

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

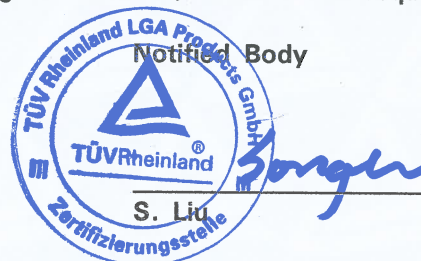
Products: Pulse Oximeters
(see attachment for additional site included)

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



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.: 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

Date: 2019-03-15

