



EC Declaration of Conformity

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

Intended use

The SlimLine washbasin combines mirror and basin in one unit, and the mirror is therefore always at the right height no matter if you are sitting in a wheelchair or standing up. You adjust the height with a push on the control switch which is always within reach as it is located right under the mirror.

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 SlimLine Washbasin	40-15601	Support washbasin	57075810005R5
ROPOX SlimLine Washbasin	40-15607	Unit	57075810005R5

Legislation:

The ROPOX SlimLine Washbasin 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 SlimLine Washbasin

Harmonised standards:

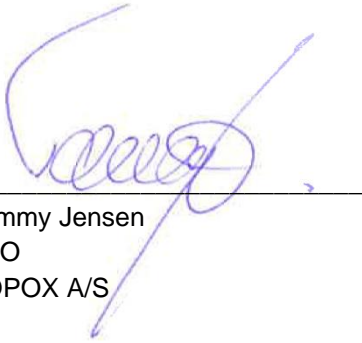
EN ISO 9001:2015	Quality management systems
EN ISO 14971:2012	Application of risk management to medical devices
EN 62366-1:2015	Application of Usability engineering to medical devices
IEC 60601-1:2005	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
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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