CORMAY

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: 590751468-883_8-890C3

Device class: A

Classification rule: 5a

Intended use: LYSING REAGENT CN FREE is intended to lyse of erythrocytes for hemoglobin release to allow further hemoglobin's assay on hematological analyzers. It prepares leukocytes for subpopulations differentiation process. 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

PZ Cormay S.A.
Poland, 05-092 Łomianki 22 Wiosenna Street
NIP: 1181872269
REGON: 140777556

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

office@cormay.com
tel. +48 (22) 751 79 10

CORMAY

Attachment 1

Device name	Device catalogue number
LYSING REAGENT CN FREE	8-883
LYSING REAGENT CN FREE	8-890

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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