L
Diluid™/Sheath 3200-4000	3832,9020	20 L
Diluid™ ST1600/2000	3976	20 L
Sheath D	3495.9010PC	10 L
Sheath Fluid 3000/3500	3471.9020PC	20 L
Lyses		
CN-free Lyse Diff AC 900	3998	5 L
CyMet™ 22	2986.0500PE	500 ml
CyMet™ 3000	3469.9010PC	10 L
CyMet™ 3200 CN free	3823,1000	1 L
CyMet™ 3500	3839.5000PC	5 L
CyMet™ 3500 CN free	3825	5 L
CyMet™ 610 CN free	3970	10 L
	3977	5 L
CyMet™ Abacus CN free	3431,1000	1 L
CyMet™ APR Baso II	3479.1000PE	1 L
CyMet™ APR CN free	3417.0500PE	500 ml
CyMet™ APR EO	3478.1000PE	1 L
CyMet™ ASA	2950.2500PE	3.8 L
CyMet™ ASB	2951.0250PE	380 ml
CyMet™ AS CN free	2952.9010PC	10 L
CyMet™ BS3 CN free	2982.0500PE	500 ml
CyMet™ III Diff	3964	5 L
	3968	1 L
CyMet™ III Diff CN free	3511,1000	1 L
CyMet™ Erma	3416,0500	500 ml
CyMet™ H20	3853,1000	1 L
CyMet™ KX CN Free	3425,0500	500 ml
CyMet™ Micro	3852,1000	1 L
CyMet™ Micro CN free	3863,1000	1 L micros
CyMet™ Mindray CN Free	3440.0500PE	500 ml
CyMet™ NR III	3484.1000PE	1 L
CyMet™ NR III CN Free	3486.1000PE	1 L
CyMet™ NR V	3485.1000PE	1 L
CyMet™ Ruby CN Free	2988.5000PC	5 L
CyMet™ ST 1600/2000 CN free	3759,5000	5 L
LeucoLyse	3475.5000PC	5 L
LeucoLyse Ruby	2989.5000PC	5 L
Cleaners		
Blanking Solution 1600/2000	3947	20 L
DetectoTerge™	3763	5 L
	3766	1 L
DetectoTerge™ BS	2970.0900PE	900 ml
ProClean™	3900	5 L
	3768,1000	1 L micros
ProClean™ Abacus	3432,5000	5 L
	3432.1000PE	1 L

J.T.Baker product list for CE marked products

ProClean™ CD	3902.0100PE	100 ml
ProClean™ Extra	3862,5000	5 L
	3867.1000PE	1 L micros
ProClean™ Plus	3901	100 ml
Rinse Mindray	3442.5000PE	5 L
Hematology Controls		
8-Parameter Control L/N/H	3427/3428/3429	2.5 ml
	3463/3464/3465	2.5 ml
8-Parameter Control L+N+H	3746	3 x 2.5 ml
8-Parameter Control 4xN	3747	4 x 2.5 ml
8-Parameter Control 1xL+4xN+1xH	3751	6 x 2.5 ml
8-Parameter Control extended L/N/H	3633/3634/3635	2.5 ml
3-Diff Control L/N/H	3433/3434/3435	2.5 ml
	3502/3503/3504	4.5 ml
3-Diff Control 4xL	3466	4 x 2.5 ml
3-Diff Control 4xN	3467	4 x 2.5 ml
3-Diff Control 4xH	3468	4 x 2.5 ml
3-Diff Control extented L/N/H	3421/3422/3423	2.5 ml
BC-Diff 5 Control L/N/H	3613/3614/3615	3.0 ml
CD-Diff Control L/N/H	3452/3453/3454	3.0 ml
CD-Diff Control 2xL+2xN+2xH	3838	6 x 3.0 ml
K-Diff Control L/N/H	3455/3456/3457	2.5 ml
Platelet Control- Extended value	3424	5 x 3.0 ml
WBC Reduced RBC L/H	3698/3699	3.0 ml
XE-Diff Control L/N/H	3731/3732/3733	4.5 ml
Fixatives		
Cervix Spray Fixative	3869,1200	12 x 125 ml
10% v/v Buffered Formaldehyde (4% w/v)	3933,1000	1 L
10% v/v Buffered Formaldehyde (4% w/v)	3933.5000PC	5 L
10% v/v Buffered Formaldehyde (4% w/v)	3933,9010	10 L
10% v/v Buffered Formaldehyde (4% w/v)	3933,9020	20 L
Clearing agents		
UltraClear™	3905.2500PE	2.5 L
UltraClear™	3905.5000PE	5 L
UltraClear™	3905.9010PE	10 L
Stains and Dyes		
Eosin-Y Alcoholic	3800.1000PE	1 L
Eosin-Y Alcoholic	3800.2500PE	2.5 L
Giemsa	3856,1000	1 L
Giemsa	3856,2500	2.5 L
Hematoxylin er (Mayer)	3870,1000	1 L
Hematoxylin er (Mayer)	3870,2500	2.5 L
Hematoxylin Modified (Harris, Gill II)	3873,1000	1 L
Hematoxylin Modified (Harris, Gill II)	3873,2500	2.5 L
May-Grünwald	3855,1000	1 L
May-Grünwald	3855,2500	2.5 L
Papanicolaou 2A	3554.1000PE	1 L
Papanicolaou 2A	3554.2500PE	2.5 L
Papanicolaou 2B	3555.1000PE	1 L
Papanicolaou 2B	3555.2500PE	2,5 L
Papanicolaou 3B	3556.1000PE	1 L
Papanicolaou 3B	3556.2500PE	2.5 L
Mounting media		
UltraKitt™	3921,0500	500 ml
UltraKitt™	3921,0600	6 x 100 ml
Mounting medium High	3882,0500	500 ml
Mounting medium Low	3883,0500	500 ml
PBS and accessories		
PBS	3059	20 L
PBS	3059.9010PC	10 L

CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT UNITED KINGDOM

UL LLC® (UL Solutions) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2016
EN ISO 13485:2016

The design and manufacture of in vitro diagnostic blood grouping reagents. The purchase for resale of in vitro diagnostic serology test kits.

UKAS MANAGEMENT SYSTEMS 4426

Authorized by

Paul Hilgeman
Senior Business Manager - Medical
CMIT – Medical Regulatory

Check Certificate Status:
here

File Number	A12241	Cycle Start	May 23, 2023
Certificate Number	1458.230523	Effective Date	May 23, 2023
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2026

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC® (UL Solutions).

UL Solutions
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

Archem Sağlık San. ve Tic. A.Ş.
Mahmutbey Mah. Halkalı Cad.
No:124 Bağcılar/İstanbul
Tel : 444 08 92 Pbx
Fax: +90 (212) 629 98 89
info@archem.com.tr
www.archem.com.tr

Appendix to

Conformity Declarations

Archem Diagnostic Systems

Conformity also declared with all aplicable harmonized standards, especially the following:

EN ISO 13485: Medical devices — Quality management systems — Requirements for regulatory purpose.

EN ISO 14971: Medical devices — Application of risk management to medical devices.

EN ISO 17511: In vitro diagnostic medical devices — Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials.

EN ISO 18113-1: In vitro diagnostic medical devices —Information supplied by themanufacturer (labelling) — Part 1: Terms, definitions and general requirements.

EN ISO 18113-2: In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for Professional use.

Other standards applied:
EN ISO 9001: Quality management systems

Note: Standards are used in this issue that is valid at date of issue of this conformity declaration.

Commercial Director
Erkan Uca
06.10.2022

archem
SAĞLIK SAN. VE TİC. ANONİM ŞTİ.
Mahmutbey Mah. Halkalı Cad. No:124/42
Bağcılar/İST. Tel: 444 08 92 Fax:0212 629 98 89
Güneşli V.D.:0730790980

Archem Diagnostics Industry Inc.
Mahmutbey Mah. Halkalı Cad. No:124 Bağcılar, ISTANBUL TURKEY
Tlf: + 90 212 444 08 92 Fax: +90 212 629 98 89 info@archem.com.tr www.archem.com.tr

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1038121-1

Manufacturer: MACHEREY-NAGEL GmbH & Co. KG
Valencienner Str. 11
52355 Düren
Germany

Products: Products for self-testing
- Single and multi-parameter disposable test strips for urine analysis
- Indicator test strips and papers for measurement of pH in urine

