



EC Declaration of Conformity

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

Intended use

The mobile height adjustable changing bed can be used to nurse children and adults up to 200 kg. The stationary changing bed is intended for use in private homes, day-care centers, day centers for persons with physical or mental disabilities, or similar institutions, to provide the right and optimal working conditions for the staff. The mobile changing bed can be used in both dry and wet rooms however it may not be used as a shower bed. The changing bed is freestanding, mobile and with brake wheels to ensure optimum working conditions.

The height of the table top can be adjusted step less from 52-92 cm using a spiral cord handset.

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 Mobilio Changing bed	40-30404	120x70cm	57075810013R4
ROPOX Mobilio Changing bed	40-30404	140x70cm	57075810013R4
ROPOX Mobilio Changing bed	40-30404	160x70cm	57075810013R4
ROPOX Mobilio Changing bed	40-30404	180x70cm	57075810013R4
ROPOX Mobilio Changing bed	40-30404	190x70cm	57075810013R4

Legislation:

The ROPOX Mobilio Changing 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 Mobilio Changing bed

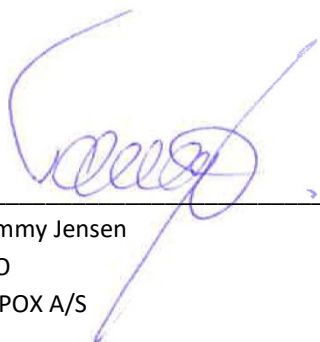
Harmonised standards:

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
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:

EN 12182:2012

Assistive products for persons with disability– Requirements and test methods



Naestved, The 29 / 5, 2020

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