

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 13612:2002	Performance evaluation of in vitro diagnostic medical devices.
EN 13640:2002	Stability testing of in vitro diagnostic reagents.
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents.
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 17511:2003	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
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.

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:

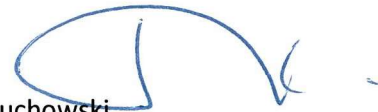


Flavio Finotello

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: 9 May 2022

No	Cat. No	Name
1	I20-R0001	AURYX 90 hs CRP Reagent Kit
2	I20-R0002	AURYX 90 hs CRP Reagent Kit
3	I20-R0003	AURYX 90 SAA Reagent Kit
4	I20-R0004	AURYX 90 SAA Reagent Kit
5	I20-R0005	AURYX 90 PCT Reagent Kit
6	I20-R0006	AURYX 90 PCT Reagent Kit
7	I20-R0007	AURYX 90 IL-6 Reagent Kit
8	I20-R0008	AURYX 90 IL-6 Reagent Kit
9	I20-R0009	AURYX 90 T4 Reagent Kit
10	I20-R0010	AURYX 90 T4 Reagent Kit
11	I20-R0011	AURYX 90 T3 Reagent Kit
12	I20-R0012	AURYX 90 T3 Reagent Kit
13	I20-R0013	AURYX 90 FT4 Reagent Kit
14	I20-R0014	AURYX 90 FT4 Reagent Kit
15	I20-R0015	AURYX 90 FT3 Reagent Kit
16	I20-R0016	AURYX 90 FT3 Reagent Kit
17	I20-R0017	AURYX 90 TSH Reagent Kit
18	I20-R0018	AURYX 90 TSH Reagent Kit
19	I20-R0019	AURYX 90 TG Reagent Kit
20	I20-R0020	AURYX 90 TG Reagent Kit
21	I20-R0021	AURYX 90 TBG Reagent Kit
22	I20-R0022	AURYX 90 TBG Reagent Kit
23	I20-R0023	AURYX 90 Anti-TG Reagent Kit
24	I20-R0024	AURYX 90 Anti-TG Reagent Kit
25	I20-R0025	AURYX 90 Anti-TPO Reagent Kit
26	I20-R0026	AURYX 90 Anti-TPO Reagent Kit
27	I20-R0027	AURYX 90 cTnl Reagent Kit
28	I20-R0028	AURYX 90 cTnl Reagent Kit
29	I20-R0029	AURYX 90 Myoglobin Reagent Kit
30	I20-R0030	AURYX 90 Myoglobin Reagent Kit

Signature:

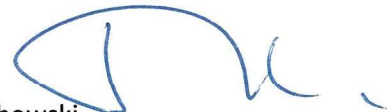


Flavio Finotello

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: 9 May 2022

No	Cat. No	Name
31	I20-R0031	AURYX 90 CK-MB Reagent Kit
32	I20-R0032	AURYX 90 CK-MB Reagent Kit
33	I20-R0033	AURYX 90 NT-proBNP Reagent Kit
34	I20-R0034	AURYX 90 NT-proBNP Reagent Kit
35	I20-R0035	AURYX 90 H-FABP Reagent Kit
36	I20-R0036	AURYX 90 H-FABP Reagent Kit
37	I20-R0037	AURYX 90 NT-proBNP STAT Reagent Kit
38	I20-R0038	AURYX 90 NT-proBNP STAT Reagent Kit
39	I20-R0039	AURYX 90 CK-MB STAT Reagent Kit
40	I20-R0040	AURYX 90 CK-MB STAT Reagent Kit
41	I20-R0041	AURYX 90 hs Troponin T STAT Reagent Kit
42	I20-R0042	AURYX 90 hs Troponin T STAT Reagent Kit
43	I20-R0043	AURYX 90 Myoglobin STAT Reagent Kit
44	I20-R0044	AURYX 90 Myoglobin STAT Reagent Kit
45	I20-R0045	AURYX 90 Lp-PLA2 Reagent Kit
46	I20-R0046	AURYX 90 Lp-PLA2 Reagent Kit
47	I20-R0047	AURYX 90 D-dimer STAT Reagent Kit
48	I20-R0048	AURYX 90 D-dimer STAT Reagent Kit
49	I20-B0001	AURYX 90 MC Cardiac Marker
50	I20-B0002	AURYX 90 MC Cardiac Marker
51	I20-R0049	AURYX 90 PIIINP Reagent Kit
52	I20-R0050	AURYX 90 PIIINP Reagent Kit
53	I20-R0051	AURYX 90 CIV Reagent Kit
54	I20-R0052	AURYX 90 CIV Reagent Kit
55	I20-R0053	AURYX 90 CG Reagent Kit
56	I20-R0054	AURYX 90 CG Reagent Kit
57	I20-R0055	AURYX 90 HA Reagent Kit
58	I20-R0056	AURYX 90 HA Reagent Kit
59	I20-R0057	AURYX 90 LN Reagent Kit
60	I20-R0058	AURYX 90 LN Reagent Kit
61	I20-R0059	AURYX 90 25-OH VD Reagent Kit
62	I20-R0060	AURYX 90 25-OH VD Reagent Kit

