

# EC CERTIFICATE

Number: 2018306CE01

## Production Quality Assurance

### Directive 93/42/EEC on Medical devices, Annex V

(Devices in Class I in sterile conditions and sterilised systems or procedure packs)

Manufacturer:

**Allion B.V.**

**Macroweg 10  
5804 CL Venray  
The Netherlands**

For the product category(ies)

### **Sterile wound dressings**

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

# 0344

Documents, that form the basis of this certificate:

### **Certification Notice 2018306CN, initially dated 1 June 2002 Addendum, initially dated 12 December 2002**

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system, that covers the aspects of manufacture concerned with securing and maintaining sterile conditions, for the above mentioned product category in accordance to the provisions of Annex V Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

The necessary information related to the quality assurance system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 11 March 2023  
Issued for the first time: 1 June 2002  
Revised: 21 December 2018  
Reissued: 28 September 2018

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands  
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

# ADDENDUM

Belonging to certificate: 2018306CE01

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Sterile wound dressings

Issued to:

**Allion B.V.**  
Macroweg 10  
5804 CL Venray  
The Netherlands

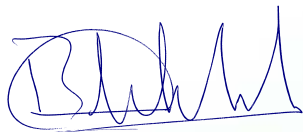
This certificate covers the following product(s):

- Absorbing dressings (Hekasorb / Hekapad AB02) (Class I sterile)
- Gauze Swabs (Hekapres Ko01) (Class I sterile)
- Non woven compresses ( Hekasoft, NW01) (Class I sterile)
- First Aid dressing (VA09) (Class I sterile)
- EYE PAD (Class I sterile)

NOTE Allion B.V. uses Van Heek Medical as trade name for the above mentioned products

Initial date: 12 December 2002  
Revision date: 28 September 2018

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands  
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396