Digitally signed by Iurchevici Valeriu
Date: 2019.03.19 18:05:52 EET
Reason: MoldSign Signature
Location: Moldova

Warsaw, 11th February 2019

Manufacturer's Authorization

WHEREAS

We **PZ Cormay S.A.**, represented by its President Janusz Płocica and Vice-President Wojciech Suchowski, incorporated under entry No. KRS 0000270105 with The National Court Register in Poland having its headquarter at 22, Wiosenna, 05-092 Lomianki, Poland,official manufacturers of high quality diagnostic reagents, and the highest quality laboratory equipment, having factories at Poland Marynin 61a, 21-030 Motycz, do hereby appointed:

EchipaMed plus SLR
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 analizers:

-ACCENT/BS series

-HITACHI series

EchipaMED plus SLR will be responsible for selling, clearance, promotion and service of the Cormay biochemistry reagents purchased from us and will be shipped to them.

This letter will remain valid for one year.

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
tel.: (22) 751 79 10, fax: (22) 751 79 11
www.cormay.pl, office@cormay.pl

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 · ISO 13485 001

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:

Product:	***Chemistry Analyzer***
Model:	***ACCENT-200***
Consumables:	***Reaction cuvettes***
Optional Module:	***ISE module***
	Bar code module

(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 13975:2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices. Statistical aspects.
EN ISO 14971:2009	Medical Devices – Application of risk management to medical devices.
EN ISO 18113-3:2009	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). In vitro diagnostic instruments for professional use.
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements.
EN 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment.
EN 61326-2-1:2006	Electrical equipment for measurement, control and laboratory use. EMC requirements.

PZ CORMAY S.A Quality Management System complies with requirements of ISO 9001:2008 and EN ISO 13485:2012 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.

Signature:.....

Janusz Plocica

President of Management Board of

PZ CORMAY S.A.

Place: Lomianki

Signature:.....

Wojciech Suchowski

Vice President of Management Board of

PZ CORMAY S.A

Date: 16 May 2017

Registered in District Court of Warsaw, XIV Department of National Court Register No 0000270105; REGON 140777556; NIP 1181872269
Fixed capital: 63 723 954,00 PLN; Capital paid: 63 723 954,00 PLN; MANAGEMENT BOARD: Janusz Plocica, Wojciech Suchowski