



## **EC Declaration of Conformity**

This declaration of conformity issued under the sole responsibility of ROPOX A/S, certifies that the ROPOX Changing and Shower bed, conforms with the relevant legislation.

### **Intended use**

The height adjustable shower/changing bed makes showering and changing safe and comfortable for disabled and people with mobility disabilities. The soft and flexible slats provide the user with optimum comfort, and the electrical height adjustment and the ergonomic design ensure the best possible working environment for the carer. The user-friendliness, the design and the welfare technology results in security and satisfaction for both user and helper. The bed can quickly be adjusted to the desired level, for example, you can lower the bench to just 30 cm above floor level making the transfer of a user onto the bed smooth and easy.

### **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 Changing and Shower Bed	40-25023	146 cm	57075810011QY
ROPOX Changing and Shower Bed	40-25026	178 cm	57075810011QY
ROPOX Changing and Shower Bed	40-25029	210 cm	57075810011QY
ROPOX Changing and Shower Bed	40-25073	146 cm with back support	57075810011QY
ROPOX Changing and Shower Bed	40-25076	178 cm with back support	57075810011QY
ROPOX Changing and Shower Bed	40-25079	210 cm with back support	57075810011QY

### **Legislation:**

The ROPOX Changing and Shower bed 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 Changing and Shower Bed

### **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
EN ISO 10993-1:2009	Biological evaluation of medical devices
IEC 60601-1:2005	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance

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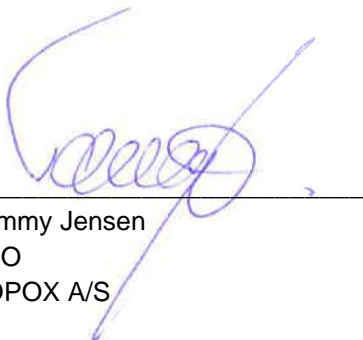
IEC 60601-1-2:2014

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  
CEO  
ROPOX A/S

Naestved, The 20 / 5, 2020

On behalf of  
ROPOX A/S  
Ringstedgade 221  
4700 Naestved  
Denmark  
Phone: +45 55 75 05 00  
Email: [info@ropox.dk](mailto:info@ropox.dk)