



EU Declaration of Conformity

Manufacturer	Etac Immedia A/S Parallelvej 3 DK-8751 Gedved Denmark www.etac.com
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
Device description	Positioning Horizontal
EMDN	Y122799
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 Standards	Separate list available upon request
Place	Gedved, Denmark
Date of issue	30. June 2025
Name and function	Sampavi Rajkumar, Quality Specialist  _____ Signature, on behalf of Etac Immedia A/S