



EC Declaration of Conformity

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

Intended use

The AdaptLine washbasins are available with manual height adjustment to better the use for wheelchair users and walking impaired patient. Height adjustment is done with the small crank. The height adjustment range is 20 cm.

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 AdaptLine Washbasin	40-42010	Standard washbasin	57075810006R7
ROPOX AdaptLine Washbasin	40-42011	Support washbasin	57075810006R7
ROPOX AdaptLine Washbasin	40-42012	Hospital washbasin	57075810006R7
ROPOX AdaptLine Washbasin	40-42110	Unit	57075810006R7

Legislation:

The ROPOX AdaptLine 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

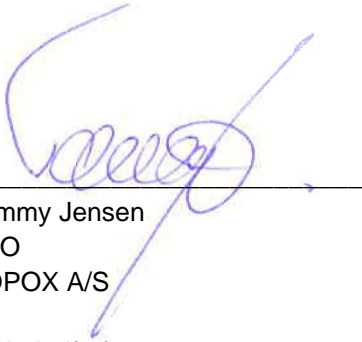
This certificate ensures and declares that this product is in compliance with harmonized standards and Common Specification for ROPOX AdaptLine Washbasin

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

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 19 / 5, 2020

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