CORMAY

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: Immunoassay System

Model: AURYX 90

Basic UDI-DI: 59075146AURYX90ZQ

Device class: A

Classification rule: 5b

Intended purpose: AURYX 90 Immunoassay System is fully automated analyzer for immunoassay analysis. It is designed for both quantitative and qualitative in vitro determination of different analytes: antigens, antibodies, hormones and specific proteins in human serum and plasma. AURYX 90 Immunoassay System 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: 29 January 2024

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.