

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 Buffer

Device catalogue numbers: I20-C0002, I20-C0005

Basic UDI-DI: 59075146I20-C0002_5B4

Device class: A

Classification rule: 5a

Intended purpose: AURYX 90 Buffer is intended to provide and maintain electrochemical reaction environment in 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.

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