

Declaration of Conformity Medical Devices

(In accordance with ISO/IEC 17050-1)

DoC NO.: 2022-023

Manufacturer: ALLION bv.
Macroweg 10
5804 CL Venray
The Netherlands

Trade Mark: Van Heek Medical

SRN: NL-MF-000003490

Product: Tape

Model Code See appendix 1

Classification MDR Annex VIII, Class I , Non Sterile

We, Van Heek Medical, herewith declare that above mentioned product, meet the provisions of the following EC Council regulation. All supporting documentation is retained under the premises of the manufacturer.

General applicable directives:

- Wet Medische Hulpmiddelen van 24 Oktober 2019 in het staatsblad 400
- Medical Device Regulation: Regulation concerning medical devices (MDR2017/745) of 5 April 2017, as amended by Regulation 2020/561 of the European Parliament and of the Council 23 April 2020.

All relevant harmonized Standards as published in the official Journal of the European communities are applicable to this type of product.

Details of the products lay down in the Technical file, which is present at above mentioned address. The Technical File complies with the requirements of the Regulation MDR 2017/745 and applicable standards.

Place & Date: Venray, 26 September 2022

Validity Signature:

Name and position: A. Gerrits, Quality Engineer



Appendix 1: List of products

Basic UDI-DI	Ref number	Description	Class / Rule
8715886TapeME	OT0220-1	Sporttape 10 m x 3.8 cm	I / 1
8715886TapeME	PL0027	Non woven adhesive plaster 9.1 m x 2.5 cm	I / 1
8715886TapeME	PL0033	Non woven adhesive plaster 5 m x 5 cm	I / 1
8715886TapeME	PL0035	Non woven adhesive plaster 5 m x 2.5 cm	I / 1
8715886TapeME	PL0040	Silicone tape 1.5 m x 2.5 cm	I / 1
8715886TapeME	PL0053	Transparant adhesive plaster 5 m x 2.5 cm	I / 1
8715886TapeME	PL0072	Silk adhesive plaster 5 m x 2.5 cm	I / 1
8715886TapeME	PL0073	Silk adhesive plaster 5 m x 1.25 cm	I / 1
8715886TapeME	PL0074	Silk adhesive plaster 5 m x 2.5 cm	I / 1
8715886TapeME	PL0081	Non woven adhesive plaster 5 m x 1.25cm	I / 1
8715886TapeME	PL0082	Non woven adhesive plaster 5 m x 2.5 cm	I / 1
8715886TapeME	PL0270	Fixation plaster 2 m x 10 cm	I / 1
8715886TapeME	PL0272	Fixation plaster 10 m x 5 cm	I / 1
8715886TapeME	PL0273	Fixation plaster 10 m x 10 cm	I / 1
8715886TapeME	PL0274	Fixation plaster 10 m x 15 cm	I / 1
8715886TapeME	PL0275	Fixation plaster 10 m x 20 cm	I / 1
8715886TapeME	PL0302	Textile adhesive plaster 10 x 6 cm	I / 1
8715886TapeME	PL1081	Textile adhesive plaster 5 m x 1.25 cm	I / 1
8715886TapeME	PL1082	Textile adhesive plaster 5 m x 2.5 cm	I / 1
8715886TapeME	PL2082	Detectable adhesive plaster 5 m x 2.5 cm	I / 1
8715886TapeME	PL6020	Textile adhesive plaster 5 m x 6 cm	I / 1
8715886TapeME	PL6030	Textile adhesive plaster 5 m x 8 cm	I / 1