SEA-BAND®

Declaration of Conformity

for Sea-Bands

Medical Devices Regulation 2017/745 concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document are in conformity with the requirements of the MDR 2017/745 that apply to them and the CE Mark may be affixed. This Declaration of Conformity is issued under the sole responsibility of the manufacturer, Sea-Band Limited.

General Product Name:	Sea-Band
Legal Manufacturer and place of issue: (Name on Label)	Sea-Band Limited 8 Hawley Road Hinckley Leicestershire LE10 0PR ENGLAND
Manufacturers SRN:	GB-MF-000026343
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Elastic wrist band to control nausea and motion sickness without the use of drugs
Classification Rule	The device is for short term use contacting only intact skin and therefore falls under Rule 1.
MDR Classification:	Class I non sterile
Notified Body and CE:	Not required for class I
EU Authorised Representative:	Advena Limited, Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta
EU Authorised Rep SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Self-certification by European Medical Device Regulation 2017/745 Annex IV and this Declaration of Conformity and the registration of persons responsible for placing the devices on the market.

Name Christian Bennett **Position** Director

Signed **Date** 23 June 2025

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

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Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
MDR 2017/745	Medical Devices Regulation
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied

Appendix II – Product Listing/Schedule

Description/Name	BASIC UDI-DI	GMDN Code
Sea-Band Acupressure Wristband for Nausea - ADULT	5015259 NAUSEA001 6M	58072
Sea-Band Acupressure Wristband for Nausea - CHILD	5015259 NAUSEA001 6M	58072
Sea-Band Acupressure Wristband for Nausea - MAMA	5015259 NAUSEA001 6M	58072
Sea-Band Acupressure Wristband for Nausea - XL	5015259 NAUSEA001 6M	58072

Version History

Version	Compiled by	Date	Description
1.0	N. Mitchinson	01/05/2020	First issue
2.0	N. Mitchinson	20/05/2021	UDI Added
3.0	N. Mitchinson	2/9/2021	Conformity statement amended to include statement for issue under the sole responsibility of Sea-Band. Directive changed to MDR. Position changed from Sea-Band to Director.
4.0	N. Mitchinson	27/10/21	Change of EC Representative
5.0	N. Mitchinson	27/07/22	Manufacturers SRN added
6.0	S. Gibbs	28/02/2024	UDI amended to UDI-DI due to typing error.
7.0	P. Joels	14/03/2024	UDI-DI amended to BASIC UDI-DI.
8.0	N. Mitchinson	18/06/2025	XL Band added
9.0	N. Mitchinson	23/06/2025	Classification Rule added

This declaration is valid for a period of 5 years or until a change is made.