

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.

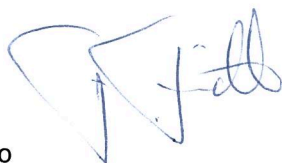
Date: 25 May 2022

Correspondence address: PZ Cormay S.A., Puławska 303 Street, 02-785 Warsaw, Poland

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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 _{1c} 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:




Flavio Finotello

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

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