

**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: ENZYMATIC CLEANER FORTE**

**Device catalogue number: 8-895**

**Basic UDI-DI: 590751468-8957H**

**Device class: A**

**Classification rule: 5a**

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

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.**

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