

КОПИЯ

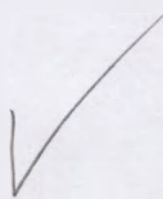


Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**WEINMANN Emergency Medical
Technology GmbH + Co. KG**
Frohbösestr. 12
22525 Hamburg
Deutschland



has established and applies a quality management system for medical devices
for the following scope:

**Design and development, production, distribution
and servicing of medical devices for
emergency and transport medicine
(see attachment for additional site included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012
EN ISO 13485:2012/AC:2012**

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 60088228 0001

An audit was performed. Report No.: 21201240 002

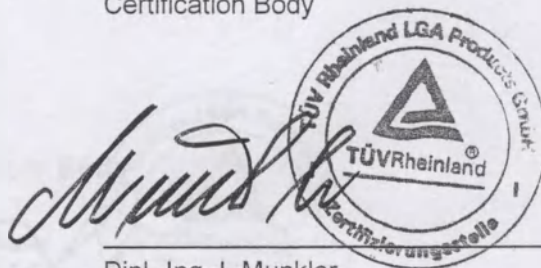
This Certificate is valid until: 30.06.2016



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Date 28.08.2013

Certification Body



Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>



Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

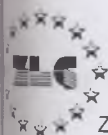
Attachment to
Registration No.: **SX 60088228 0001**
Report No.: **21201240 002**

Organization: **WEINMANN Emergency Medical
Technology GmbH + Co. KG
Frohbösestr. 12
22525 Hamburg
Deutschland**

Scope: **Additional site included:**

**WEINMANN Emergency Medical Technology GmbH + Co. KG
Siebenstücken 14
24558 Henstedt-Ulzburg, Germany**

Activities: Production and Service



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten

ZLG-ZQ-995.00.01-46

Certification Body

Dipl.-Ing. I. Munkler



Date: **2013-08-28**

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**WEINMANN Emergency Medical
Technology GmbH + Co. KG**
Frohbösestr. 12
22525 Hamburg
Deutschland

has established and applies a quality management system
for the following scope:

**Design and development, production, distribution
and servicing of medical devices for
emergency and transport medicine
(see attachment for additional site included)**

Proof has been furnished that the requirements specified in

EN ISO 9001:2008

are fulfilled. The quality management system is subject to yearly surveillance.

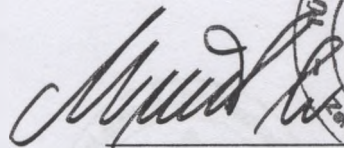
Certificate Registration No.: SY 60088233 0001

An audit was performed. Report No.: 21201240 002

This Certificate is valid until: 30.06.2016

Certification Body

Date 28.08.2013


Dipl.-Ing. I. Munkler



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

120



EC Certificate

Directive 2002/95/EC Annex B, harmonized Section 1

High Quality Assurance System

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to

Registration No.: SY 60088233 0001

Report No.: 21201240 002

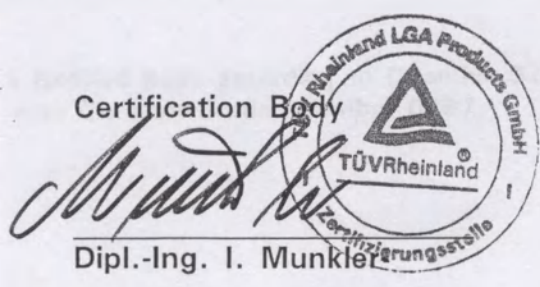
Organization: **WEINMANN Emergency Medical**
Technology GmbH + Co. KG
Frohbösestr. 12
22525 Hamburg
Deutschland

Scope: Additional site included:

WEINMANN Emergency Medical Technology GmbH + Co. KG
Siebenstücken 14
24558 Henstedt-Ulzburg, Germany

Activities: Production and Service

date: 2013-08-28



EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60088226 0001

Report No.: 21201240 002

Manufacturer: WEINMANN Emergency Medical
Technology GmbH + Co. KG
Frohbösestr. 12
22525 Hamburg
Deutschland

