VAN HEEK MEDICAL
Onderdeel van Mosadex Groep

Declaration of Conformity Medical Devices

(In accordance with ISO/IEC 17050-1)

DoC NO.: 2022-017

Manufacturer ALLION b.v.
Macroweg 10
5804 CL Venray
The Netherlands

Trade Mark: Van Heek Medical

We hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Health Products (Medical Devices) Regulations (MDD 93/42/EEC)

This is based on conformity of said products, which fall in Class I sterile and covered by the CE-Certificates;

- Certificate nr. 2018306CE01, issued on June 1, 2002
  by DEKRA Certification BV., The Netherlands,
  Notified Body Identification Number 0344, and is valid until March 11, 2023.
- Certificate nr. 2018306CE02, issued on February 1, 2014
  by DEKRA Certification BV., The Netherlands,
  Notified Body Identification Number 0344, and is valid until October 20, 2023.
- Certificate nr .2018306CE03, issued on November 23, 2017
  by DEKRA Certification BV., The Netherlands,
  Notified Body Identification Number 0344, and is valid until April 22, 2023.

It describes conformity of the production quality assurance system with Annex V of the Directive, comprising manufacture and final inspection of the products. On the certificates references are made to the required technical documentation set out in Annex V.

This Declaration of Conformity covers the following CE marked products:

- **Wound Dressing Products,**
- **Catheters**
  (for product list see appendix 1)

General applicable directives:

Medical Device Directives: Council Directive 93/42/EEC concerning medical devices as amended by directive 2007/47/EC.

Details of the products lay down in the Technical file, which is present at above mentioned address. The Technical File and the Design Dossier comply with the requirements of the Directive MDD 93/42/EEC and applicable standards.

Place & Date : Venray, 18 Juli 2022
Validity Signature :

Name and position : Annette Gerrits, Quality Engineer

Appendix 1: List of products

Group	Description	Art.Number	Sterilization Method	Class / Rule *
AB02	Hekasorb and Hekapad	AB0099	Gamma	Is / 4
		AB0100	Gamma	Is / 4
		AB0101	Gamma	Is / 4
		AB0102	Gamma	Is / 4
		AB0103	Gamma	Is / 4
		AB0104	Gamma	Is / 4
		AB0215	Gamma	Is / 4
		AB0217	Gamma	Is / 4
		AB0220	Gamma	Is / 4
		AB0225	Gamma	Is / 4
KO01	Hekapres gaaskompres	KO0017	ETO	Is / 4
		KO0017DA	ETO	Is / 4
		KO0036	ETO	Is / 4
		KO0036TR	Gamma	Is / 4
		KO0282	ETO	Is / 4
		KO0283	ETO	Is / 4
		KO0284	ETO	Is / 4
		KO0284AD	ETO	Is / 4
		KO0284TR	Gamma	Is / 4
		KO0385	ETO	Is / 4
		KO0386	ETO	Is / 4
		KO0505	ETO	Is / 4
		KO0505TR	Gamma	Is / 4
		KO0510	ETO	Is / 4
		KO0511	ETO	Is / 4
		KO0704	ETO	Is / 4
		KO0705	ETO	Is / 4
		GG0301	ETO	Is / 4
		VA0009	ETO	Is / 4
NW01	Heka soft non-woven compress	NK0251	ETO	Is / 4
		NK0281	ETO	Is / 4
		NK0511	ETO	Is / 4
		NK0512	ETO	Is / 4
		NK0516	ETO	Is / 4
		NK0517	ETO	Is / 4
		NK0581	ETO	Is / 4
		NK0582	ETO	Is / 4
		NK0721	ETO	Is / 4
		NK0781	ETO	Is / 4
		OT0010-1	ETO	Is / 4
		OT0012-1	ETO	Is / 4
		OT0012DA	ETO	Is / 4
		OT0014-1	ETO	Is / 4
		OT0014DA	ETO	Is / 4
VA09	First aid dressing	VA0404	Gamma	Is / 4
		VA0406	Gamma	Is / 4
		VA0408	Gamma	Is / 4

Group	Description	Art.Number	Sterilization Method	Class / Rule *
		VA0421	Gamma	Is / 4
		VA0422	Gamma	Is / 4
		VA0423	Gamma	Is / 4
		VA0461	Gamma	Is / 4
		VA0462	Gamma	Is / 4
		VA0463	Gamma	Is / 4
VA09	Eye Pad	VA0913	Gamma	Is / 4
UZ60	PVC Catheter	UZ6110	ETO	Is / 5
		UZ6112	ETO	Is / 5
		UZ6118	ETO	Is / 5
PL01	Heka film	PL0140	ETO	Is / 4
		PL0142	ETO	Is / 4
SW01	Decifera Silicone sheet	SW0100	ETO	Is / 4
		SW0101	ETO	Is / 4
		SW0103	ETO	Is / 4

*See classification in MDD 93/42/EEC, annex IX