



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 analyzers:

-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
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PZ CORMAY S.A.
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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.





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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



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

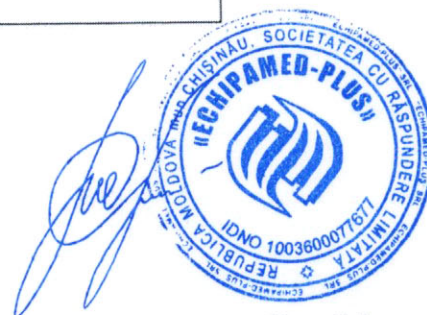
Signed by:.....

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.

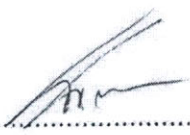
Place: Lublin

Date: 11 May 2012



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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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: Lomianki

Date: 08 January, 2010

