



PZ CORMAY S.A.  
05-092 Lomianki, 22 Wiosenna Str.  
phone: +48 22 751 7910 ;  
fax: +48 22 751 7911  
www.cormay.pl; office@cormay.pl



## EC DECLARATION OF CONFORMITY

In accordance with Directive 98/79/EC

We, **PZ CORMAY S.A.**, 22 Wiosenna Str., 05-092 Lomianki, Poland, declare that the following devices:

**Product:** Urine analyser  
**Model:** URI-TEX 300

(classified as other IVDD – all devices with exception of devices listed in List A and List B and self-testing devices) comply with essential requirements of the ANNEX I – Directive 98/79/EC and their conformity assessment has been made accordingly to the ANNEX III – Directive 98/79/EC.

The devices named above have been designed and manufactured according to the specifications:

EN ISO 15223-1:2012	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.
EN ISO 14971:2009	Medical Devices – Application of risk management to medical devices.
EN ISO 18113-3:2009	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). In vitro diagnostic instruments for professional use.
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements.
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use. EMC requirements. Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment.
EN 61000-3-2:2006	Electromagnetic compatibility (EMC) -- Part 3-2: Limits - Limits for harmonic current emissions (equipment input current $\leq 16$ A per phase).
EN 61000-3-3:1995/A2:2005	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current $\leq 16$ A per phase and not subject to conditional connection.

PZ CORMAY S.A Quality Management System complies with requirements of ISO 9001:2008 and EN ISO 13485:2012 standards and has been approved by Lloyd's Register Quality Assurance Limited in the range concerning design, manufacturing and distribution of in vitro diagnostic medical devices for medical, industrial and research laboratories and sale and service of medical equipment.

Signature:.....

Janusz Płocica

President of Management Board of

PZ CORMAY S.A.

Signature:.....

Wojciech Suchowski

Vice President of Management Board of

PZ CORMAY S.A

Place: Łomianki

Date: 16 May 2017

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