

“Echipamed-Plus” SRL
str. Valea Trandafirilor, 24B, of. 2-7
MD-2001, Chisinau, Moldova
+373 22 234-349
Date: 25.01.2026

LETTER OF AUTHORIZATION

To whom it may concern,

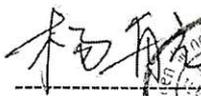
We, Shenzhen Mindray Bio-Medical Electronics Co., Ltd., (“Mindray”) manufacturer of biochemical, immunological and coagulation analyzers, reagents and consumables (“Product(s)”), hereby certify that “Echipamed-Plus” SRL, with business office at str. Valea Trandafirilor, 24B, of. 2-7, MD-2001, Chisinau, Republic of Moldova (“You”) is our official distributor and local representative for registration, sales and service of the Product(s) in Republic of Moldova (“Territory”).

As the manufacturer, Mindray guarantees the Product(s) against defects in materials and workmanship, and provide services based on the standard terms and conditions of Mindray’s warranty policy.

This authorization of distribution rights is valid from the date of issuance to **December 31, 2026**. Mindray reserves the right to terminate the authorization upon fifteen (15) days written notice without any compensation to You.

Neither this Letter of Authorization nor any further extension, will impose any obligation or grant any rights regarding further distribution of the Product(s), nor allow any party to seek compensation for goodwill developed during the term of Letter of Authorization or any further extension.

Best regards,


Yang Hang
General Manager of Sales and Marketing Division, Central Asia Region III

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Date: 25.01.2026





Product Service

Certificate

No. Q5 044751 0164 Rev. 05

Holder of Certificate: **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**

Mindray Building
 Keji 12th Road South
 High-Tech Industrial Park
 Nanshan
 518057 Shenzhen
 PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of: Active Medical Devices(intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro Diagnostic Instruments; Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits(intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 044751 0164 Rev. 05

Report No.: SH2305501

Valid from: 2023-09-01
Valid until: 2026-08-31

Date, 2023-06-19

C. Dicks

Christoph Dicks
 Head of Certification/Notified Body





Product Service

Certificate

No. Q5 044751 0164 Rev. 05

Applied Standard(s): EN ISO 13485:2016
 Medical devices - Quality management systems -
 Requirements for regulatory purposes
 (ISO 13485:2016)
 DIN EN ISO 13485:2016

Facility(ies): **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
 Mindray Building, Keji 12th Road South, High-Tech Industrial Park,
 Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of: Active Medical Devices(intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro Diagnostic Instruments; Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits(intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
 1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen,
 PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of: Active Medical Devices(intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro Diagnostic Instruments; Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits(intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)



Certificate

No. Q5 044751 0164 Rev. 05

For the product(s)/product category (ies):

Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Anesthesia Machine and accessories, Ventilator, Air compressor, Endoscope Camera System, Endoscope Light Source and accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for invitro diagnostic use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker&Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer, Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer.



Declaration of Conformity



Manufacturer: Beijing Mindray Medical Instrument Co., Ltd.
1F,2F,4F&5F, Building 3, No. 18 Science Park Road,
Life Science Park, Changping District, Beijing 102206,
China

Manufacturer SRN: CN-MF-000022542

Authorized Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80 20537 Hamburg, Germany

Product: Auto Coagulation Analyzer

Modle: C3510

Basic UDI-DI: 697080106A0320F05HTP

Classification: Class A (According to Rule 5 of IVDR annex VIII)

Conformity Assessment Route: Annex II and III of IVDR

GMDN code: 56689

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: /

Notified Body No. : /

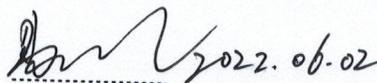
Identification of the Certificate: /

Start of CE-Marking: 2022-02-15

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Management Representative of Beijing Mindray Medical Instrument Co., Ltd., Effective immediately.

