

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

Pertifizierung 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.

Fuxiu Sheng



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate

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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

