

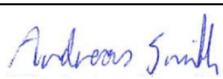
EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of Tidewave Medical AS. We hereby declare that the medical device(s) specified here meet the provision of the Regulation (EU) MDR 2017/745. The Quality management system of Tidewave™ Medical AS conforms to the requirements of Article 10 and is self-validated, as per requirements for Medical Devices Class 1. All supporting documentation is retained at the premises of the manufacturer.

Document Number	TW-COC11278-3
Manufacturer Name	Tidewave Medical AS
Manufacturer Address	Hillevågsveien 101, 4016 Stavanger, Norway
Registered Trade Name	Tidewave
Registered Trademark	Tidewave™
SRN (Single Registration Number)	NO-MF-000000557
Device Name	Tidewave™ Turning Mattress
Device Identification (Part No.)	TWTURNING
Risk Classification	Class I (<i>as per Annex VIII in MDR</i>)

Conformity Assessment Route: Tidewave Medical AS uses the following procedures, either in full or in parts, for the CE-labelling of their products according to the Regulation MDR 2017/745:

Standard	Description
IEC 60601-1:2006+A1:2013+A12:2014	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2015	Medical electrical equipment Part 1-2: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6:2010+A1:2015	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-11:2015	Medical electrical equipment Part 1-11: Requirements for medical electrical equipment and medical electrical systems used in the Home Healthcare environment
ISO 21856:2022	Assistive products – General requirements and test methods
ISO 20342-1:2022	Assistive products for tissue integrity when lying down – Part 1: General Requirements
ISO 20342-7:2021	Assistive products for tissue integrity when lying down – Part 7: Foam properties, characteristics, and performance
ISO 20342-10:2022	Assistive products for tissue integrity when lying down – Part 10: Guidance to cleaning, disinfecting and care of polyurethane APTI covers
ISO 20417:2021	Information supplied by the manufacturer of medical devices
ISO 15223-1:2016	Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements
ISO 14971:2019	Application of risk management to medical devices
ISO 10993-1:2011	Biological evaluation of medical devices
EN 597-1:2015 & EN 597-2:2015	Assessment of the ignitability of mattresses and upholstered bedbases
ISO 13485:2016	Quality management systems

Signature	Place and Date of Issue
 Andreas Smith, Regulatory Assurance of Tidewave Medical AS	Stavanger 2023-06-02

Annex

Name	Catalogue No.	Product Code	GTIN
Tidewave Turning Mattress, Configurable Device	TWTURNING	TW-UDI-DI-0001	0 7073196 00001 0
Air-cells 85x190; Incontinence sheet 85x190; Soft foam mattress 85x190 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	85.190.001.EU.S	All these variations are configurations of Tidewave Turning Mattress, UDI assignment is not applicable to these on individual level. Each separate component is traced with a serial number in supply chain.	
Air-cells 85x190; Incontinence sheet 85x190; Medium foam mattress 85x190 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	85.190.001.EU-M		
Air-cells 85x190; Incontinence sheet 85x190; Hard foam mattress 85x190 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	85.190.001.EU-H		
Air-cells 85x200; Incontinence sheet 85x200; Soft foam mattress 85x200 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	85.200.001.EU.S		
Air-cells 85x200; Incontinence sheet 85x200; Medium foam mattress 85x200 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	85.200.001.EU-M		
Air-cells 85x200; Incontinence sheet 85x200; Hard foam mattress 85x200 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	85.200.001.EU.H		
Air-cells 85x210; Incontinence sheet 85x210; Soft foam mattress 85x210 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	85.210.001.EU.S		
Air-cells 85x210; Incontinence sheet 85x210; Medium foam mattress 85x210 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	85.210.001.EU-M		
Air-cells 85x210; Incontinence sheet 85x210; Hard foam mattress 85x210 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	85.210.001.EU.H		
Air-cells 90x190; Incontinence sheet 90x190; Soft foam mattress 90x190 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	90.190.001.EU.S		

Name	Catalogue No.	Product Code	GTIN
Air-cells 90x190; Incontinence sheet 90x190; Medium foam mattress 90x190 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	90.190.001.EU.M		
Air-cells 90x190; Incontinence sheet 90x190; Hard foam mattress 90x190 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	90.190.001.EU.H		
Air-cells 90x200; Incontinence sheet 90x200; Soft foam mattress 90x200 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	90.200.001.EU.S		
Air-cells 90x200; Incontinence sheet 90x200; Medium foam mattress 90x200 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	90.200.001.EU.M		
Air-cells 90x200; Incontinence sheet 90x200; Hard foam mattress 90x200 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	90.200.001.EU.H		
Air-cells 90x210; Incontinence sheet 90x210; Soft foam mattress 90x210 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	90.210.001.EU.S		
Air-cells 90x210; Incontinence sheet 90x210; Medium foam mattress 90x210 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	90.210.001.EU.M		
Air-cells 90x210; Incontinence sheet 90x210; Hard foam mattress 90x210 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	90.210.001.EU.H		
Air-cells 90x220; Incontinence sheet 90x220; Soft foam mattress 90x220 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	90.220.001.EU.S		
Air-cells 90x220; Incontinence sheet 90x220; Medium foam mattress 90x220 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	90.220.001.EU.M		
Air-cells 90x220; Incontinence sheet 90x220; Hard foam mattress 90x220 ; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	90.220.001.EU.H		

Name	Catalogue No.	Product Code	GTIN
Air-cells 70x160; Incontinence sheet 70x160; Child foam mattress 70x160; Pump unit for Tidewave Turning Mattress; Power supply unit including power mains cable	70.160.001.EU.S		