

**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	7-826	A-800 ALAT
2	7-804	A-800 ALBUMIN
3	7-830	A-800 ALP
4	7-853	A-800 ALPHA 1-ANTITRIPSIN
5	7-852	A-800 ALPHA 1-GLYCOPROTEIN ACID
6	7-828	A-800 AMYLASE
7	7-829	A-800 AMYLASE EPS
8	7-861	A-800 APOLIPOPROTEIN B
9	7-827	A-800 ASAT
10	7-844	A-800 ASO
11	7-808	A-800 BIL DIRECT
12	7-819	A-800 BILE ACIDS
13	7-807	A-800 BIL TOTAL
14	7-820	A-800 CALCIUM ARSENAZO
15	7-803	A-800 CHOL
16	7-838	A-800 CHOLINESTERASE
17	7-851	A-800 CERULOPLASMIN
18	7-832	A-800 CK
19	7-833	A-800 CK-MB
20	7-842	A-800 COMPLEMENT C3
21	7-843	A-800 COMPLEMENT C4
22	7-812	A-800 CREA ENZYMATIC
23	7-847	A-800 CRP ULTRA
24	7-863	A-800 CYSTATIN C
25	7-856	A-800 D-DIMER
26	7-825	A-800 dTIBC
27	7-818	A-800 ETHANOL
28	7-858	A-800 FERRITIN
29	7-823	A-800 FERRUM
30	7-855	A-800 FIBRINOGEN
31	7-834	A-800 GGT
32	7-801	A-800 GLUCOSE
33	7-802	A-800 GLUCOSE HEX

Signature:

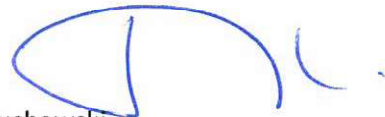


Flavio Finotello

Vice President of Management Board of  
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Place: Lomianki

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Vice President of Management Board of  
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No	Cat. No	Name
34	7-850	A-800 HAPTOGLOBIN
35	7-862	A-800 HbA1C DIRECT
36	7-815	A-800 HDL DIRECT
37	7-839	A-800 IgA
38	7-840	A-800 IgG
39	7-841	A-800 IgM
40	7-817	A-800 LACTATE
41	7-836	A-800 LDH
42	7-816	A-800 LDL DIRECT
43	7-873	A-800 LIPASE
44	7-837	A-800 LIPASE
45	7-849	A-800 LIPOPROTEIN (a)
46	7-821	A-800 MG
47	7-864	A-800 MICROALBUMIN
48	7-857	A-800 MYOGLOBIN
49	7-822	A-800 PHOSPHORUS
50	7-876	A-800 PROCALCITONIN
51	7-845	A-800 RF
52	7-809	A-800 TG
53	7-810	A-800 TG mono
54	7-848	A-800 TOTAL IgE
55	7-805	A-800 TOTAL PROTEIN
56	7-859	A-800 TRANSFERRIN
57	7-813	A-800 UA
58	7-824	A-800 UIBC
59	7-814	A-800 UREA
60	7-806	A-800 URINE PROTEINS

Signature:

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