

PZ CORMAY S.A.

Wiosenna 22 street
05-092 Łomianki
tel.: +48 22 751 79 10
fax: +48 22 751 79 11
www.cormay.pl

Warsaw, 3rd December 2021

Letter of Authorization

WHEREAS,

We, PZ Cormay S.A., represented by its President Mr. Janusz Płocica and Vice-President Mr. Wojciech Suchowski, incorporated under entry No. KRS 0000270105 with The National Court Register in Poland having its headquarter at 22, Wiosenna, 05-092 Łomianki, Poland, hereby authorize:

"Echipamed-Plus" SRL
Moldova, MD-2001, Chisinau,
str. Valea Trandafirilor 24B, of. 2-7

As our exclusive representative in Moldova for Cormay biochemistry reagents dedicated for following automated biochemistry analyzers:

- BS series

"Echipamed-Plus" SRL will be responsible for purchasing reagents exclusive from Cormay, selling, clearance, promotion and service of the Cormay biochemistry reagents dedicated for BS series.

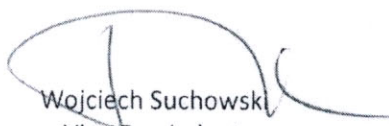
The same reagents dedicated for Cormay Accent series analyzers are not a topic of this agreement.

This letter will remain valid until 31.12.2022.

On behalf of PZ Cormay S.A.



Janusz Płocica
President
PZ Cormay S.A.



Wojciech Suchowski
Vice-President
PZ Cormay S.A.

Correspondence address: PZ Cormay S.A., Puławska 303 Street, 02-785 Warsaw, Poland





Lloyd's
Register

Current issue date: 17 August 2021
Expiry date: 16 August 2024
Certificate identity number: 10370649

Original approval(s):
ISO 13485 - 17 August 2009
ISO 9001 - 16 January 1998

Certificate of Approval

This is to certify that the Management System of:

PZ CORMAY Spółka Akcyjna

ul. Wiosenna 22, 05-092 Łomianki, Poland

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016, ISO 9001:2015

Approval number(s): ISO 13485 – 0053001, ISO 9001 – 0053000

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

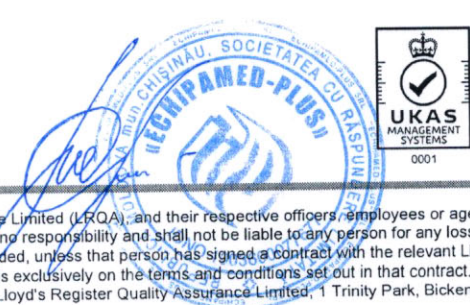
Design, production and distribution of reagents of in vitro diagnostics for medical, industrial and scientific laboratories and design, production, sales and maintenance of in vitro diagnostic medical-devices.

Paul Graaf

Chief Operating Officer, Management Systems, MSIS

Issued by: Lloyd's Register (Polska) sp. z o.o.

for and on behalf of: Lloyd's Register Quality Assurance Limited



Lloyd's Register Group Limited, its affiliates and subsidiaries, including Lloyd's Register Quality Assurance Limited (LRQA), and their respective officers, employees or agents are, individually and collectively, referred to in this clause as 'Lloyd's Register'. Lloyd's Register assumes no responsibility and shall not be liable to any person for any loss, damage or expense caused by reliance on the information or advice in this document or howsoever provided, unless that person has signed a contract with the relevant Lloyd's Register entity for the provision of this information or advice and in that case any responsibility or liability is exclusively on the terms and conditions set out in that contract. Issued by: Lloyd's Register (Polska) sp. z o.o., al. Zwycięstwa 13A, 80-219 Gdańsk for and on behalf of: Lloyd's Register Quality Assurance Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom



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



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 Assurance 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.

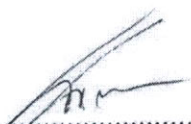
Place: Łomianki

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





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



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 Assurance 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



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

October 25, 2022

LETTER OF AUTHORIZATION

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, ("**Mindray**") manufacturer of biochemical, imunological 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, 2023**. 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, CIS I Region
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.





America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Certificate Holder:

**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:

See Page 2 for Overall Scope Statement.

Standard(s):

ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.:

SH2005501

Effective Date:

2020-08-12

Expiry Date:

2023-06-30

Page 1 of 4

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com



Declaration of Conformity



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

