



# EU Declaration of Conformity

<b>Manufacturer</b>	R82 A/S Parallelvej 3 DK-8751 Gedved Denmark Phone: +45 7965 5888 <a href="http://www.etac.com">www.etac.com</a>
<b>SRN</b>	DK-MF-000000772
<b>Statement</b>	This declaration of conformity is issued under the sole responsibility of the manufacturer. The device(s) covered by present declaration is/are in conformity with EU Regulation 2017/745 on medical devices.
<b>Device name</b>	Orca
<b>Intended purpose</b>	Assistive device for washing, bathing and showering for persons with disabilities
<b>Basic UDI-DI</b>	57072920933074F
<b>EMDN</b>	Y093399
<b>Risk class of the device</b>	Class I, rule 1
<b>Common specifications</b>	Separate list available upon request
<b>Place</b>	Gedved, Denmark
<b>Date of issue</b>	2023-11-14
<b>Name and function</b>	Dianna Hessellund Jensen – Director QA/RA

A handwritten signature in blue ink, appearing to read "Dianna Hessellund Jensen".

Signature, on behalf of manufacturer