

**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***

***Devices 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 ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices.
EN ISO 14971:2012	Medical Devices – Application of risk management to medical devices.
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 23640:2013	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 in vitro diagnostic reagents for medical, industrial and scientific laboratories and design, production, sales and maintenance of in vitro diagnostic medical-devices.

Signature:

Janusz Płocica

President of Management Board of  
PZ CORMAY S.A.

Place: Łomianki

Signature:

Wojciech Suchowski

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

Date: 30 June 2021

No	Cat. No	Name
1	5-521	B50-ALAT
2	5-500	B50-ALBUMIN
3	5-528	B50-ALP
4	5-523	B50-AMYLASE
5	5-522	B50-ASAT
6	5-561	B50-ASO
7	5-506	B50-BIL DIRECT
8	5-504	B50-BIL TOTAL
9	5-537	B50-CALCIUM ARSENAZO
10	5-507	B50-CHOL
11	5-533	B50-CHOLINESTERASE
12	5-531	B50-CK
13	5-532	B50-CK-MB
14	5-545	B50-COMPLEMENT C3
15	5-546	B50-COMPLEMENT C4
16	5-514	B50-CREA ENZYMATIC
17	5-513	B50-CREATININE
18	5-553	B50-CRP ULTRA
19	5-556	B50-FERRITIN
20	5-538	B50-FERRUM
21	5-530	B50-GGT
22	5-510	B50-GLUCOSE
23	5-562	B50-HbA1C DIRECT
24	5-508	B50-HDL DIRECT
25	5-540	B50-IgA
26	5-541	B50-IgG
27	5-542	B50-IgM
28	5-526	B50-LDH
29	5-509	B50-LDL DIRECT
30	5-525	B50-LIPASE
31	5-535	B50-MG
32	5-565	B50-MICROALBUMIN

Signature:

Janusz Płocica

President of Management Board of  
PZ CORMAY S.A.

Place: Łomianki

Signature:

Wojciech Suchowski

Vice President of Management Board of  
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Correspondence address: PZ Cormay S.A., Puławska 303 Street, 02-785 Warsaw, Poland

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No	Cat. No	Name
33	5-534	B50-PHOSPHORUS
34	5-560	B50-RF
35	5-517	B50-TG
36	5-518	B50-TG mono
37	5-501	B50-TOTAL PROTEIN
38	5-543	B50-TRANSFERRIN
39	5-515	B50-UA
40	5-539	B50-UIBC
41	5-516	B50-UREA
42	5-502	B50-URINE PROTEINS

Signature:

Janusz Płocica

President of Management Board of  
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Wojciech Suchowski

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

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