

**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

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No	Cat. No	Name
1	8-601	HAEM 8 CONTROL L
2	8-602	HAEM 8 CONTROL N
3	8-603	HAEM 8 CONTROL H
4	8-604	HAEM 12 CONTROL L
5	8-605	HAEM 12 CONTROL N
6	8-606	HAEM 12 CONTROL H

Signature:

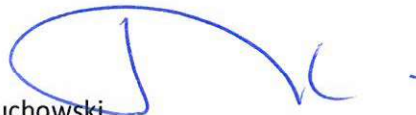


Flavio Finotello

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

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