Digitally signed by Iurchevici Valeriu
Date: 2023.02.22 20:33:25 EET
Reason: MoldSign Signature
Location: Moldova

CORMAY DIAGNOSTICS

The Lifeline
To Better Health

PZ CORMAY S.A.
Wiosenna 22 street
05-092 Łomianki
Phone.: +48 22 751 79 10
fax: +48 22 751 79 11
www.cormaydiagnostics.com

Warsaw, 21st February 2023

Letter of Authorization

WHEREAS,

We, PZ Cormay SA., represented by Mr. Marcin Sieczek – President and Mr. Wojciech Suchowski – Vice-President, incorporated under entry no. KRS 0000270105 with The National Court Register in Poland, having its headquarter at 22, Wiosenna, 05-092 Lomianki, Poland, hereby authorize:

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

As our exclusive distributor in Moldova for Cormay clinical chemistry reagents dedicated for the BS 200 biochemistry analyzers.

"Echipamed-Plus" SRL will be responsible for purchasing reagents exclusive from Cormay, selling, clearance, promotion and service of the Cormay reagents dedicated for BS 200 analyzers.

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

This letter will remain valid until 21.02.2024.

On behalf of PZ Cormay S.A.

Marcin Sieczek
President
PZ Cormay S.A.

Wojciech Suchowski
Vice-Presiedent
PZ Cormay S.A.

"ECHIPAMED-PLUS" MUN. CHISINAU, SOCIETATEA CU RASPUNDERE LIMITATA
REPUBLICA MOLDOVA
IDNO 1003600077677

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

Lomianki, Poland 05.12.2016

To Whom It May Concern

We, PZ Cormay S.A. are an established and reputable manufacturer of various diagnostic test kits having its headquarters at 22, Wiosenna, 05-092 Lomianki, Poland, hereby confirm that our clinical chemistry reagents manufactured and adopted for use on the following automated analyzers:

- **CORMAY ACCENT-200**
- **MINRAY BS-200**

Sincerely,

PZ CORMAY S.A.
05-092 Lomianki, ul. Wiosenna 22
tel. 022 751 79 10, fax 022 751 79 11
NIP 1181872269

Alexander Bosik
Area Sales Manager
PZ Cormay S.A.

Lloyd's Register

Current issue date:	17 August 2021	Original approval(s):
Expiry date:	16 August 2024	ISO 13485 - 17 August 2009
Certificate identity number:	10370649	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

UKAS MANAGEMENT SYSTEMS 0001

PZ CORMAY S.A.
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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.**, 22 Wiosenna Str., 05-092 Lomianki, Poland, declare that the following devices:

Devices name: See ATTACHMENT 1

Devices number: See ATTACHMENT 1

(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 their conformity assessment has been made accordingly to the ANNEX III – Directive 98/79/EC.

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

EN 980:2008	Graphical symbols for use in the labelling of medical devices.
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices.
EN 13640:2002	Stability testing of in vitro diagnostic reagents.
EN ISO 14971:2009	Medical Devices – Application of risk management to medical devices.
EN ISO 18113-2:2009	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents for professional use.

PZ CORMAY S.A Quality Management System complies with requirements of ISO 9001:2008 and ISO 13485:2003 standards 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 and sale and service of medical equipment.

Signed by:.....

Name: Barbara Tuora-Wysocka

Position: Member of Management Board of PZ CORMAY S.A.

Place: Lublin

Date: 11 May 2012

"EQUIPAMED-PLUS" SOCIETATEA CU RĂSPUNDERE LIMITATĂ IDNO 1003600077677 REPUBLICA MOLDOVA mun. CHIȘINĂU

Registered in District Court of Warsaw, XIV Department of National Court Register No 0000270105; REGON 140777556; NIP 1181872269
Fixed capital: 30 561 977 PLN; Capital paid: 30 561 977 PLN; MANAGEMENT BOARD: Tomasz Tuora; Barbara Tuora-Wysocka

