

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: ACCENT WASHING SOLUTION

Device catalogue number: 3-119

Basic UDI-DI: 590751463-11947

Device class: A

Classification rule: 5a

Intended use: ACCENT WASHING SOLUTION is intended to use for cleaning the reagent and sample probes of the biochemistry analyzers: ACCENT S120 / BS-230, ACCENT MC240 / BS-240Pro, ACCENT M320 / BS-360E during routine analyzer operation and to eliminate carryover effect. ACCENT WASHING SOLUTION is also intended to use for cleaning the reagent and sample probes of the biochemistry analyzer ACCENT-200 (II GEN) / BS-200 to eliminate carryover effect for magnesium determinations. 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

Page 1/1

PZ Cormay S.A.

Poland, 05-092 Łomianki 22 Wiosenna Street

NIP: 1181872269

REGON: 140777556

Correspondence address:

PZ Cormay S.A.

Poland, 02-785 Warsaw, 303 Pulawska Street

office@cormay.com

tel. +48 (22) 751 79 10