

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:

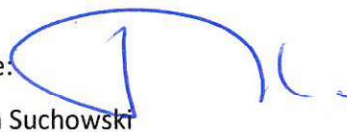


Flavio Finotello

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	6-251	CORMAY ASO Latex 100
2	6-254	CORMAY CRP Latex 100
3	6-252	CORMAY RF Latex 100
4	6-256	CORMAY RPR Carbon 500
5	6-259	CORMAY TPHA 100

Signature:

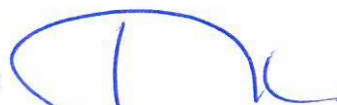


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