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: URI-TEX 300

Basic UDI-DI: 59075146Uritex300R3

Device class: A

Classification rule: 5b

Intended use: Semiautomatic reader URI-TEX 300 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 the Regulation (EU) 2017/746 of the European Parliament and of the 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:

Joanna Stec

Person responsible for regulatory compliance of PZ CORMAY S.A.

Place: Lublin

Date: 20 August 2024

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