

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: AURYX 90 Auffer

Device catalogue numbers: I20-C0001, I20-C0004

Basic UDI-DI: 59075146I20-C0001_4AV

Device class: A

Classification rule: 5a

Intended purpose: AURYX 90 Auffer is intended for cleaning the aspiration probe, analytical liquid line and measuring cell of AURYX 90 Immunoassay System. 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: 23 February 2024

PZ Cormay S.A.

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