



EC Declaration of Conformity

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

Intended use

The shower seat is a flexible and stable aid for users who need to shower sitting down, and it can be used in all kinds of bathrooms. It is possible to fold the seat up to a vertical position which makes it possible to use the seat even in bathrooms with limited space. If you have mounted arm supports, these can also be folded up to free up space. It is possible to get the shower seat with height adjustment. The height is easily adjusted on the button that is located on the wall above the seat, and you can adjust the height up to 12,5 cm. The maximum user weight is 200 kg for models with a support leg and 150 kg for models without legs.

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). Enheden er normalt beregnet til langvarig kontinuerlig brug (mere end 30 dage). Dette er en ikke-steril enhed.

Unique Device Identifier and product codes

Trade name	Product code	Model	Basic UDI-DI
ROPOX Shower seat	40-43011	With leg	57075810009RD
ROPOX Shower seat	40-43016	Without leg	57075810009RD
ROPOX Back rest	40-43025	With armrest	57075810009RD
ROPOX Back rest	40-43030	Without armrest	57075810009RD
ROPOX Height adjustment	40-43043	Height adjustable unit	57075810009RD

Legislation:

The ROPOX Shower seat 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

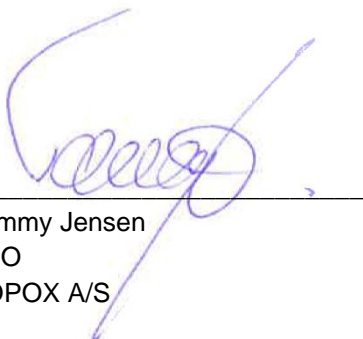
This certificate ensures and declares that this product is in compliance with harmonized standards and Common Specification for ROPOX Shower seat

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

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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