

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 23640:2015-10	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: 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 _{1c} 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:



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