LÖWENSTEIN
medical

EU – Declaration of Conformity no. 082503

Name of the device: "elisa 800", "elisa 800 VIT", "elisa 800 R-VIT and "elisa 800 VIT RO"

Device	Art. Nr.	Basic UDI-DI
elisa 800	AG-370830	426019209elisa600/800YP
elisa 800 VIT	AG-370830-VIT	426019209elisa600/800YP
elisa 800 VIT RO	AG-370836-VIT	426019209elisa600/800YP
elisa 800 R-VIT	AG-370831	426019209elisa600/800YP

Description: Critical Care Ventilator

UMDNS (GMDNS) Code: 42-411 (42411)

CDN Code: Intensive Care Ventilators - Z12030105

Intended Use: elisa 800 is designed for adult, paediatric, and neonatal patients requiring ventilation support. The range of application covers invasive and non-invasive ventilation by mask or helmet as well as nasal respiratory therapy (Highflow O2 therapy, nasal CPAP and nasal BiLevel).

Patient category	Patient weight
Adults	30 - 500 kg
Children	3 - 150 kg
Neonates	0.3 - 6 kg

There are no known contraindications. It is the user's responsibility to select appropriate settings in consideration of the clinical situation of the ventilated patient, periodically review these settings and adapt them when necessary. When combined with an application system for volatile anaesthetic agents, elisa 800 can also be used as an anaesthesia workstation.

Software Index: **2.16.3**

Hardware Index: **a04 (elisa 800/ elisa 800 VIT); a02 (elisa VIT RO); a00 (elisa 800 R-VIT)**

Accessories: see list attached

MD-Classification: II b (Regulation (EU) 2017/745, Annex VIII)

Conformity Assessment: Regulation (EU) 2017/745 article 52 (4)

Standards / CS: List of standards including date of issue and common specification in the Technical Documentation

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We hereby declare that the above specified device has been designed and manufactured in compliance with Regulation (EU) 2017/745 on Medical Devices, Annex I.
The manufacturer has established and maintains a quality system which complies with Regulation (EU) 2017/745, Annex IX excluding chapter 2. The quality system is under continuous surveillance of the Notified Body TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany (CE0123). The certificate G1 0012094 0035 Rev.00 has been issued by the notified body and provides this proof.

This declaration is given in sole responsibility of the manufacturer:

Company name:	**Löwenstein Medical Innovation GmbH & Co. KG**
Address:	**Weißkirchener Str. 1, D-61449 Steinbach, Germany**
Single Registration Number:	**DE-MF-000016838**

Declared by:

Thomas Reins
General Manager

Steinbach, February 24th, 2025

This Declaration of Conformity has to be revised in case of change of Software or Hardware Index.