

# 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.

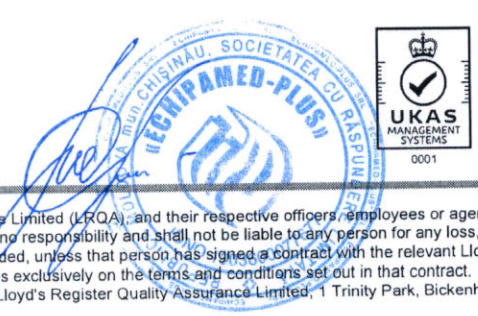


**Paul Graaf**

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



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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



**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**

**Catalogue 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 13612:2006	Performance evaluation of in vitro diagnostic medical devices.
EN ISO 14971:2012	Medical Devices – Application of risk management to medical devices.
EN ISO 15223-1:2021	Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements.
EN ISO 18113-2:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use.
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents.

PZ CORMAY S.A Quality Management System complies with requirements of ISO 9001:2015 and EN ISO 13485:2016 standards and has been approved by Lloyd's Register Quality Assurance Limited in the range concerning 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.

Signature:

Flavio Finotello

Vice 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: 25 May 2022



No	Cat. No	Name
1	7-216	ACCENT-200 ALAT
2	7-238	ACCENT-200 ALBUMIN
3	7-212	ACCENT-200 ALP
4	7-222	ACCENT-200 ALPHA 1-ANTITRYPSIN
5	7-221	ACCENT-200 ALPHA 1-GLYCOPROTEIN ACID
6	7-255	ACCENT-200 AMYLASE
7	7-276	ACCENT-200 AMYLASE EPS
8	7-207	ACCENT-200 APOLIPOPROTEIN B
9	7-214	ACCENT-200 ASAT
10	7-240	ACCENT-200 ASO
11	7-248	ACCENT-200 BIL DIRECT
12	7-245	ACCENT-200 BIL TOTAL
13	7-198	ACCENT-200 BILE ACIDS
14	7-251	ACCENT-200 CALCIUM
15	7-247	ACCENT-200 CALCIUM ARSENAZO
16	7-218	ACCENT-200 CERULOPLASMIN
17	7-204	ACCENT-200 CHOL
18	7-256	ACCENT-200 CHOLINESTERASE
19	7-220	ACCENT-200 CK
20	7-227	ACCENT-200 CK-MB
21	7-211	ACCENT-200 COMPLEMENT C3
22	7-213	ACCENT-200 COMPLEMENT C4
23	7-277	ACCENT-200 CREA ENZYMATIC
24	7-233	ACCENT-200 CREATININE
25	7-225	ACCENT-200 CRP ULTRA
26	7-200	ACCENT-200 CYSTATIN C
27	7-246	ACCENT-200 D-DIMER
28	7-265	ACCENT-200 dTIBC
29	7-278	ACCENT-200 ETHANOL
30	7-230	ACCENT-200 FERRITIN
31	7-258	ACCENT-200 FERRUM
32	7-219	ACCENT-200 FIBRINOGEN
33	7-224	ACCENT-200 GGT

Signature:

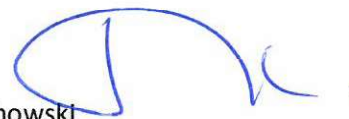


Flavio Finotello

Vice President of Management Board of  
PZ CORMAY S.A.

Place: Lomianki

Signature:



Wojciech Suchowski

Vice President of Management Board of  
PZ CORMAY S.A.

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No	Cat. No	Name
34	7-201	ACCENT-200 GLUCOSE
35	7-252	ACCENT-200 GLUCOSE HEX
36	7-215	ACCENT-200 HAPTOGLOBIN
37	7-111	ACCENT-200 HbA <sub>1c</sub> DIRECT
38	7-279	ACCENT-200 HDL DIRECT
39	7-202	ACCENT-200 IgA
40	7-203	ACCENT-200 IgG
41	7-205	ACCENT-200 IgM
42	7-266	ACCENT-200 LACTATE
43	7-239	ACCENT-200 LDH
44	7-280	ACCENT-200 LDL DIRECT
45	7-209	ACCENT-200 LIPASE
46	7-290	ACCENT-200 LIPASE
47	7-228	ACCENT-200 LIPOPROTEIN (a)
48	7-229	ACCENT-200 MG
49	7-262	ACCENT-200 MG
50	7-244	ACCENT-200 MICROALBUMIN
51	7-226	ACCENT-200 MYOGLOBIN
52	7-243	ACCENT-200 PHOSPHORUS
53	7-237	ACCENT-200 RF
54	7-253	ACCENT-200 TG
55	7-273	ACCENT-200 TG mono
56	7-231	ACCENT-200 TOTAL IgE
57	7-236	ACCENT-200 TOTAL PROTEIN
58	7-210	ACCENT-200 TRANSFERRIN
59	7-208	ACCENT-200 UA
60	7-259	ACCENT-200 UIBC
61	7-206	ACCENT-200 UREA
62	7-242	ACCENT-200 URINE PROTEINS

