



UK DECLARATION OF CONFORMITY

In accordance with UK Government Guidance

Manufacturer

Etac Immedia 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

57080121001LJ

Device description

Positioning Horizontal

GMDN

37163

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 requiring reduction of friction at pressure points due to reduced mobility or physical strength.

Device name(s)

SatinSheet BaseSheet SatinSheet 2Direction SatinSheet 4Direction

SatinSheet In2Sheet4Direction

SatinSheet PillowCase

Risk class of the device

Class I, rule I

Harmonized/Established

Separate list available upon request

Standards

Place

Gedved, Denmark

Date of issue

30. June 2025

Name and function

Sampavi Rajkumar, Quality Specialist

Signature, on behalf of Etac Immedia A/S