Place, Date of Issue: Beijing,

Signature:

 2022.06.02

Name of Authorized Signatory: Mr. Ge Pengfei

Position Held in Company: Management Representative

Declaration of Conformity V 1.0

Attachment of Declaration of Conformity: Applied Standards List-V1.0

Applied Standards List

Product: Auto Coagulation Analyzer

Catalogue Number: C3510

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-3:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009)
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 61010-1:2010/A1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN IEC 61010-2-081:2020	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
IEC 61010-2-101:2018	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61010-2-010:2020	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials

Declaration of Conformity V 1.0

EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

Declaration of Conformity **CE**

Manufacturer: Beijing Mindray Medical Instrument Co., Ltd.
1F,2F,4F&5F, Building 3, No. 18 Science Park Road, Life
Science Park, Changping District, Beijing 102206, China
100176, China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80 20537 Hamburg, Germany

Product: Auto Coagulation Analyzer

Model: C3510

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 2011/65/EU, amended by Directive 2015/863/EU. All supporting documentations are retained under the premises of the manufacturer.

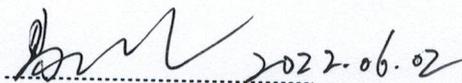
Standards Applied:

EN IEC 63000: 2018 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Start of CE-Marking: 2022-02-15

Place, Date of Issue: Beijing.

Signature:

 2022.06.02

Name of Authorized Signatory: Mr. Ge Pengfei

Position Held in Company: Management Representative



DECLARATION OF CONFORMITY

Manufacturer: Shanghai Long Island Biotec. Co., Ltd
No.839, Gaofeng Road, Fengxian District, 201401
Shanghai, P.R. China

Manufacturer SRN /

EC Representative: Shanghai International Holding Corp
GmbH (Europe) Eiffestraße 80, 20537 Hamburg,
Germany

Product: Cleaning Solution I

Catalogue Number: CLI1015

Basic UDI-DI: /

Classification: Class A(According to Rule 5 of IVDR annex VIII)

Conformity Assessment Route: Annex IX (excluding CHAPTER II)

GMDN code:

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPE PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

Reference to CS: /

Notified Body: TUV SUD Product Service GmbH RidlerstraBe 65
80339 Munchen, Germany

Notified Body No.: 0123

Identification of the Certificate: 2022-05-22

Start of CE -Marking: 2009-06-01

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Shanghai Long Island Biotec. Co., Ltd, Effective immediately.

Place, Date of Issue Shanghai

Signature: 

Name of Authorized Signatory: Ms. Xi Qimin

Position Held in Company: Management Representative

Applied Standards List

Product: **Cleaning Solution I**

Catalogue Number: **CLI1015**

Applied Standards:

EN ISO 183113-1:2011	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1:Terms,definitions and general requirements(ISO 183113-1:2009)
EN ISO 183113-2:2011	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 2:In vitro dignostic reagents for professional use(ISO 183113-2:2009)
EN ISO 15223-1:2016	Medical devices-Symbols to be used with medical device labels,labelling and information to be supplied-Part 1:General requirements.
EN ISO 14971:2012	Medical devices-Application of risk managemt to medical devices(ISO 14971:2007,Corrected version 2007-10-1)
EN 13612:2002/AC:2002	Performance evaluation of in vitrodiagnostic medical devices.
EN iso 23640:2015	In vitro diagnostic medic devices-Evaluation of stability of in vitro diagnostic reagents.
EN13641:2002	Elimination or reduction of risk of infection related to in vitro dignostic reagents.
EN ISO 17511:2003	In vitro diagnostic medic devices-Measurement of quantities in biological samples-Metrological traceability of values assigned to calibrators and control materials(ISO 17511:2003)
EN62366-1:2015	Medical devices-Part1:Application of usability engineering to in vitro diagnostic medic devices.
EN ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 9001:2015	Quality management systems — Requirements



DECLARATION OF CONFORMITY

Manufacturer: Shanghai Long Island Biotec. Co., Ltd
No.839, Gaofeng Road, Fengxian District, 201401
Shanghai, P.R. China

Manufacturer SRN: /

EC Representative: Shanghai International Holding Corp GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany

Product: Cleaning Solution II

Catalogue Number: CLII102500

Basic UDI-DI: /

Classification: Class A(According to Rule 5 of IVDR annex VIII)

Conformity Assessment Route: Annex IX (excluding CHAPTER II)

GMDN Code:

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPE PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

Reference to CS: /

Notified Body: TUV SUD Product Service GmbH RidlerstraBe 65
80339 Munchen, Germany

Notified Body No.: 0123

Identification of the Certificate: 2022-05-22

Start of CE -Marking: 2009-06-01

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Shanghai Long Island Biotec. Co., Ltd, Effective immediately.

