EC Certificate

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

Registration No.: HD 60137550 0001

Report No.: 50150647 002

Manufacturer:
DELBIO, INC.
3, 7F., No. 252, SHANGYING RD.
GUISHAN DIST.
TAOYUAN CITY 333
Taiwan

Products: Pulse Oximeters

(see attachment for additional site included)

Expiry Date: 2023-12-19

The 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 applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-03-15

Date: 2019-03-15

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

S. Liu

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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60137550 0001
Report No.: 50150647 002

Manufacturer:
DELBIO, INC.
3, 7F., No. 252, SHANGYING RD.
GUISHAN DIST.
TAOYUAN CITY 333
Taiwan

Site included:

DELBIO (Wujiang) Co., Ltd.
3F, Advanced Technology Center,
No. 1688, Jiangxing East Road, Wujiang Eco & Tech Development Zone, Suzhou City, Jiangsu, P.R.C

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierstelle Grundsatz

Notified Body

Date: 2019-03-15