

CERTIFICATE

Number: 2118806

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Lettix B.V.

Prinsenweide 66
7317 BC Apeldoorn
The Netherlands

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:

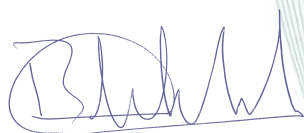
Design, development, manufacture, assembling, packaging, warehousing and distribution of sterile and non-sterile, non-active, non-implantable devices: for anesthetic procedures (syringes); for wound and skin care (absorbing swabs, wound dressings and ointment dressings, fixation and support bandages / devices, used as mechanical barrier, compression or for absorption or cleansing); for administration, channeling and removal of substances, including devices for dialysis (accessories for liquids infusion, accessories for delivering accessories for radioactive pharmaceuticals, accessories for bladder irrigation kits, accessories for urologic procedures, accessories for aspiration, drains); single instruments for general surgical use, ophthalmologic procedures, biopsy procedures, obstetric procedures and gynecological procedures.

Design, development, manufacture, assembling, packaging, warehousing and distribution of sterile and non-sterile, non-active, non-implantable procedure packs (including anesthesia kits, bowls, patient preparation kits, surgical intervention kits, suturing kits, wound dressing kits and instrument trays for ophthalmic surgeries and treatments).

Certificate expiry date: 1 June 2028
Certificate effective date: 10 June 2025
Certified since: 17 September 2008

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed.



ADDENDUM

To certificate: 2118806

The management system of the organization(s) and/or location(s) of:

Lettix B.V.

Prinsenweide 66
7317 BC Apeldoorn
The Netherlands

Certified organization(s) and/or locations:

Different scope

Lettix B.V.
Prinsenweide 70
7317 BC Apeldoorn
The Netherlands

Manufacture of non-sterile devices for wound and skin care (skin
cleansing, wound dressings, bandages), and warehousing

Addendum expiry date: 1 June 2028
Addendum effective date: 10 June 2025