Place, Date of Issue: Shanghai

Signature: 

Name of Authorized Signatory: Ms. Xi Qimin

Position Held in Company: Management Representative

Applied Standards List

Product: **Cleaning Solution II**

Catalogue Number: **CLII102500**

Applied Standards:

EN ISO 183113-1:2011	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 1:Terms,definitions and general requirements(ISO 183113-1:2009)
EN ISO 183113-2:2011	In vitro diagnostic medical devices-Information supplied by the manufacturer(labelling)-Part 2:In vitro dignostic reagents for professional use(ISO 183113-2:2009)
EN ISO 15223-1:2016	Medical devices-Symbols to be used with medical device labels,labelling and information to be supplied-Part 1:General requirements.
EN ISO 14971:2012	Medical devices-Application of risk managemt to medical devices(ISO 14971:2007,Corrected version 2007-10-1)
EN 13612:2002/AC:2002	Performance evaluation of in vitrodiagnostic medical devices.
EN iso 23640:2015	In vitro diagnostic medic devices-Evaluation of stability of in vitro diagnostic reagents.
EN13641:2002	Elimination or reduction of risk of infection related to in vitro dignostic reagents.
EN ISO 17511:2003	In vitro diagnostic medic devices-Measurement of quantities in biological samples-Metrological traceability of values assigned to calibrators and control materials(ISO 17511:2003)
EN62366-1:2015	Medical devices-Part1:Application of usability engineering to in vitro diagnostic medic devices.
EN ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 9001:2015	Quality management systems — Requirements

Declaration of Conformity

Manufacturer: Beijing Precil Instrument Co., Ltd.
Room 203,204&401,Building 2,No.2 Tongji Middle
Road,Beijing Economic & Technological Development
Area,Beijing,100176,China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Product: Auto Coagulation Analyzer
Model: C3100

Consumables: Auto Cuvettes
Probe Cleanser
Cleanser

Classification: Others (Not listed in the Annex II, Directive 98/79/EC)

Conformity assessment route: Annex III(Except 6), Directive 98/79/EC

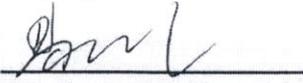
We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives 98/79/EC for in-vitro-diagnostics. All supporting documentation is retained under the premises of the manufacturer.

Standard applied:

List of(harmonized) standards for which documented evidence for compliance can be provided as attachment.

Start of CE-Marking: 2019-10-28

Place, Date: Beijing, 2019-10-28

Signature: 

Name of Authorized Signatory: Ge Pengfei

Position Held in Company: Management Representative



To whom it may concern



Konformitätserklärung / Declaration of Conformity

Konformitätserklärung für Siemens Healthcare Diagnostics Products GmbH CE-markierte Produkte.

Hiermit erklären wir, dass ein Konformitätsbeurteilungsverfahren für die hier aufgelisteten In-vitro-Diagnostika-Produkte durchgeführt wurde und sie mit den grundlegenden Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen und die Anforderungen gemäß Annex III erfüllt werden.

Declaration of Conformity for Siemens Healthcare Diagnostics Products GmbH CE-marked products.

We hereby declare that a conformity assessment has been performed for the in vitro diagnostic devices listed in the attachment and that they conform to all applicable Essential Requirements of Directive 98/79/EC on in vitro Diagnostic Medical Devices and accordance was shown by conformity assessment procedures of Annex III.

IVD-Kategorie / IVD category:

Sonstige	Others
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Legal Hersteller / Legal Manufacturer:

Siemens Healthcare Diagnostics Products GmbH
--

Adresse (innerhalb Deutschland):

Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg

Address (international):

Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany

Mit freundlichen Grüßen,

Sincerely,

Siemens Healthcare Diagnostics Products GmbH

Christian Hainer
Regulatory Affairs Manager

Simone Biek
Regulatory Affairs Professional

Datum /Date: 2019-09-17

Anhang /Enclosure: Product List

Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany



Konformitätserklärung

Declaration of Conformity

Enclosure to Certification, dd. 2019-09-17

Produktliste /Product List

Product Number (REF)	Package Size	Product Name (English)
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Hemostasis

