



# EU Declaration of Conformity

<b>Manufacturer</b>	<b>Etac Immedia A/S</b> Parallelvej 3 DK-8751 Gedved Denmark www.etac.com
<b>SRN</b>	DK-MF-000019241
<b>Statement</b>	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.
<b>Basic UDI-DI</b>	57080128002N5
<b>Device description</b>	Positioning Cushions
<b>EMDN</b>	V080399
<b>Intended purpose</b>	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 lacking the ability to position themselves due to reduced mobility or physical strength.
<b>Device name(s)</b>	PositioningWedge
<b>Parts covered by this declaration</b>	Inner cushions with replaceable Non-Slip Cover (inner cushion with Non-Slip Cover is defined as system and equals the term "positioning wedge") with sizes as specified and listed in the Instructions For Use.
<b>Risk class of the device</b>	Class I, rule I
<b>Harmonized/Established Standards</b>	Separate list available upon request
<b>Place</b>	Gedved, Denmark
<b>Date of issue</b>	15. January 2024
<b>Name and function</b>	Michael Bruun, Senior Vice President

A handwritten signature in blue ink, appearing to read 'M. Bruun', is written over a horizontal line.

Signature, on behalf of Etac Immedia A/S