



EU DECLARATION OF CONFORMITY

Manufacturer

Etac Immedia A/S

Parallelvej 3 DK-8751 Gedved

Denmark

SRN

DK-MF-000019241

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

57080121001LJ

Intended purpose

The SatinSheet system is used for repositioning and turn a user in bed.

Product / device name

Immedia SatinSheet 2Direction BaseSheet Mini Immedia SatinSheet 2Direction BaseSheet Midi Immedia SatinSheet 2Direction BaseSheet Maxi Immedia SatinSheet 2Direction BaseSheet Fit Immedia SatinSheet 2Direction BaseSheet Elastic Fit Immedia SatinSheet 2Direction BaseSheet Corner

Immedia SatinSheet 2Direction PillowCase Immedia SatinSheet 2Direction DrawSheet Immedia SatinSheet 4Direction DrawSheet

Immedia In2Sheet 4Direction

Brand

Immedia

Risk class of the device

Class I

Place

Gedved, Denmark

Date of issue

9 August 2022

Name and function

Michael Bruun, Senior Vice President

Signature, on behalf of Etac Immedia A/S