



# EU Declaration of Conformity

Manufacturer	R82 A/S Parallelvej 3 DK-8751 Gedved Phone: +45 79655888 <a href="http://www.etac.com">www.etac.com</a>
SRN	DK-MF-000000772
Statement	This declaration of conformity is issued under the sole responsibility of the manufacturer. The device(s) covered by this declaration of conformity is/are in conformity with EU Regulation 2017/745 on medical devices.
Basic UDI-DI	57072920933074F
EMDN	Y093399
Intended Purpose	Assistive device for washing, bathing and showering for persons with disabilities
Device name(s)	Orca
Risk class of the device	Class I, Rule 1
Harmonized/Established Standards	Separate list available upon request
Place	Gedved, Denmark
Date of issue	2025-12-11
Name and function	Claus Riis – QA & RA Manager

Signature, on behalf of manufacturer