EC – Declaration of Conformity no. 052004

Name of the device: **"elisa 300" and "elisa 500"**

Device	Art. Nr.
elisa 500	AG-480500
elisa 300	AG-480300

Description:	Critical Care Ventilator
UMDNS (GMDNS) Code:	17-429 (17429)
Software Index:	**2.08.0**
Hardware Index:	**a02**
Accessories:	see list attached
MD-Classification:	II b (MDD 93/42/EEC, Annex IX)
Conformity Assessment:	MDD 93/42/EEC Clause 11 (3) a)
Standards:	List of standards including date of issue in the Technical Documentation

We hereby declare that the above specified device has been designed and manufactured in compliance with Council Directive 93/42/EEC, Annex I.

The manufacturer has established and maintains a quality system which complies with Council Directive 93/42/EEC, Annex II without Section 4. The quality system is under continuous surveillance of the Notified Body TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany (CE_{0123}).

This declaration is given in sole responsibility of the manufacturer:

Company name: **Löwenstein Medical Innovation GmbH & Co. KG**

Address: **Niederhoechstaedter Str. 62, D-61476 Kronberg, Germany**

Declared by:

Digitally signed by Ermicev Alexandr
Date: 2021.05.27 12:44:29 EEST
Reason: MoldSign Signature
Location: Moldova

Thomas Reins
General Manager

Kronberg, September 4th, 2020

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