EC CERTIFICATE

Number: 2174275CE01

Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V
(Devices in Class IIa, IIb or III)

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

For the product category(ies)

Sterile custom procedure packs, non-active instruments and accessories for treatment or surgery in the following areas:
Surgical interventions
Single use instruments for general surgical interventions (class IIa), Preparation (class IIa), Biopsy (class IIa), Bone marrow biopsy (class IIa), Obstetrics delivery instruments (class IIa), Wound drainage (class IIa) and Suture kits (class IIa)
Anesthesia
Basic and regional anesthesia (class IIa) and Pain relief (class IIa)
Ophthalmic surgery and treatment
Instrument trays for ophthalmic surgeries and treatments (class IIa)
Wound dressing (invasive – X-ray)
Compresses (class IIa), Gauze compresses (class IIa), Cotton balls (class IIa) and Tampons (class IIa)
Injection transfusion or dialysis
Tubing for blood administration sets (class IIa), Fluid dispensing sets (class IIa), Drains (class IIa), Specimen containers (class IIa), Suction tips and tubes (class IIa), Connection tubes (class IIa), Infusion pump administration sets (class IIa) and Insemination sets (class IIa)

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 for the manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex V of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III or Class IIb devices an additional EC type-examination certificate according to Annex III is mandatory.
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:	22 January 2015
Revised:	8 July 2019
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
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