

UK CA

UK DECLARATION OF CONFORMITY

In accordance with UK Government Guidance

Manufacturer

R82 A/S

UK Responsible Person

Etac Ltd

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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 UK MDR 2002

(Medical Device Regulations 2002)

Basic UDI-DI

57072921809034J

GMDN

58827

Intended purpose

R82 Seating devices are assistive devices intended for compensation for a physical

impairment due to an injury or disability. The device are designed for an individual lacking the

ability to maintain a seated position or move around without the use of an assistive device due

to mobility impairment.

Device name(s)

x:panda shape TS

Risk class of the device

Class I, rule 1

Harmonized/Established

Standards

Separate list available upon request

Place

Gedved, Denmark

Date of issue

2024-05-31

Name and function

Dianna Hessellund Jensen, Director QA/RA

Signature, on behalf of manufacturer