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EU – Declaration of Conformity no. 082208

Name of the device: "elisa 800" "elisa 800 VIT"

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

Description:	Critical Care Ventilator
UMDNS (GMDNS) Code:	17-429 (17429)
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 as well as HFOT (high-flow oxygen therapy). 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 600 / elisa 800 / elisa 800 VIT can also be used as an anaesthesia workstation.
Software Index:	**2.10.4**
Hardware Index:	**a04**
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

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

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Notified Body TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany (CE0123). The certificate G100120940035 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, August 22nd, 2022

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