



# EU DECLARATION OF CONFORMITY

<b>Manufacturer</b>	<b>Etac Immedia A/S</b> Parallevej 3 DK-8751 Gedved Denmark
<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>	<b>57080126004MT</b>
<b>Intended purpose</b>	Positioning Wedge can be used to support and position users in baths, for lower body hygiene, bed-baths, resting, raising head or foot end. Etc.
<b>Product / device name</b>	Immedia Positioning Wedge
<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>Brand</b>	Immedia
<b>Risk class of the device</b>	Class I
<b>Place</b>	Gedved, Denmark
<b>Date of issue</b>	1 June 2022
<b>Name and function</b>	Michael Bruun, Senior Vice President

Signature, on behalf of Etac Immedia A/S