Replaces Certificate, Registration No.: HL 60119814 0001

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 1106581-20

Effective date: 2022-02-16

Expiry date: 2025-05-26

Issue date: 2022-02-16

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1038121-1

Manufacturer: MACHEREY-NAGEL GmbH & Co. KG
Valencienner Str. 11
52355 Düren
Germany

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design and development, manufacture and quality control
/02	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 1106581-20

Effective date: 2022-02-16

Expiry date: 2025-05-26

Issue date: 2022-02-16

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

EC Declaration of Conformity according to MDD 93/42/EEC

Product Description:	**SurgiLance™ Safety Lancet**
Product Designation:	**Lancing Devices, Blood**
UMDNS- Code:	**16380**
Model No's:	**SLN100, SLN170, SLN200, SLN240, SLN300, SLN100S, SLN170S, SLN200S, SLN240S, SLN300S, SLN103, SLN173, SLN203, SLN243, SLN303, SLB200, SLB250, SLB200S, SLB250S, SLB203, SLB253**

We herewith declare that the products listed above are in compliance with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive 93/42/EEC.

Conformity Assessment Procedure: **Annex II without section 4** (MDD 93/42/EEC)
Classification of the Product: **Class IIa** Rule: **6** (MDD 93/42/EEC Annex IX)

Manufacturer : **MediPurpose Pte. Ltd.**

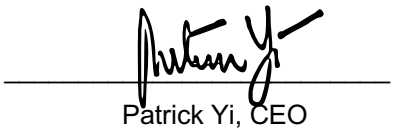
Address : **10 Anson Road**
#12-08 International Plaza, Singapore 079903

EU Authorized Representative: **Obelis S. A.**
Bd. Général Wahis, 53
1030 Brussels,
Belgium

This declaration is supported by EC quality assurance statement (Annex II without section 4), demonstrated by compliance to certificate number HD 60146306 0001 (Issued 10 February 2020/Exp: 26 May 2024), issued by Notified Body TÜV Rheinland LGA Products GmbH (0197).

This Declaration of conformity is valid in connection with the release of document for the respective batch of produced devices.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.



Patrick Yi, CEO

06 April 2020
Date

SURGILANCE SAFETY NEEDLE G23 - automatic lancets

Code:	**24514**
Category:	**Lancets**
Unit of sale:	**box of 100 pcs.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**II A**
NSIS:	**16427**
CND:	**V9009**
EAN13:	**8023279245141**

Description:

SURGILANCE™ SAFETY AUTOMATIC LANCETS - NEEDLES

Colour: Grey
Depth of penetration: 1,8 mm
Entire needle Gauge: 21G
Needle tip Gauge: 23G
Blood Flow: 10-20 µl
Finger Stick: yes
Glucose: yes
Hematocrit: -

Multi purpose capillary blood sampling devices for all testing requirements.
The one-step safety lancet is easier to use, no arming is required, and safer, once lancet is used it is rendered inoperable.
High-speed delivery and penetration method minimizes patient pain and operator error.
Latex-free, hypo-allergenic, disposable, sterile.

Multilingual box: GB, FR, IT, ES, DE, PT, NL, SE, DK, RU, GR

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1614112-1

Organization: KABE-Labortechnik GmbH
Jägerhofstr. 17
51588 Nümbrecht
Germany

Scope: Design and development, production and distribution of in vitro diagnostic devices and consumption materials for sample withdrawal, preparation and storage as well as single-use medical devices

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1092786-40
Effective date: 2021-10-25
Expiry date: 2024-10-15
Issue date: 2021-10-25

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Dipl.-Ing. F. Schwingen
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1614112-1

Organization: KABE-Labortechnik GmbH
Jägerhofstr. 17
51588 Nümbrecht
Germany

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o KABE-Labortechnik GmbH Jägerhofstr. 17 51588 Nümbrecht Germany	Design and development, production and distribution of in vitro diagnostic devices and consumption materials for sample withdrawal, preparation and storage as well as single-use medical devices
/02	c/o KABE-Labortechnik GmbH Werner-von-Siemens-Str. 1 51674 Wiehl Germany	Warehouse

Report No.: 1092786-40
Effective date: 2021-10-25
Expiry date: 2024-10-15
Issue date: 2021-10-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Dipl.-Ing. F. Schwingen
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

