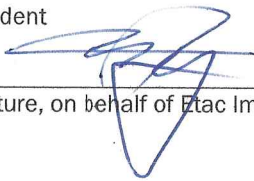




EU Declaration of Conformity

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)	SainSheet BaseSheet SainSheet 2Direction SainSheet 4Direction SainSheet In2Sheet4Direction
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