

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: see Attachment 1

Device class: A

Classification rule: 5a

Intended use: ALKALINE WASHING SOLUTION is intended to use for cleaning the reagent and sample probes of the biochemistry analyzers during routine analyzer operation. 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:

Signature:

Anna Smolira

Robert Wiśniewski

Sume fielire

PZ CORMAY S.A.

Person responsible for regulatory compliance of Person responsible for regulatory compliance of

PZ CORMAY S.A.

Place: Lublin

Date: 20 June 2022

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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.



Attachment 1

Device name	Device catalogue number	Basic UDI-DI
ACCENT-200 ALKALINE WASHING SOLUTION	3-108	590751463-10842
ACCENT-300 ALKALINE WASHING SOLUTION	3-112	590751463-1123R
A-400 ALKALINE WASHING SOLUTION	3-110	590751463-1103M
A-800 ALKALINE WASHING SOLUTION	7-897	590751467-8977A

Signature:

Anna Smolira

Person responsible for regulatory compliance of

PZ CORMAY S.A.

Signature:

Robert Wiśniewski

Person responsible for regulatory compliance of

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