Digitally signed by Iurchevici Valeriu
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Reason: MoldSign Signature
Location: Moldova
CA-GJLA202401260006

mindray

"Echipamed-Plus" SRL
str. Valea Trandafirilor, 24B, of. 2-7
MD-2001, Chisinau, Moldova
+373 22 234-349

Date: 26.01.2024

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, 2024.** 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,

Duan Liang
General Manager of Sales and Marketing Division, Central Asia Region
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.
Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan,
Shenzhen 518057, P.R. China
Tel: +86 755 26582888
Fax: +86 755 26582680
Website: www.mindray.com

"ECHIPAMED-PLUS" CHIŞINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ
IDNO 1003600077677

REGISTRATION NO. 04721Q10132R7L

CERTIFICATE
OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

ShenZhenMindray Bio-Medical Electronics Co., Ltd.

Registered Address:Floor 1st~Floor 4th, Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, P.R.China

Manufacturing Address:Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, P.R.China; 1203 Nanhuan Avenue, Guangming District, Shenzhen, P. R. China

Has been assessed and conformed to the following standard(s)
GB/T 19001-2016 idt ISO 9001:2015

The certificate is valid for the following scope:

The Design, Development, Production and Service of Endoscope light source ,Diagnostic Ultrasound System , Endoscope Camera System, Microplate washer , UltraSync, patient monitor, Center Monitoring System, Telemetry Monitoring System, Vital Signs Monitor, Pulse Oximeter, Vital Signs Monitor & Patient Monitors, Disposable SpO2 Sensor, SpO2 Sensor, ECG Cable, NIBP Cuff, Temperature Probe, Holter, Wearable ECG Monitor, Analysis system, Defibrillator/Monitor, Electrocardiograph, Anesthesia Machine, Ventilator, Ultrasound Diagnostic System, Digital Ultrasonic Diagnostic Imaging System, Ultrasound Imaging Administration System, Digital Radiography System, Mobile radiography system, Mobile Stand, Radiography Imaging Information System, retropad detector and its imaging system, Auto Hematology Analyzer, Urine Analyzer, Auto Silde Maker&Statiner, Flow Cytometer, Automatic Glycohemoglobin Analyzer, Specific Protein Analyzer, Sample Processing System, Chemistry Analyzer, Semi-auto Chemistry Analyzer, Microplate reader, Chemiluminescence Immunoassay Analyzer, CPR sensor, VS-900 Neo Vital Signs Monitor, Automated External Defibrillator, Ultrasonic Transducer, Automated Digital Cell Morphology Analyzer and Vitro Diagnostic Reagent (within the scope of manufacturing license)

Date of issue: April 15,2021
Date of expiry: April 05,2024
Date of change: May 31,2022

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

CNAS

中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or the website of CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
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:

TÜV SÜD
EN ISO 13485
tuvsud.com/ps-cert

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

Christoph Dicks
Head of Certification/Notified Body

"TECHIPAMED-PLUS" IDNO 1003600077677

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
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)

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

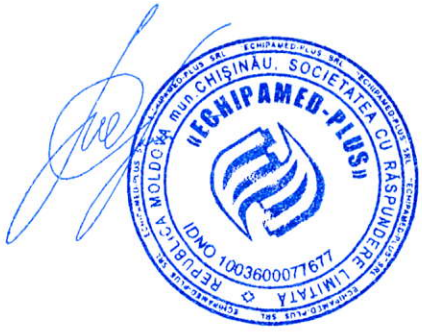
TÜV SÜD
Product Service

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.



TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Chemistry Analyzer**
Model:	**BS-240**
Consumables:	Reaction cuvette Mindray reagent bottles CD-80 DETERGENT
Optional Module:	ISE unit bar code reader(optional)
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation

Conformity Assessment Route: IVDD Annex III (not includes Section 6)

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Start of CE-Marking: 2016-03-29

Place, Date of Issue: Shenzhen, 2016.3.29

Signature: .....

