



UK DECLARATION OF CONFORMITY

In accordance with UK Government Guidance

Manufacturer

Etac Immedia A/S

UK Responsible Person

Etac Ltd

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N.

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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

57080122004LX

Device description

Positioning Sitting

GMDN

11100

Intended purpose

The assistive device is intended for alleviation of, or compensation for, a functional impairment due to an injury or disability. The device is designed for an individual lacking the

ability to position or turn themselves in sitting position due to reduced mobility or physical

strength.

Device name(s)

OneWayGlide

Risk class of the device

Class I, rule I

Harmonized/Established

Standards

Separate list available upon request

Place

Gedved, Denmark

Date of issue

15. January 2024

Name and function

Michael Bruun, Senior Vice President

Signature, on behalf of Etac Immedia A/S