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

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
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ADDENDUM

Belonging to certificate: 2018306CE01

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.

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