281007		Thromboclotin
291070		Dade Ci-Trol 1
291071		Dade Ci-Trol 2
291072		Dade Ci-Trol 3
B4212-40, -50, -100		Dade Innovin
B4218-1, -2		Dade Actin Activated Cephaloplastin Reagent
B4218-20, -100		Dade Actin FS Activated PTT Reagent
B4219-1, -2		Dade Actin FSL Activated PTT Reagent
B4224-50		Dade Ci-Trol Heparin Control, Low
B4224-60		Dade Ci-Trol Heparin Control, High
B4233-15SY		Dade Fibrinogen Determination Reagents
B4233-22		Dade Data-Fi Abnormal Fibrinogen Control
B4233-25, -27		Dade Thrombin Reagent
B4234-25		Dade Owren's Veronal Buffer
B4238-40		Factor VIII Chromogenic Assay
B4244-10		Dade Ci-Trol Coagulation Control Level 1
B4244-20		Dade Ci-Trol Coagulation Control Level 2
OPAB	03	vWF Ag
OPAP	03	Protein S Ac
OPAT	03	PT-Multi Calibrator
OPBC	03	ProC Ac R
OPBP	03, 07	INNOVANCE D-Dimer
OPBR	03	INNOVANCE D-Dimer Sample Diluent
OPDY	03	INNOVANCE D-Dimer Controls
OPFH	03, 05	INNOVANCE Antithrombin
OPHL	03	INNOVANCE VWF Ac
OQAA	33	Imidazole Buffer Solution
OQAB	45	Kaolin Suspension
OQGP	17	LA 1 Screening Reagent
OQGR	13	LA 2 Confirmation Reagent
OQGS	29, 35	Pathromtin SL
OQKE	17	ProC Control Plasma
OQLS	13	ProC Global
OQVK	11	Fibrinogen Calibrator Kit
OQWD	11	LA Control High



Konformitätserklärung

Declaration of Conformity

Enclosure to Certification, dd. 2019-09-17

OQWE	11	LA Control Low
OQYG	11	Protein C Reagent
ORHO	37	Calcium Chloride Solution
ORKE	41	Control Plasma N
ORKL	17	Standard Human Plasma
ORSM	19	Coagulation Factor V Deficient Plasma
OSDF	13	Coagulation Factor XI Deficient Plasma
OSDG	13	Coagulation Factor XII Deficient Plasma
OSGR	13	Coagulation Factor II Deficient Plasma
OTXV	13	Coagulation Factor VII Deficient Plasma
OTXW	17	Coagulation Factor VIII Deficient Plasma
OTXX	17	Coagulation Factor IX Deficient Plasma
OTXY	13	Coagulation Factor X Deficient Plasma
OUBD 23		Von Willebrand Reagent
OUBD 37		BC von Willebrand Reagent
OUBU	15	Berichrom α_2 -Antiplasmin
OUCA	17	Berichrom Plasminogen
OUHP	29, 49	Thromborel S
OUIA	15	Berichrom C1-Inhibitor
OUPZ	17	Control Plasma P
OUVV	15	Berichrom Protein C
OWHM	13	Test Thrombin Reagent
OWNA	11	BC Thrombin Reagent
OWOA	15	Berichrom PAI
OWSU	11	Berichrom F XIII
OWWR	15, 17	Berichrom Antithrombin III (A)
OWZG	19, 23	Multifibren U

- End of Product List -





Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zfz.de
BS-IVDR-099



Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class A Devices in Sterile Condition)

No. V11 042464 0039 Rev. 00

Manufacturer:

**Zhejiang Gongdong Medical
Technology Co., Ltd.**

No.10 Beiyuan Ave., Huangyan
318020 Taizhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer:

CN-MF-000005694

**Authorized
Representative:**

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).

The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The involvement of the notified body is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V11_042464_0039_Rev_00

Report No.:

SH2211102

Valid from:

2023-04-11

Valid until:

2028-04-10

Issue date: 2023-04-11

Marta Carnielli
Head of Notified Body IVD





Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zig.de
 BS-IVDR-099



Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
 Annex IX Chapters I and III (Class A Devices in Sterile Condition)

No. V11 042464 0039 Rev. 00

Classification: Class A
Device Group: W050101 - BLOOD COLLECTION DEVICES
Intended Purpose: IVR 0803 - Specimen receptacles referred to in point 2.5 (rule 5),
 under c), of Annex VIII to Regulation (EU) 2017/746

The validity of this certificate depends on conditions and/or is limited to the following:

Revision History:

Rev.	Dated	Report	Description
00	2023-04-11	SH2211102	Initial issuance