ATTACHMENT 1

No	Cat. No	Name
1	7-249	ACCENT-200 ACP
2	7-216	ACCENT-200 ALAT
3	7-238	ACCENT-200 ALBUMIN
4	7-212	ACCENT-200 ALP
5	7-222	ACCENT-200 ALPHA 1-ANTITRYPSIN
6	7-221	ACCENT-200 ALPHA 1-GLYCOPROTEIN ACID
7	7-235	ACCENT-200 ALPHA 1-MICROGLOBULIN
8	7-232	ACCENT-200 ALPHA-FETOPROTEIN
9	7-255	ACCENT-200 AMYLASE
10	7-276	ACCENT-200 AMYLASE EPS
11	7-223	ACCENT-200 ANTITHROMBIN III
12	7-207	ACCENT-200 APOLIPOPROTEIN B
13	7-214	ACCENT-200 ASAT
14	7-240	ACCENT-200 ASO
15	7-248	ACCENT-200 BIL DIRECT
16	7-298	ACCENT-200 BIL DIRECT VANAD
17	7-245	ACCENT-200 BIL TOTAL
18	7-299	ACCENT-200 BIL TOTAL VANAD
19	7-198	ACCENT-200 BILE ACIDS
20	7-251	ACCENT-200 CALCIUM
21	7-247	ACCENT-200 CALCIUM ARSENAZO
22	7-218	ACCENT-200 CERULOPLASMIN
23	7-204	ACCENT-200 CHOL
24	7-256	ACCENT-200 CHOLINESTERASE
25	7-220	ACCENT-200 CK
26	7-227	ACCENT-200 CK-MB
27	7-211	ACCENT-200 COMPLEMENT C3
28	7-213	ACCENT-200 COMPLEMENT C4
29	7-277	ACCENT-200 CREA ENZYMATIC
30	7-233	ACCENT-200 CREATININE
31	7-225	ACCENT-200 CRP ULTRA
32	7-200	ACCENT-200 CYSTATIN C
33	7-246	ACCENT-200 D-DIMER
34	7-278	ACCENT-200 ETHANOL
35	7-230	ACCENT-200 FERRITIN
36	7-258	ACCENT-200 FERRUM
37	7-219	ACCENT-200 FIBRINOGEN
38	7-224	ACCENT-200 GGT
39	7-201	ACCENT-200 GLUCOSE
40	7-252	ACCENT-200 GLUCOSE HEX
41	7-215	ACCENT-200 HAPTOGLOBIN
42	7-111	ACCENT-200 HbA_{1C} DIRECT

Signed by:.....

Name: Barbara Tuora-Wysocka

Position: Member of Management Board of PZ CORMAY S.A.

Place: Lublin

Date: 11 May 2012

ATTACHMENT 1

No	Cat. No	Name
43	7-241	ACCENT-200 HBDH
44	7-279	ACCENT-200 HDL DIRECT
45	7-202	ACCENT-200 IgA
46	7-203	ACCENT-200 IgG
47	7-205	ACCENT-200 IgM
48	7-266	ACCENT-200 LACTATE
49	7-239	ACCENT-200 LDH
50	7-280	ACCENT-200 LDL DIRECT
51	7-209	ACCENT-200 LIPASE
52	7-228	ACCENT-200 LIPOPROTEIN (a)
53	7-229	ACCENT-200 MG
54	7-262	ACCENT-200 MG
55	7-244	ACCENT-200 MICROALBUMIN
56	7-226	ACCENT-200 MYOGLOBIN
57	7-243	ACCENT-200 PHOSPHORUS
58	7-237	ACCENT-200 RF
59	7-253	ACCENT-200 TG
60	7-273	ACCENT-200 TG mono
61	7-231	ACCENT-200 TOTAL IgE
62	7-236	ACCENT-200 TOTAL PROTEIN
63	7-210	ACCENT-200 TRANSFERRIN
64	7-208	ACCENT-200 UA
65	7-263	ACCENT-200 UA PLUS
66	7-259	ACCENT-200 UIBC
67	7-206	ACCENT-200 UREA
68	7-242	ACCENT-200 URINE PROTEINS
69	3-109	ACCENT-200 ACID WASHING SOLUTION
70	3-108	ACCENT-200 ALKALINE WASHING SOLUTION
71	3-102	WASHING SOLUTION CONCENTRATE
72	3-103	WASHING SOLUTION CONCENTRATE

Signed by:.....

Name: Barbara Tuora-Wysocka

Position: Member of Management Board of PZ CORMAY S.A.

Place: Lublin

Date: 11 May 2012

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05-092 Lomianki, 22 Wiosenna Str.
phone: +48 22 751 7910 ; fax: +48 22 751 7911
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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
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

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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
and conformity assessment made accordingly to the ANNEX III - Directive 98/79/EC.

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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

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-200**
Internal code:	**BA20**
Consumables:	Reaction cuvette Mindray reagent bottles
Optional Module:	**ISE Module** **Bar Code Module**
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: 2005-12-15

Place, Date of Issue: Shenzhen, 2010-11-03

Signature: .....

Name of Authorized Signatory: Mr. Yang long

Position Held in Company: Management Representative

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

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