

**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: URI-TEX**

**Basic UDI-DI: 59075146UritexR8**

**Device class: A**

**Classification rule: 5b**

**Intended use:** Semiautomatic reader URI-TEX is intended to read results of urine analysis performed with urine strips. 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: 19 August 2022

**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