

**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	9-417	OS-ALAT
2	9-403	OS-ALBUMIN
3	9-420	OS-ALP
4	9-443	OS-ALPHA 1-ANTITRYPSIN
5	9-442	OS-ALPHA 1-GLYCOPROTEIN ACID
6	9-419	OS-AMYLASE
7	9-476	OS-AMYLASE EPS
8	9-450	OS-APOLIPOPROTEIN B
9	9-418	OS-ASAT
10	9-432	OS-ASO
11	9-406	OS-BIL DIRECT
12	9-405	OS-BIL TOTAL
13	9-475	OS-BILE ACIDS
14	9-413	OS-CALCIUM
15	9-456	OS-CALCIUM ARSENAZO
16	9-441	OS-CERULOPLASMIN
17	9-402	OS-CHOL
18	9-458	OS-CHOLINESTERASE
19	9-421	OS-CK
20	9-422	OS-CK-MB
21	9-434	OS-COMPLEMENT C3
22	9-435	OS-COMPLEMENT C4
23	9-470	OS-CREA ENZYMATIC
24	9-408	OS-CREATININE
25	9-437	OS-CRP ULTRA
26	9-462	OS-CYSTATIN C
27	9-452	OS-D-DIMER
28	9-479	OS-dTIBC
29	9-460	OS-ETHANOL
30	9-446	OS-FERRITIN
31	9-416	OS-FERRUM
32	9-436	OS-FIBRINOGEN
33	9-423	OS-GGT

Signature:   
 Flavio Finotello  
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No	Cat. No	Name
34	9-401	OS-GLUCOSE
35	9-477	OS-GLUCOSE HEX
36	9-440	OS-HAPTOGLOBIN
37	9-457	OS-HbA <sub>1c</sub> DIRECT
38	9-411	OS-HDL DIRECT
39	9-429	OS-IgA
40	9-430	OS-IgG
41	9-431	OS-IgM
42	9-461	OS-LACTATE
43	9-425	OS-LDH
44	9-412	OS-LDL DIRECT
45	9-426	OS-LIPASE
46	9-490	OS-LIPASE
47	9-439	OS-LIPOPROTEIN (a)
48	9-414	OS-MG
49	9-463	OS-MICROALBUMIN
50	9-445	OS-MYOGLOBIN
51	9-415	OS-PHOSPHORUS
52	9-433	OS-RF
53	9-407	OS-TG
54	9-473	OS-TG mono
55	9-438	OS-TOTAL IgE
56	9-404	OS-TOTAL PROTEIN
57	9-451	OS-TRANSFERRIN
58	9-409	OS-UA
59	9-427	OS-UIBC
60	9-410	OS-UREA

Signature:

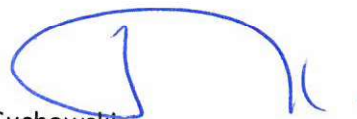


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