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: 9 May 2022

No	Cat. No	Name
63	I20-R0061	AURYX 90 CT Reagent Kit
64	I20-R0062	AURYX 90 CT Reagent Kit
65	I20-R0063	AURYX 90 PTH Reagent Kit
66	I20-R0064	AURYX 90 PTH Reagent Kit
67	I20-R0065	AURYX 90 Ferritin Reagent Kit
68	I20-R0066	AURYX 90 Ferritin Reagent Kit
69	I20-R0067	AURYX 90 Vitamin B12 Reagent Kit
70	I20-R0068	AURYX 90 Vitamin B12 Reagent Kit
71	I20-R0069	AURYX 90 Folate Reagent Kit
72	I20-R0070	AURYX 90 Folate Reagent Kit
73	I20-R0071	AURYX 90 C-peptide Reagent Kit
74	I20-R0072	AURYX 90 C-peptide Reagent Kit
75	I20-R0073	AURYX 90 Insulin Reagent Kit
76	I20-R0074	AURYX 90 Insulin Reagent Kit
77	I20-R0075	AURYX 90 PG I Reagent Kit
78	I20-R0076	AURYX 90 PG I Reagent Kit
79	I20-R0077	AURYX 90 Gastrin 17 Reagent Kit
80	I20-R0078	AURYX 90 Gastrin 17 Reagent Kit
81	I20-R0079	AURYX 90 PG II Reagent Kit
82	I20-R0080	AURYX 90 PG II Reagent Kit
83	I20-R0081	AURYX 90 Total β -hCG Reagent Kit
84	I20-R0082	AURYX 90 Total β -hCG Reagent Kit
85	I20-R0083	AURYX 90 PROG Reagent Kit
86	I20-R0084	AURYX 90 PROG Reagent Kit
87	I20-R0085	AURYX 90 PRL Reagent Kit
88	I20-R0086	AURYX 90 PRL Reagent Kit
89	I20-R0087	AURYX 90 TESTO Reagent Kit
90	I20-R0088	AURYX 90 TESTO Reagent Kit
91	I20-R0089	AURYX 90 Estradiol Reagent Kit
92	I20-R0090	AURYX 90 Estradiol Reagent Kit
93	I20-R0091	AURYX 90 FSH Reagent Kit
94	I20-R0092	AURYX 90 FSH Reagent Kit

Signature:

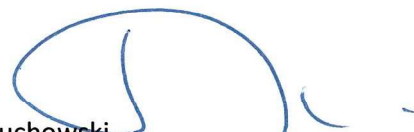


Flavio Finotello

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

Place: Lomianki

Signature:



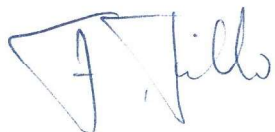
Wojciech Suchowski

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

Date: 9 May 2022

No	Cat. No	Name
95	I20-R0093	AURYX 90 LH Reagent Kit
96	I20-R0094	AURYX 90 LH Reagent Kit
97	I20-R0095	AURYX 90 AMH Reagent Kit
98	I20-R0096	AURYX 90 AMH Reagent Kit
99	I20-R0126	AURYX 90 SARS-CoV-2 IgG Reagent Kit
100	I20-R0097	AURYX 90 SARS-CoV-2 IgG Reagent Kit
101	I20-R0127	AURYX 90 SARS-CoV-2 IgM Reagent Kit
102	I20-R0098	AURYX 90 SARS-CoV-2 IgM Reagent Kit
103	I20-R0128	AURYX 90 SARS-CoV-2 Nab Reagent Kit
104	I20-R0099	AURYX 90 SARS-CoV-2 Nab Reagent Kit
105	I20-R0100	AURYX 90 CA 125 Reagent Kit
106	I20-R0111	AURYX 90 CA 125 Reagent Kit
107	I20-R0101	AURYX 90 CA 15-3 Reagent Kit
108	I20-R0112	AURYX 90 CA 15-3 Reagent Kit
109	I20-R0102	AURYX 90 HE4 Reagent Kit
110	I20-R0113	AURYX 90 HE4 Reagent Kit
111	I20-R0103	AURYX 90 CEA Reagent Kit
112	I20-R0114	AURYX 90 CEA Reagent Kit
113	I20-R0104	AURYX 90 SCC Reagent Kit
114	I20-R0115	AURYX 90 SCC Reagent Kit
115	I20-R0105	AURYX 90 proGRP Reagent Kit
116	I20-R0116	AURYX 90 proGRP Reagent Kit
117	I20-R0108	AURYX 90 CA 19-9 Reagent Kit
118	I20-R0119	AURYX 90 CA 19-9 Reagent Kit
119	I20-R0109	AURYX 90 AFP Reagent Kit
120	I20-R0120	AURYX 90 AFP Reagent Kit
121	I20-R0110	AURYX 90 CYFRA 21-1 Reagent Kit
122	I20-R0125	AURYX 90 CYFRA 21-1 Reagent Kit
123	I20-R0121	AURYX 90 CA 72-4 Reagent Kit
124	I20-R0122	AURYX 90 CA 72-4 Reagent Kit
125	I20-R0123	AURYX 90 NSE Reagent Kit
126	I20-R0124	AURYX 90 NSE Reagent Kit

Signature:

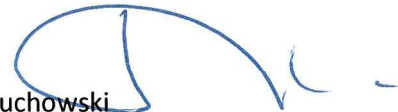


Flavio Finotello

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: 9 May 2022