




UK DECLARATION OF CONFORMITY

In accordance with UK Government Guidance

Manufacturer	Etac Immedia A/S Parallevej 3 DK-8751 Gedved Denmark www.etac.com	UK Responsible Person	Etac Ltd Unit 60, Hartlebury Trading Estate, Hartlebury, Kidderminster, DY10 4JD Email enquiries.uk@etac.com Web www.etac.com/uk Phone +44 (0)121 561 2222
Statement	This declaration of conformity is issued under the sole responsibility of the manufacturer. The device(s) covered by this declaration of conformity is/are in conformity with UK MDR 2002 (Medical Device Regulations 2002)		
Basic UDI-DI	57080128002N5		
Device description	Positioning Cushions		
GMDN	41058		
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 lacking the ability to position themselves due to reduced mobility or physical strength.		
Device name(s)	PositioningWedge		
Parts covered by this declaration	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.		
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