

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: Chemistry Analyzer

Model: ACCENT M320

Basic UDI-DI: 59075146AccentM320SW

Device class: A

Classification rule: 5b

Intended purpose: Automatic chemistry analyzer ACCENT M320 is intended to measure activity/concentration of clinical chemistry analytes in serum, plasma, urine and cerebrospinal fluid samples. 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 as well as with the Directives: 2014/30/EU, 2014/35/EU, 2011/65/EU.

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: 22 December 2022

PZ Cormay S.A.

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