

Declaration of Conformity Medical Devices

(In accordance with ISO/IEC 17050-1)

DoC NO.: 2021-011

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 IIb and covered by the following Certificates

- Certificate nr. 2018306CE04, issued on February 2, 2018 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 II 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 II

This Declaration of Conformity covers the following CE marked products:

- **Wound Dressing Products,**
(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, 20 mei 2021

Validity Signature :



Name and position : T. van Bommel, Quality Engineer

Appendix 1: List of products

Group	Description	Art.Number	Sterilization Method	Class / Rule *
SW01	Decifera Hydrogel	SW0040	Gamma	IIb
		SW0041	Gamma	IIb
	Decifera Foam	SW0060	Gamma	IIb
	Decifera Foam Silicone	SW0071	ETO	IIb
		SW0072	ETO	IIb
	Decifera Foam Silicone Extra Thin	SW0025	ETO	IIb
		SW0026	ETO	IIb
		SW0027	ETO	IIb
	Decifera Silicone foam border	SW0073	ETO	IIb
		SW0130	ETO	IIb
		SW0131	ETO	IIb
	Decifera Alginate	SW0001	Gamma	IIb
		SW0003	Gamma	IIb
		SW0013	Gamma	IIb

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