



## **EC Declaration of Conformity**

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

### **Intended use**

The Swing Washbasin is a washbasin which can be swung to the user, which makes it possible for the user to wash hands before leaving the toilet. This increases the hygiene, makes the user more self-reliant and gives the assistant better working conditions. The Swing washbasin is available with manual height adjustment. Depending on the model, the height adjustment range is 15 cm for models without dock-in and 20 cm for models with dock-in. This means that the user and carer can set the level of the sink to the height that fits the user's needs. The height adjustment also makes the sink suited for both standing and seated use. It can be lowered for seated users, e.g., wheelchair users or elderly users who prefer to sit while washing hands or brushing teeth, and it can be raised for standing users or carers.

### **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 Swing Washbasin Complete | 40-40071     | Complete Right                | 57075810001QV |
| ROPOX Swing Washbasin Complete | 40-40072     | Complete Left                 | 57075810001QV |
|                                |              |                               |               |
| ROPOX Swing Washbasin Fixed    | 40-41110     | Fixed                         | 57075810001QV |
|                                |              |                               |               |
| ROPOX Swing Washbasin Fixed    | 40-41120     | Fixed - hidden installations  | 57075810001QV |
|                                |              |                               |               |
| ROPOX Swing Washbasin Manual   | 40-41130     | Manual                        | 57075810001QV |
|                                |              |                               |               |
| ROPOX Swing Washbasin Manual   | 40-41140     | Manual - hidden installations | 57075810001QV |

### **Legislation:**

The ROPOX SwingLine 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 SwingLine Washbasin

### **Harmonised standards:**

|                   |   |
|-------------------|---|
| EN ISO 9001:2015  | Quality management systems                        |
| EN ISO 14971:2012 | Application of risk management to medical devices |

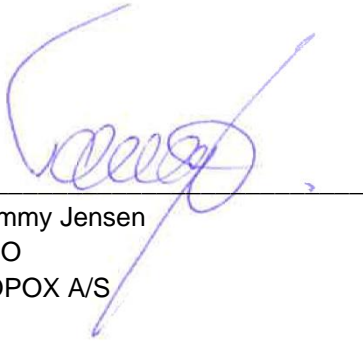
EN 62366-1:2015

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



Naestved, The 20 / 5, 2020

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