

**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:

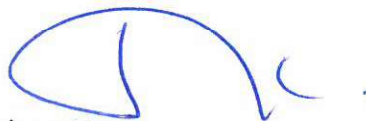


Flavio Finotello

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	4-516	HC-ALAT
2	4-538	HC-ALBUMIN
3	4-512	HC-ALP
4	4-555	HC-AMYLASE
5	4-576	HC-AMYLASE EPS
6	4-514	HC-ASAT
7	4-548	HC-BIL DIRECT
8	4-545	HC-BIL TOTAL
9	4-597	HC-BILE ACIDS
10	4-551	HC-CALCIUM
11	4-547	HC-CALCIUM ARSENAZO
12	4-504	HC-CHOL
13	4-596	HC-CHOLINESTERASE
14	4-520	HC-CK
15	4-527	HC-CK-MB
16	4-537	HC-CREA ENZYMATIC
17	4-533	HC-CREATININE
18	4-500	HC-CYSTATIN C
19	4-546	HC-D-DIMER
20	4-565	HC-dTIBC
21	4-578	HC-ETHANOL
22	4-558	HC-FERRUM
23	4-524	HC-GGT
24	4-501	HC-GLUCOSE
25	4-523	HC-GLUCOSE HEX
26	4-595	HC-HbA <sub>1c</sub> DIRECT
27	4-579	HC-HDL DIRECT
28	4-566	HC-LACTATE
29	4-539	HC-LDH
30	4-569	HC-LDL DIRECT
31	4-556	HC-LIPASE
32	4-575	HC-LIPASE
33	4-529	HC-MG

Signature:



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No	Cat. No	Name
34	4-544	HC-MICROALBUMIN
35	4-543	HC-PHOSPHORUS
36	4-553	HC-TG
37	4-573	HC-TG mono
38	4-536	HC-TOTAL PROTEIN
39	4-508	HC-UA
40	4-502	HC-UIBC
41	4-506	HC-UREA
42	4-591	CORMAY ALPHA 1-ANTITRYPSIN
43	4-590	CORMAY ALPHA 1-GLYCOPROTEIN ACID
44	4-584	CORMAY APOLIPOPROTEIN B
45	6-309	CORMAY ASO
46	4-588	CORMAY CERULOPLASMIN
47	4-585	CORMAY COMPLEMENT C3
48	4-586	CORMAY COMPLEMENT C4
49	6-300	CORMAY CRP ULTRA
50	6-303	CORMAY FERRITIN
51	4-589	CORMAY FIBRINOGEN
52	4-587	CORMAY HAPTOGLOBIN
53	4-580	CORMAY IgA
54	4-581	CORMAY IgG
55	4-582	CORMAY IgM
56	6-302	CORMAY LIPOPROTEIN (a)
57	6-301	CORMAY MYOGLOBIN
58	6-308	CORMAY RF
59	6-304	CORMAY TOTAL IgE
60	4-583	CORMAY TRANSFERRIN

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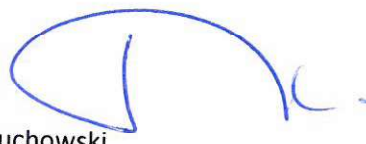


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