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 device:

Device name: DILUENT

Device catalogue number: 8-892

Basic UDI-DI: 590751468-8927B

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 analyzer MINDRAY BC-3000Plus. It is only for in vitro diagnostics, for healthcare professional users.

complies 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:

Robert Wiśniewski

Person responsible for regulatory compliance of

PZ CORMAY S.A.

Date: 7 March 2023

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Registered in District Court of Warsaw, XIV Department of National Court Register No 0000270105. Fixed capital: 84 205 008.00 PLN total paid.