

Declaration of Conformity

Urologic ApS

Vedbæk Stationsvej 6,2

2950 Vedbæk

Danmark

-hereby warrants that it is the legal manufacturer of the UROX Urine System for male incontinence.

The Urox system consists of the following components subject to be controlled by the MDR 2017/745 by the Council, the "Medical Device Regulation":

The UROX cup, product codes	1010, 1011, 1012, 1013, and 1014
The UROX gaiter, product codes	2010, 2011, 2012, 2013, and 2014
The UROX rinsing liquid, product codes	4015 and 4016
The UROX fixation pants, product codes	3010, 3011, 3012, 3013, and 3014.

All of the above are registered in EUDAMED with the following UDI. (as listed on labels)

Item	Size	EAN-prefix	EAN-suffix
Cup	S M L XL	57400110	10111 10128 10135 10142 10104 UroxcupK6 <i>A06030399</i>
Gaiter	S M L XL	57400110	20110 20127 20134 20141 20103 UroxbagGK <i>A06030301</i>
Fix Pants	S M L XL	57400110	31116 31123 31130 31147

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	XXL		31154
Rinsing Liquid	250ml	57400110	40156
Storage Bag		57400110	40132
Starter Kit • 1 cup • 1 gaiter • 1 fix pant • 1 rinsing liquid		57400110	40149

We hereby declare that the products are developed, manufactured, and quality controlled in accordance with the Medical Device Regulative, to the standards of "EN ISO 14971 Risk Management for medical devices" and "EN ISO 8669 Urine Collection Bags".

Vedbæk August 12, 2026

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