TÜVRheinland®

EC Certificate

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

Registration No.: DD 60148985 0001

Report No.: 17062485 009

Manufacturer:
Biocare Enterprise Limited
Flat 1A, 9/F, Brill Plaza, No.84
Tokwawan Road
Kowloon
Hong Kong

Products: Low-intensity Laser Devices

Replaces Approval, Registration No.: DD 60138420 0001

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: 2020-09-17

Date: 2020-09-17

Notified Body

Dipl.-Ing. W. Hsu

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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.