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: 590751468-868_8-894DS

Device class: A

Classification rule: 5a

Intended use: CLEANER is intended to remove biological material's residues from the measurement system of the 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

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

Registered in District Court of Warsaw, XIV Department of National Court Register No 0000270105. Fixed capital: 84 205 008,00 PLN total paid.

CORMAY

Attachment 1

Device name	Device catalogue number
CLEANER	8-868
CLEANING REAGENT	8-894

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

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