

**PZ CORMAY S.A.**  
ul. Wiosenna 22  
05-092 Łomianki  
tel.: +48 22 751 79 10  
fax: +48 22 751 79 11  
www.cormay.pl

**Warsaw, 27th of January 2020**

**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 24 „B”, of. 80**

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.

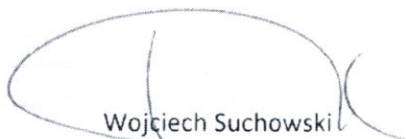
The same reagents dedicated for Cormay Accent series analyzers are not a topic of this agreement.

This letter will remain valid until 31.12.2020.

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



# 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 LRQA to the following standards:

ISO 9001:2015  
EN ISO 13485:2016



P.G. Cornelissen - Area Manager North Europe

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

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

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.

Current issue date: 25 January 2019  
Expiry date: 16 August 2021  
Certificate identity number: 10168229

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

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

The scope of this approval is applicable to:  
ISO 9001:2015

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

EN ISO 13485:2016

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



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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 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







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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

