

Declaration of Conformity Medical Devices

(In accordance with ISO/IEC 17050-1)

DoC NO.: 2021-041

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

Trade Mark: Van Heek Medical

SRN: NL-MF-000003490

Product: Wound dressing, First aid devices, Plasters, Maternity dressing,
Urine bags, Under pads, Gloves, Bandages, cotton wool,
stretch pants

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:

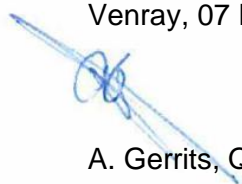
- Wet Medische Hulpmiddelen van 24 Oktober 2019 in het staatsblad 400
- Medical Device Regulation: Regulation concerning medical devices (MDR2017/745) of 5 April 2017, as amended by Regulation 2020/561 of the European Parliament and of the Council 23 April 2020.

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, 07 December 2021

Validity Signature:



Name and position: A. Gerrits, Quality Engineer

Appendix 1: List of products

Group	Ref number	Description	Class
8715886PleistersAW	OT0100-1	Heka elastisch pleisters 10 x 6 cm	I / 4
8715886PleistersAW	OT0101-1	Heka elastisch pleisters assorti	I / 4
8715886PleistersAW	OT0150-1	Heka hechtpleister textiel 5 m x 2.5 cm	I / 4
8715886PleistersAW	OT0131-1	Heka kinderpleisters (waterafstotend) 19 x 76 mm	I / 1
8715886PleistersAW	PL5280	Heka Plast detecteerbare blauwe lange vingerpleister 120 x 20 mm	I / 4
8715886PleistersAW	PL2014	Heka Plast detecteerbare blauwe lange vingerpleister 180 x 20 mm	I / 4
8715886PleistersAW	PL5270	Heka Plast detecteerbare blauwe lange vingerpleister 180 x 20 mm	I / 4
8715886PleistersAW	PL2013	Heka Plast detecteerbare blauwe vingertoppleister 50 x 45 mm	I / 4
8715886PleistersAW	PL0303	Heka Plast detecteerbare blauwe wondpleister 10 x 6 cm	I / 4
8715886PleistersAW	PL0303-1	Heka Plast detecteerbare blauwe wondpleister 10 x 6 cm	I / 4
8715886PleistersAW	PL5210	Heka Plast detecteerbare blauwe wondpleister 19 x 72 mm	I / 4
8715886PleistersAW	PL5220	Heka Plast detecteerbare blauwe wondpleister 25 x 72 mm	I / 4
8715886PleistersAW	PL6220	Heka Plast detecteerbare blauwe wondpleister 5 m x 6 cm	I / 4
8715886PleistersAW	PL6230	Heka Plast detecteerbare blauwe wondpleister 5 m x 8 cm	I / 4
8715886PleistersAW	PL2011	Heka Plast detecteerbare blauwe wondpleister 72 x 19 mm	I / 4
8715886PleistersAW	PL2012	Heka Plast detecteerbare blauwe wondpleister 72 x 25 mm	I / 4
8715886PleistersAW	PL0323	Heka Plast detecteerbare blauwe wondpleister assorti	I / 4
8715886PleistersAW	PL0333	Heka Plast detecteerbare lange vingerpleister 180 x 20 mm	I / 4
8715886PleistersAW	PL5080	Heka Plast elastisch textiel lange vingerpleister 120 x 20 mm	I / 4
8715886PleistersAW	PL5070	Heka Plast elastisch textiel lange vingerpleister 180 x 20 mm	I / 4
8715886PleistersAW	PL5010	Heka Plast elastisch textiel wondpleister 19 x 72 mm	I / 4
8715886PleistersAW	PL5020	Heka Plast elastisch textiel wondpleister 25 x 72mm	I / 4
8715886PleistersAW	PL0053	Heka Plast film transparante hechtpleister 5 m x 2.5 cm	I / 1
8715886PleistersAW	PL0272	Heka Plast Fix huidvriendelijke fixatiepleister met schutvel 10 m x 5 cm	I / 1
8715886PleistersAW	PL0273	Heka Plast Fix huidvriendelijke fixatiepleister met schutvel 10 m x 10 cm	I / 1
8715886PleistersAW	PL0274	Heka Plast Fix huidvriendelijke fixatiepleister met schutvel 10 m x 15 cm	I / 1

