

Declaration of Conformity Medical Devices

DoC NO.: 2022-023

Manufacturer: Allion b.v. h.o.d.n. Van Heek Medical
Macroweg 10
5804 CL Venray
The Netherlands

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, and that this EU declaration of conformity is issued under the sole responsibility of Van Heek Medical.

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.

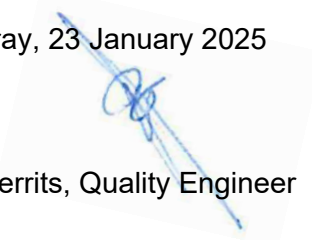
All relevant harmonized Standards as published in the official Journal of the European communities are applicable to this type of product.

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, 23 January 2025

Validity Signature:

Name and position: A. Gerrits, Quality Engineer



Appendix 1:

List of products

Basic UDI-DI	Ref number	Description	Class / Rule
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	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