



EU DECLARATION OF CONFORMITY

Manufacturer Etac Immedia A/S
Egeskovvej 12
DK-8700 Horsens
Denmark

SRN NA

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

Brand Immedia

Risk class of the device Class I

Place Horsens, Denmark

Date of issue 16 April 2021

Name and function Michael Bruun, Senior Vice President

Signature, on behalf of Etac Immedia A/S