EC Certificate

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

Registration No.: DD 60118286 0001

Report No.: 17062485 001

Manufacturer:
Biocare Enterprise Limited
FLAT 1301, 13/F
Chinachem Tsuen Wan Plaza
457 Castle Peak Road
Tsuen Wan, N.T.
Hong Kong

Products: Low-intensity Laser Devices

Expiry Date: 2022-03-08

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: 2017-06-08

Date: 2017-06-08

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle
Notified Body
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.