CE

EC Declaration of Conformity

This declaration of conformity issued under the sole responsibility of ROPOX A/S, certifies that the ROPOX Toilet lifter, conforms with the relevant legislation.

Intended use

The ROPOX Toilet Lifter gives people with reduced mobility the possibility to extend their independence. It lowers and lifts the user to the best seated or standing position. Importantly it is straight-forward to set to the optimum height for both user and helper. It is a solution using modern welfare technology to help users become more self-reliant in their bathroom routines. The Toilet Lifter is an assistive aid which can support users to keep their privacy for as long as possible. The height adjustment has an adjustment range of 40 cm going from 40,5-80,5 cm.

MDR Medical Device Risk Classification

This product is classed as a Class I product by Rule 13 (EU Regulation 2017/745 Annex VIII - Chapter III) and Class I by rule 12 in the 93/42 EEC due to being an active device. The device is normally intended for long term accumulated use (more than 30 days). This is a non-sterile device.

Unique Device Identifier and product codes

Trade name	Product code	Model	Basic UDI-DI
ROPOX Toilet lifter electric	40-45020	Electric	57075810008RB
ROPOX Toilet lifter manual	40-45030	Manual	57075810008RB

Legislation:

The ROPOX Toilet lifter is the sole responsibility of the manufacturer and is in conformity with the:

- European Medical Device Regulation 2017/745 (articles 10, 19 and Annex IV),
- the Danish Medicines Agencies BEK nr 1263, dated 15/12/2008 (articles 3 and 6 and Annex IV), and the
- European Directive 93/42/EEC (Annex V) EC Verification of conformity

This certificate ensures and declares that this product is in compliance with harmonized standards and Common Specification for Ropox Toilet lifter

Harmonised standards:

EN ISO 9001:2015	Quality management systems
EN ISO 14971:2012	Application of risk management to medical devices
EN 62366-1:2015	Application of Usability engineering to medical devices
IEC 60601-1:2005	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and test

Non harmonized standards and common specifications:

ISO 17966:2016	Assistive products for personal hygiene that supports users – Requirements and test methods

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Tommy Jensen
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ROPOX A/S

Naestved, The __02_ / _06__, 2021

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