Signature:

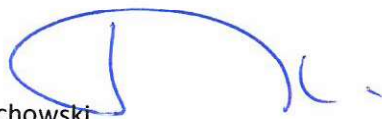


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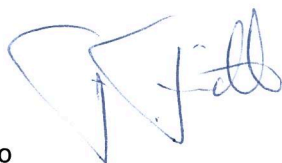
Vice President of Management Board of  
PZ CORMAY S.A.

Date: 25 May 2022



No	Cat. No	Name
1	4-289	CORMAY APOLIPOPROTEIN CALIBRATORS
2	4-278	CORMAY ASO CALIBRATOR
3	3-125	CORMAY BILE ACIDS CALIBRATOR
4	5-182	CORMAY CK-MB CALIBRATOR
5	4-276	CORMAY CRP ULTRA CALIBRATORS
6	5-185	CORMAY CYSTATIN C CALIBRATORS
7	4-259	CORMAY D-DIMER CALIBRATOR
8	5-105	CORMAY ETHANOL CALIBRATORS
9	5-106	CORMAY ETHANOL CALIBRATOR 100
10	4-491	CORMAY FERRITIN CALIBRATORS
11	4-292	CORMAY FIBRINOGEN CALIBRATOR
12	4-308	CORMAY HbA <sub>1c</sub> DIRECT CALIBRATORS
13	5-178	CORMAY HDL/LDL CALIBRATOR
14	4-280	CORMAY IgE CALIBRATORS
15	4-287	CORMAY IMMUNO-MULTICAL
16	4-281	CORMAY Lp(a) CALIBRATORS
17	5-193	CORMAY MICROALBUMIN CALIBRATOR
18	5-174	CORMAY MULTICALIBRATOR LEVEL 1
19	5-176	CORMAY MULTICALIBRATOR LEVEL 1
20	5-175	CORMAY MULTICALIBRATOR LEVEL 2
21	5-177	CORMAY MULTICALIBRATOR LEVEL 2
22	4-279	CORMAY MYOGLOBIN CALIBRATORS
23	5-136	CORMAY PROCALCITONIN CALIBRATORS
24	4-277	CORMAY RF CALIBRATORS
25	5-181	CORMAY URINE PROTEINS CALIBRATORS

Signature:



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Vice President of Management Board of  
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EN ISO 23640:2015-10	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents.

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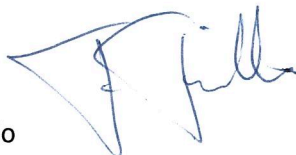
Wojciech Suchowski

Vice President of Management Board of  
PZ CORMAY S.A.

Date: 9 May 2022

No	Cat. No	Name
1	5-163	CORMAY AMMONIA / ETHANOL CONTROLS
2	5-165	CORMAY AMMONIA/ETHANOL CONTROLS
3	4-293	CORMAY APOLIPOPROTEIN CONTROL
4	5-149	CORMAY BILE ACIDS CONTROLS
5	5-183	CORMAY CK-MB CONTROL N
6	5-184	CORMAY CK-MB CONTROL P
7	4-460	CORMAY CYSTATIN C CONTROLS
8	4-459	CORMAY D-DIMER CONTROLS
9	4-328	CORMAY HbA <sub>1c</sub> DIRECT CONTROLS
10	4-288	CORMAY IMMUNO-CONTROL I
11	4-290	CORMAY IMMUNO-CONTROL II
12	4-291	CORMAY IMMUNO-CONTROL III
13	5-179	CORMAY LIPID CONTROL 1
14	5-180	CORMAY LIPID CONTROL 2
15	4-492	CORMAY Lp(a) CONTROL N
16	4-493	CORMAY Lp(a) CONTROL P
17	4-461	CORMAY MICROALBUMIN CONTROL
18	5-166	CORMAY PROCALCITONIN CONTROLS
19	5-172	CORMAY SERUM HN
20	5-173	CORMAY SERUM HP
21	5-161	CORMAY URINE CONTROL LEVEL 1
22	5-162	CORMAY URINE CONTROL LEVEL 2
23	5-164	CORMAY URINE CONTROLS
24	6-054	CORMAY URINALYSIS CONTROLS
25	6-056	CORMAY URINALYSIS CONTROLS

Signature:



Flavio Finotello

Vice 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: 9 May 2022