



EU DECLARATION OF CONFORMITY

Manufacturer	R82 A/S Parallelvej 3 DK-8751 Gedved Denmark
SRN	DK-MF-000000772
Statement	<p>This EU declaration of conformity is issued under the sole responsibility of the manufacturer</p> <p>The device(s) covered by present declaration is/are in conformity with EU Regulation 2017/745 on medical devices</p>
Basic UDI-DI	57072921809214L
Intended purpose	Portable seat for persons with disabilities
Product / device name	Scallop
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



EC Declaration of Conformity

Manufacturer :

Company : R82 A/S
Address : Parallevej 3
DK-8751 Gedved
Telephone : +45 7968 5888
Fax : +45 7566 5192

hereby declares, that

Product :

Product-id. : 89101xx-xx
Name : x:panda 1/2/3/4 and all accessories
Type : Seat for disabled children
MDD classification : Non-invasive – Class I
GMDN code : 10797

is in conformity with:

- the Council Directive 93/42/EEC concerning medical devices, and manufactured in conformity with the following harmonized standard(s):

EN 12182 2012

EN 1041 2009

EN ISO 14971 2012

Position : Quality Manager
Name : Kent Rasmussen
Company : R82 A/S

Date 29.11.2012

Signature