



## **EC Declaration of Conformity**

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

### **Intended use**

The support washbasin is especially suitable for walking-impaired because you can use the integrated, ergonomic grab rails as support and as help when getting up or sitting down. The washbasin is available with fixed height and with height adjustment. It is possible to choose between manual or electrical height adjustment. This makes it able to suit the individual user who will be using the washbasin.

### **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 Support Washbasin Fixed	40-44000	Fixed complete left	57075810002QX
ROPOX Support Washbasin Fixed	40-44001	Fixed complete right	57075810002QX
ROPOX Support Washbasin Basic	40-44002	Basic Complete left	57075810002QX
ROPOX Support Washbasin Basic	40-44003	Basic Complete right	57075810002QX
ROPOX Support Washbasin Manual	40-44004	Manual Complete left	57075810002QX
ROPOX Support Washbasin Manual	40-44005	Manual Complete right	57075810002QX
ROPOX Support Washbasin Electric	40-44006	Electric Complete left	57075810002QX
ROPOX Support Washbasin Electric	40-44007	Electric Complete right	57075810002QX
ROPOX Support Washbasin Fixed	40-44010	Fixed left	57075810002QX
ROPOX Support Washbasin Fixed	40-44011	Fixed right	57075810002QX
ROPOX Support Washbasin Basic	40-44012	Basic left	57075810002QX
ROPOX Support Washbasin Basic	40-44013	Basic right	57075810002QX
ROPOX Support Washbasin Manual	40-44014	Manual left	57075810002QX
ROPOX Support Washbasin Manual	40-44015	Manual right	57075810002QX
ROPOX Support Washbasin Electric	40-44016	Electric left	57075810002QX
ROPOX Support Washbasin Electric	40-44017	Electric right	57075810002QX

### **Legislation:**

The ROPOX Support 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

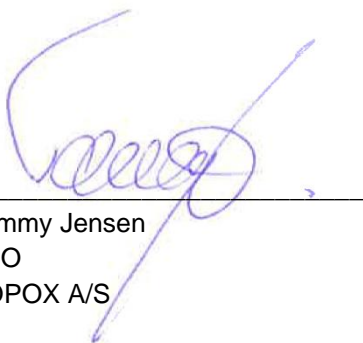
This certificate ensures and declares that this product is in compliance with harmonized standards and Common Specification for ROPOX Support Washbasin

**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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Naestved, The 20 / 5, 2020

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ROPOX A/S

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