Manufacturer's Declaration of Conformity

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURE

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name:	WEINMANN Emergency Medical Technology GmbH + Co. KG
Business address:	Frohbösestraße 12, 22525 Hamburg GERMANY
Medical device(s):	**MEDUVENT Standard**
Classification:	Class IIb Classification rule no. 11 according to Medical Device Directive 93/42/EEC (according to Annex II excluding (4))
GMDN code and term:	36289; Ventilator, transportable
Scope of application:	All devices are manufactured and tested according to the applicable Quality Assurance Procedures. The serial numbers of the devices are documented in the device history record.

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

Full quality assurance procedures certificate:

EN ISO 13485:2016	Certificate number: SX 60137577 0001 Issue date: March 26, 2019 Issued by TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg, Germany to WEINMANN Emergency Medical Technology GmbH + Co. KG.

EN ISO 9001:2015	Certificate number: 01 100 1810024 Issue date: June 18, 2019 Issued by TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg, Germany to WEINMANN Emergency Medical Technology GmbH + Co. KG.
EC Certificate - Full Quality Assurance System Approval Certificate (Annex II, Article 3 of the Directive 93/42/ EEC on Medical Devices)	Certificate number: HD 60148646 0001 Issue date: April 16, 2020 Issued by TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg, Germany to WEINMANN Emergency Medical Technology GmbH + Co. KG. EC code number: 0197
Design examination certificate (if applicable):	Not applicable (not class III device). Applicable requirements included in the scope of above certificates.
Standards applied	See document "Applied Directives, Laws and Standards" in the Technical Documentation

Authorised signatory:

Hamburg, 10/12/2020

André Schulte
Chief Executive Officer