

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: CONCENTRATED DETERGENT B

Device catalogue numbers: 3-117, 3-118

Basic UDI-DI: 590751463-117_3-118UZ

Device class: A

Classification rule: 5a

Intended use: CONCENTRATED DETERGENT B is intended to use for cleaning the cuvettes of the following biochemistry analyzers: ACCENT MC240 / BS-240Pro, ACCENT M320 / BS-360E, ACCENT 800 / BS-800M, BS-400, BS-480 and BS-800. 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: 10 June 2022

PZ Cormay S.A.

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