

**Business Stream Products
Certification Department**



Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Besmed Health Business Corp.
No. 5, Lane 116, Wu-Kong 2nd Road
Wu-Ku District
NEW TAIPEI CITY, 24888
TAIWAN

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date January 10, 2020

Application for : QMS Produktion, Anhang V MDD
Certificate No. : DD 60142199 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Your Quality Management System has been tested and found to be in accordance with the above mentioned requirements.

Enclosed please find the certificate
No. DD 60142199 0001.

Kind regards

Certification body

A blue ink handwritten signature, appearing to read 'Fuxiu Sheng'.

Fuxiu Sheng

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

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Board of Management

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Dipl.-Kfm.
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Chairman of the
Supervisory Board

Dipl.-Ing.
Ralf Scheller

Nuremberg HRB 26013
VAT No.: DE 811835490

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60142199 0001

Report No.: 50248503 002

Manufacturer: Besmed Health Business Corp.
No. 5, Lane 116, Wu-Kong 2nd Road
Wu-Ku District
New Taipei City, 24888
Taiwan

Products: Manual Resuscitator Sets
(see attachment for additional site included)

Expiry Date: 2024-05-26

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

Effective Date: 2020-01-10

Date: 2020-01-10



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**

**Attachment to
Certificate**

Registration No.: DD 60142199 0001
Report No.: 50248503 002

Manufacturer: Besmed Health Business Corp.
No. 5, Lane 116, Wu-Kong 2nd Road
Wu-Ku District
New Taipei City, 24888
Taiwan

Site included:

Besmed Health Business Corp.
No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District,
New Taipei City 24888, Taiwan

Besmed Health Business Corp.
No. 2, Lane 106, Wu-Kong 3rd Road, Wu-Ku District,
New Taipei City 24889, Taiwan

Date: 2020-01-10

