CE

EC Declaration of Conformity

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

Intended use

The StandardLine washbasin is especially suitable for private homes and institutions. The height is adjusted electrically. There are three types of washbasins to choose from so you can be sure to get the model that fit the users best.

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 StandardLine Washbasin Electric	40-14770	Unit	57075810004R3
ROPOX StandardLine Washbasin Electric	40-14771	Standard washbasin	57075810004R3
ROPOX StandardLine Washbasin Electric	40-14772	Support washbasin	57075810004R3
ROPOX StandardLine Washbasin Electric	40-14773	Hospital washbasin	57075810004R3

Legislation:

The ROPOX StandardLine 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

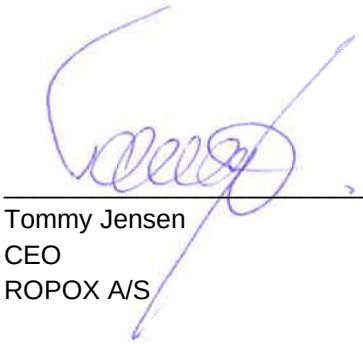
This certificate ensures and declares that this product is in compliance with harmonized standards and Common Specification for ROPOX StandardLine Washbasin

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



Naestved, The __20_ / _5___, 2020

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