EC CERTIFICATE

Number: 2174275CE02

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:

Lettix B.V.
Prinsenweide 66
7317 BC Apeldoorn
The Netherlands

For the product category(ies)

Wound care products (Mechanical barrier, compression or absorption) (Class Is), Other low risk devices for wound care (Class Is), Non active medical devices for desinfecting, cleaning and rinsing (Class Is), Non active devices for flushing (Class Is), Non active instruments kits (Class Is), Non active single use instruments (Class Is), Ophthalmic single use instruments (Class Is) and Suture removal sets (Class Is)

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 2118806CN, initially dated 17 September 2008

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: 26 May 2024
Issued for the first time: 7 October 2016
Revised: 12 October 2020
Reissued: 8 July 2019

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

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