Medical devices for emergency and transport medicine
(see attachment for products and sites included)
Replaces Approval, Registration No.: HD 60086808 0001

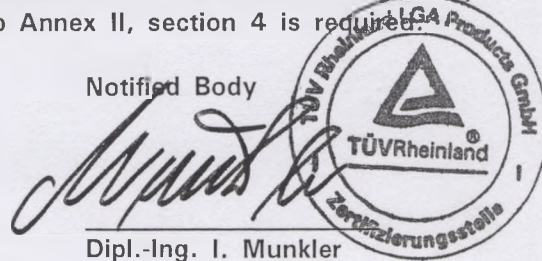
Date: 2018-06-30

Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and maintains a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 4 of the aforementioned directive. For placing on the market of class III devices covered by the directive, an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body

Date: 2013-08-28

2013-08-28



Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev. 0

Attachment to
Certificate

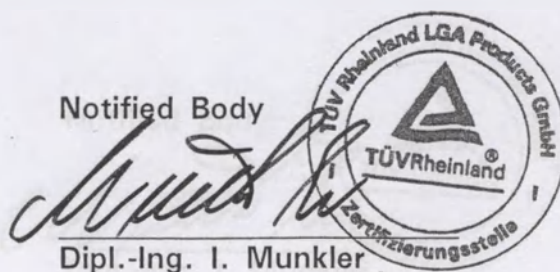
Registration No.: HD 60088226 0001
Report No.: 21201240 002

Manufacturer: **WEINMANN Emergency Medical
Technology GmbH + Co. KG
Frohbösestr. 12
22525 Hamburg
Deutschland**

Products included:

Emergency and transport medicine
Suction pumps
Ventilators
Module systems
Resuscitators
Ventilation masks
Patient hose systems
Pressure reducers
Click dial flowmeter
Defibrillators-/Monitor systems

Notified Body



Dipl.-Ing. I. Munkler

Date: 2013-08-28

103



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

Attachment to
Certificate

Registration No.: HD 60088226 0001
Report No.: 21201240 002

Manufacturer: WEINMANN Emergency Medical
Technology GmbH + Co. KG
Frohbösestr. 12
22525 Hamburg
Deutschland

Additional site included:

WEINMANN Emergency Medical Technology GmbH + Co. KG
Lebenstücken 14
9558 Henstedt-Ulzburg, Germany

Activities: Production

Notified Body

Dipl.-Ing. I. Munkler



2013-08-28

124
I, the undersigned

Dr. Florian Möhrle,

a Notary Public of this Free and Hanseatic City of Hamburg, Federal Republic of Germany, do hereby certify and attest that the foregoing copy is a true and faithful copy of the original deeds, which were presented to me today.

Hamburg, this 12th day of September, 2013



Dr. Florian Möhrle
- Notary Public -

1. the undersigned

Dr. Florian Möhrle,

a Notary Public of this Free and Hanseatic City of Hamburg, Federal Republic of Germany, do hereby certify and attest that the foregoing copy is a true and faithful copy of the notarially certified copy dated September 12, 2013.

Hamburg, this 13th day of September, 2013



Dr. Florian Möhrle
- Notary Public -

Apostille

(Convention de La Haye du 5 octobre 1961)

1. Land: Bundesrepublik Deutschland

Diese öffentliche Urkunde

2. ist unterschrieben von Dr. Florian Möhrle

3. in der Eigenschaft als **Notar**

4. sie ist versehen mit dem Siegel/Stempel des

Notars Dr. Florian Möhrle

Bestätigt

5. in Hamburg

6. am 16. Dezember 2013

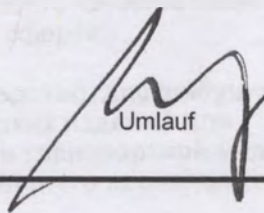
7. durch die Präsidentin des Landgerichts

8. unter Nr. 9101 E/I 5189/2013

9. Siegel/Stempel

10. Unterschrift:




Umlauf