

EC DECLARATION OF CONFORMITY

In accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council

Manufacturer:

PZ CORMAY S.A.

22 Wiosenna Str.

05-092 Lomianki

Poland

Single Registration Number (SRN): PL-MF-000023053

We, PZ CORMAY S.A., declare that the following devices:

Device name: see Attachment 1

Device catalogue number: see Attachment 1

Basic UDI-DI: 590751468-866_8-886CR

Device class: A

Classification rule: 5a

Intended use: DILUENT is intended to dilute blood samples before assay and to maintain appropriate environment during assay on hematology analyzers. It is only for in vitro diagnostics, for healthcare professional users.

comply with General Safety and Performance Requirements of the ANNEX I – Regulation (EU) 2017/746 of the European Parliament and of the Council and their Conformity Assessment has been made accordingly to the ANNEX IX – Regulation (EU) 2017/746 of the European Parliament and of the Council.

This Declaration of Conformity is issued under the sole responsibility of PZ CORMAY S.A.

Signature:

Anna Smolira

Person responsible for regulatory compliance of
PZ CORMAY S.A.

Signature:

Robert Wiśniewski



Person responsible for regulatory compliance of
PZ CORMAY S.A.

Place: Lublin

Date: 1 August 2022

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PZ Cormay S.A.

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NIP: 1181872269
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Correspondence address:

PZ Cormay S.A.
Poland, 02-785 Warsaw, 303 Pulawska Street

office@cormay.com

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Attachment 1

Device name	Device catalogue number
DILUENT	8-866
DILUENT	8-879
DILUENT	8-882
DILUENT	8-886

Signature:

Anna Smolira



Person responsible for regulatory compliance of

PZ CORMAY S.A.

Signature:

Robert Wiśniewski



Person responsible for regulatory compliance of

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