Name of Authorized Signatory: Mr. Tan Chuanbin

Position Held in Company: Manager of Technical Regulation

MOLDOVA mun.CHIŞINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TEHNIPAMED-PLUS" REPUBLICA

PZ CORMAY S.A.
05-092 Lomianki, 22 Wiosenna Str.
phone: +48 22 751 7910 ; fax: +48 22 751 7911
www.cormay.pl; office@cormay.pl

ISO 9001 Quality Management System

ISO 13485 Quality Management System

EC DECLARATION OF CONFORMITY

In accordance with Directive 98/79/EC

We, **PZ CORMAY S.A.,** ul. Wiosenna 22, 05-092 Łomianki, Poland
declare that the following devices:

Devices name: see ATTACHMENT A

Devices number: see ATTACHMENT A

(classified as other IVDD - all devices with exception of devices listed in List A and List B and self-testing devices)
comply with essential requirements of the ANNEX I - Directive 98/79/EC
and conformity assessment made accordingly to the ANNEX III - Directive 98/79/EC.

The devices named above have been designed and manufactured to the following specifications:

EN ISO 14971:2000	Medical Devices – Application of risk management to medical devices.
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents.
EN 375:2001	Information supplied by the manufacturer with in vitro diagnostic reagents for professional use.
EN 980:2006	Graphical symbols for use in the labeling of medical devices.
EN 13640: 2002	Stability testing of in vitro diagnostic reagents.
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices.

PZ CORMAY S.A Quality Management System complies with requirements of ISO 9001:2008 and ISO 13485:2003 standard and has been approved by Lloyd's Register Quality Assuarance Limited in the range concerning design, manufacturing and distribution of in vitro diagnostic medical devices for medical, industrial and research laboratories. Sale and service of medical equipment.

Signed by: .....

Name: Tomasz Tuora

Position: President PZ CORMAY S.A.

Place: Łomianki

Date: 16 September, 2010

Attachment A to the EC DECLARATION OF CONFORMITY

Device number	Device name
5-174	CORMAY MULTICALIBRATOR LEVEL 1
5-176	CORMAY MULTICALIBRATOR LEVEL 1
5-175	CORMAY MULTICALIBRATOR LEVEL 2
5-177	CORMAY MULTICALIBRATOR LEVEL 2
5-170	CORMAY MULTICAL
5-178	CORMAY HDL/LDL CALIBRATOR
4-287	CORMAY IMMUNO-MULTICAL
4-289	CORMAY APOLIPOPROTEIN CALIBRATORS
4-292	CORMAY FIBRINOGEN CALIBRATOR
4-295	CORMAY CRP NORMAL CALIBRATOR
4-276	CORMAY CRP ULTRA CALIBRATORS
4-279	CORMAY MYOGLOBIN CALIBRATORS
4-281	CORMAY Lp(a) CALIBRATORS
4-491	CORMAY FERRITIN CALIBRATORS
4-280	CORMAY IgE CALIBRATORS
4-282	CORMAY AFP CALIBRATORS
4-283	CORMAY BETA 2-MGLOB CALIBRATORS (S)
4-284	CORMAY BETA 2-MGLOB CALIBRATORS (U)
4-286	CORMAY ALPHA 1-MGLOB CALIBRATORS (S)
4-285	CORMAY ALPHA 1-MGLOB CALIBRATORS (U)
4-277	CORMAY RF CALIBRATORS
4-278	CORMAY ASO CALIBRATOR
4-318	CORMAY HbA1c CALIBRATORS
4-308	CORMAY HbA1c DIRECT CALIBRATORS
5-182	CORMAY CK-MB CALIBRATOR
4-259	CORMAY D-DIMER CALIBRATOR
5-181	CORMAY URINE PROTEINS CALIBRATORS
5-185	CORMAY CYSTATIN C CALIBRATORS
5-105	CORMAY ETHANOL CALIBRATORS
5-106	CORMAY ETHANOL CALIBRATOR 100
5-112	CORMAY CARBAMAZEPINE CALIBRATORS
5-114	CORMAY DIGITOXIN CALIBRATORS
5-113	CORMAY DIGOXIN CALIBRATORS
5-110	CORMAY GENTAMICIN CALIBRATORS
5-111	CORMAY PHENOBARBITAL CALIBRATORS
5-109	CORMAY THEOPHYLLINE CALIBRATORS
4-380	CORMAY BILIRUBIN CALIBRATOR

Signed by:.....

Name: Tomasz Tuora

Position: President PZ CORMAY S.A.