KABE LABORTECHNIK

EG-KONFORMITÄTSERKLÄRUNG - EC DECLARATION OF CONFORMITY

Name und Adresse des Herstellers: Name and address of the manufacturer:	KABE-Labortechnik GmbH Jägerhofstraße 17 51588 Nümbrecht-Elsenroth Deutschland / Germany

Wir erklären in alleiniger Verantwortung, dass die In-Vitro-Diagnostika der Produktgruppe
We declare under our sole responsibility that the in-vitro-diagnostica of product group

Kapillaren
Capillaries

Kapillaren	Capillaries
– kapillare Probenbehältnisse aus Kunststoff – Blutgaskapillaren (BK) – Hämatokritkapillaren (HK) – end-to-end Kapillaren (EK)	– capillary sample containers made of plastic – blood gas capillaries (BK) – haematocrit capillaries (HK) – end-to-end capillaries (EK)

der Klasse of class	Andere IVD-Produkte Other IVD-devices
Steriles Medizinprodukt Sterile medical device	Ja Yes

den einschlägigen Bestimmungen der IVD-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Konformitätserklärung gilt für die durch die KABE-Labortechnik GmbH freigegebenen Chargen.

meets the provisions of the directive 98/79/EEC and its transpositions in national laws which apply to it. This declaration is valid for the batches released by KABE-Labortechnik GmbH.

Konformitätsbewertungsverfahren: Conformity assessment procedure:	Richtlinie 98/79/EWG Anhang III Directive 98/79/EEC Annex III

Diese Erklärung ist gültig bis: This declaration is valid until:	26. Mai 2027 26th May 2027

Nümbrecht-Elsenroth, 24. Mai 2022

André Kolpe, Geschäftsführer/Managing Director

CERTIFICATO N° 505SGQ06

CERTIFICATE N° 505SGQ06

Si certifica che il

this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da

implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di

Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma

is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi

concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile. Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro. Commercializzazione di articoli da laboratorio.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis and non-sterile class I medical devices. Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics. Marketing of laboratory items.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.

This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana

In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO

MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

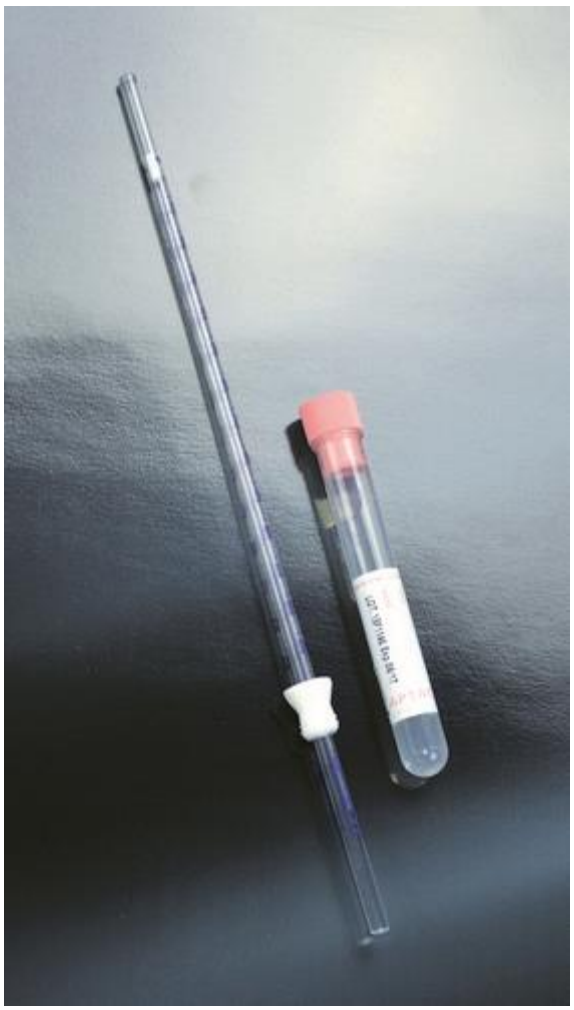
Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2023-10-24	2026-10-29

Settore IAF 14 - 29

SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC

Signatory of EA, IAF and ILAC Mutual Recognition Agreements



E.S.R. GRADUATED PIPETTE AND Ø 12 X 86 MM TEST TUBE

E.S.R. graduated pipettes + Ø 12 x 86 mm test tubes with 0.2 ml of Na Citrate for 0.8 ml of blood, labelled, with pink cap.

Cod.
10110