КОПИЯ

TÜVRheinland®

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

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierstelle

Dipl.-Ing. I. Munkler

Date 28.08.2013

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

TÜVRheinland®

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

Date: 2013-08-28

Certification Body

TÜVRheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Dipl.-Ing. I. Munkler

TÜVRheinland®

Certificate

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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

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Dipl.-Ing. I. Munkler

Date 28.08.2013

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

TÜVRheinland®

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

Certification Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Dipl.-Ing. I. Munkler

Date: 2013-08-28

EC Certificate

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

TÜVRheinland®

Registration No.: HD 60088226 0001

Report No.: 21201240 002

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

cts: 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

tified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive EC have been met for the listed products. The above named manufacturer has established plies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, 5 of the aforementioned directive. For placing on the market of class III devices covered by rtificate an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dipl.-Ing. I. Munkler

Date: 2013-08-28

2013-08-28

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.

TÜVRheinland

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

ttachment to
ertificate
egistration No.: HD 60088226 0001
eport No.: 21201240 002

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

oducts included:

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

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Dipl.-Ing. I. Munkler

te: 2013-08-28

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

ttachment to
ertificate
egistration No.: HD 60088226 0001
eport No.: 21201240 002

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

itional site included:

INMANN Emergency Medical Technology GmbH + Co. KG
benstücken 14
558 Henstedt-Ulzburg, Germany

ivities: Production

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

2013-08-28

Dipl.-Ing. I. Munkler

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 -

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 notarially certified copy dated September 12, 2013.

Hamburg, this 13th day of September, 2013

Dr. Florian Möhrle
- Notary Public -

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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:

Landgericht Hamburg 128 Hamburg

Umlauf