



EU DECLARATION OF CONFORMITY

Manufacturer R82 A/S

Parallelvej 3 DK-8751 Gedved

DK-8751 Geaved Denmark

SRN DK-MF-000000772

Statement This EU 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

Basic UDI-DI 57072920912033L

Intended purpose Assistive device for toileting, washing, bathing and showering for persons with

disabilities

Product / device name Flamingo

Flamingo High-low

Heron Swan

Risk class of the device Class I

Place Gedved, Denmark

Date of issue 26. April 2021

Name and function Ulla Lange, Director of QA and Regulatory Affairs

Signature, on behalf of R82 A/S





Declaration of Conformity

Class 1 Medical Device

Manufacturer R82 A/S

Parallelvej 3 8751 Gedved Denmark

The undersigned hereby declares that the following product,

Product ID/Name Manatee

Size 1, 2, 3 and all accessories

Type Bathing stretcher for diabled children

GMDN code 31092

complies with the requirements of Council Directive 93/42/EEC Medical Devices

The product is manufactured in conformity with the following standard(s):

Standard EN 12182:2012 Assistive products for persons with disability

General requirements and test methods

Gedved, 15.02.2017

Ulla Lange / Director of Quality and Regulatory Affairs