Place: Łomianki

Date: 16 September, 2010

REPUBLICA MOLDOVA mun. CHIȘINĂU, SOCIETATEA CU RASPUNDERE LIMITATA "TECHNIPAMED-PLUS" IDNO 1003600077677

PZ CORMAY S.A.
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ISO 9001 Quality Management System

ISO 13485 Quality Management System

EC DECLARATION OF CONFORMITY

In accordance with Directive 98/79/EC

We, **PZ CORMAY S.A.**, ul. Wiosenna 22, 05-092 Łomianki, Poland
declare that the following devices:

Devices name: see ATTACHMENT A

Devices number: see ATTACHMENT A

(classified as other IVDD - all devices with exception of devices listed in List A and List B and self-testing devices)
comply with essential requirements of the ANNEX I - Directive 98/79/EC
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EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents.
EN 375:2001	Information supplied by the manufacturer with in vitro diagnostic reagents for professional use.
EN 980:2006	Graphical symbols for use in the labeling of medical devices.
EN 13640: 2002	Stability testing of in vitro diagnostic reagents.
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices.

PZ CORMAY S.A Quality Management System complies with requirements of ISO 9001:2008 and ISO 13485:2003standard and has been approved by Lloyd's Register Quality Assuarance Limited in the range concerning design, manufacturing and distribution of in vitro diagnostic medical devices for medical, industrial and research laboratories. Sale and service of medical equipment.

Signed by:.....

Name: Tomasz Tuora

Position: President PZ CORMAY S.A.

Place: Łomianki

Date: 08 January, 2010

Attachment A to the EC DECLARATION OF CONFORMITY

Device number	Device name
5-172	CORMAY SERUM HN
5-173	CORMAY SERUM HP
4-288	CORMAY IMMUNO-CONTROL I
4-290	CORMAY IMMUNO-CONTROL II
4-291	CORMAY IMMUNO-CONTROL III
4-492	CORMAY Lp (a) CONTROL N
4-493	CORMAY Lp (a) CONTROL P
5-179	CORMAY LIPID CONTROL 1
5-180	CORMAY LIPID CONTROL 2
4-319	CORMAY HbA1c CONTROLS
4-328	CORMAY HbA1c DIRECT CONTROLS
4-293	CORMAY APOLIPOPROTEIN CONTROL
4-459	CORMAY D-DIMER CONTROLS
5-183	CORMAY CK-MB CONTROL N
5-184	CORMAY CK-MB CONTROL P
5-161	CORMAY URINE CONTROL LEVEL 1
5-162	CORMAY URINE CONTROL LEVEL 2
4-460	CORMAY CYSTATIN C CONTROLS
5-163	CORMAY AMMONIA/ETHANOL CONTROLS
5-108	CORMAY DIGITOXIN CONTROLS
5-107	CORMAY TDM CONTROLS

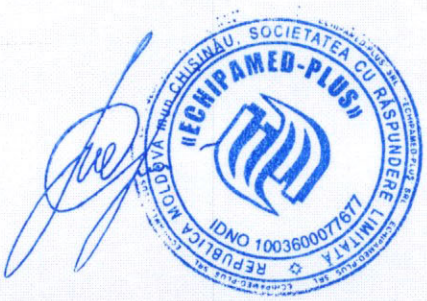
Signed by:.....

Name: Tomasz Tuora

Position: President PZ CORMAY S.A.

Place: Łomianki

Date: 08 January, 2010



Zhejiang SKG Medical Technology Co., Ltd

Add: No.39, Anye Road,Gaoqiao Street, Huangyan, Taizhou,Zhejiang,China,318020

Tel: 0086-576-84031666 Fax: 0086-576-84036668 Http://www.skgmed.com

CE Declaration of Conformity

Manufacturer: Zhejiang SKG Medical Technology Co.,Ltd.

NO.39 Anye Road, Gaoqiao Street, Huangyan 318020 Taizhou, Zhejiang

PEOLPLE'S REPUBLIC OF CHINA

European

Representative: Shanghai International Holding corp.GmbH(Europe)

Eiffestrabe 80 20537 Hamburg GERMANY

Product Name: Sample Cup

Model Number: BS-200, 700

Classification (IVDD): Other

Conformity Assessment Route: IVDD Annex III

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied:

ISO13485:2003, ISO11135-1:2007, ISO14971:2007, ISO 15223-1-2012

Notified Body: TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65·80339

München Germany

Identification number: Not applicable

(EC) Certificate(s): Not applicable

Expire date of the Certificate: Not applicable

Start of CE Marking: Not yet

Place, Date of Issue: HuangYan 2021-12-17

Signature:

Name: Sujian

Position: General Manager

ZHEJIANG SKG MEDICAL TECHNOLOGY CO.,LTD. 浙江双康医疗科技有限公司

MECHIPAMED-PLUS