CE

EC Declaration of Conformity

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

Intended use

Ropox QuickWash is intended for use in both homecare and professional healthcare environments.
Adjusting the height and depth of the wash basin, accommodates ergonomical requirements, stemming from the difference in height between seated wheelchair users and standing users.
Ropox QuickWash is not intended for playing with or as an exercise-equipment.

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). 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 Quick Wash	40-42120-1	Unit only	57075810014R6
Ropox Quick Wash	40-42121-1	Complete	57075810014R6

Legislation:

The ROPOX (product name) 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 comply harmonized standards and Common Specification for Ropox Quick Wash

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, 20/ 4 - 2021

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ROPOX
Better ways to better days

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