Group	Ref number	Description	Class
8715886PleistersAW	PL0275	Heka Plast Fix huidvriendelijke fixatiepleister met schutvel 10 m x 20 cm	I / 1
8715886PleistersAW	PL0270	Heka Plast Fix huidvriendelijke fixatiepleister met schutvel 2 m x 10 cm	I / 1
8715886PleistersAW	PL1014	Heka Plast non-woven lange vingerpleister 120 x 20 mm	I / 4
8715886PleistersAW	PL1013	Heka Plast non-woven vingertoppleister 75 x 45 mm	I / 4
8715886PleistersAW	PL1011	Heka Plast non-woven wondpleister 72 x 19 mm	I / 4
8715886PleistersAW	PL1012	Heka Plast non-woven wondpleister 72 x 25 mm	I / 4
8715886PleistersAW	PL2010	Heka Plast pleisterdispenser blauw assorti	I / 4
8715886PleistersAW	PL1010-1	Heka Plast pleisterdispenser groen PL1011/PL1012/PL1013/PL1014	I / 4
8715886PleistersAW	PL1010-2	Heka Plast pleisterdispenser groen PL1011/PL1012/PL1013/PL1014	I / 4
8715886PleistersAW	OT0121	Heka Plast sensitive pleisters assorti	I / 4
8715886PleistersAW	PL0040	Heka Plast silicone tape 1.5 m x 2.5 cm	I / 1
8715886PleistersAW	PL2082	Heka Plast textiel detecteerbare hechtpleister 5 m x 2.5 cm	I / 1
8715886PleistersAW	PL1081	Heka Plast textiel hechtpleister 5 m x 1.25 cm	I / 1
8715886PleistersAW	PL1082	Heka Plast textiel hechtpleister 5 m x 2.5 cm	I / 1
8715886PleistersAW	PL0322	Heka Plast textiel pleisters assorti	I / 4
8715886PleistersAW	PL0322-1	Heka Plast textiel pleisters assorti	I / 4
8715886PleistersAW	PL0302	Heka Plast textiel wondpleister 10 x 6 cm	I / 4
8715886PleistersAW	PL0302	Heka Plast textiel wondpleister 10 x 6 cm	I / 4
8715886PleistersAW	PL6020	Heka Plast textiel wondpleister 5 m x 6 cm	I / 4
8715886PleistersAW	PL6030	Heka Plast textiel wondpleister 5 m x 8 cm	I / 4
8715886PleistersAW	OT0131	Heka Plast waterbestendig kinderpleisters assorti	I / 4
8715886PleistersAW	PL5180	Heka Plast waterresistente lange vingerpleister 120 x 20 mm	I / 4
8715886PleistersAW	PL5170	Heka Plast waterresistente lange vingerpleister 180 x 20 mm	I / 4
8715886PleistersAW	PL5110	Heka Plast waterresistente wondpleister 19 x 72 mm	I / 4
8715886PleistersAW	PL5120	Heka Plast waterresistente wondpleister 25 x 72 mm	I / 4
8715886PleistersAW	PL0321	Heka Plast waterresistente wondpleister assorti	I / 1
8715886PleistersAW	PL0341	Heka Plast waterresistente wondpleister assorti	I / 1
8715886PleistersAW	PL0332	Heka Plast waterresistente wondpleister kind 10 x 6 cm	I / 1

Group	Ref number	Description	Class
8715886PleistersAW	OT0120-1	Heka sensitive pleisters 10 x 6 cm	I / 1
8715886PleistersAW	OT0121-1	Heka sensitive pleisters assorti	I / 4
8715886PleistersAW	OT0220-1	Heka sporttape 10 m x 3.8 cm	I / 1
8715886PleistersAW	OT0111-1	Heka waterbestendig wondpleister assorti	I / 4
8715886PleistersAW	OT0110-1	Heka waterbestendige pleisters 10 x 6 cm	I / 4