

EC Declaration of Conformity

Manufacturer:

Wuhan Gigaa Optronics Technology Co.,Ltd.
Add.: 5, 6/F, Unit A, B, Building B8, Hi-Tech
Medical Device Industrial Park, #818 Gaoxin
Avenue, East Lake Development Zone,
Wuhan 430206,China

whose single Authorized Representative:

Lotus NL B.V.
Add.: Koningin Julianaplein 10,le Verd,
2595AA,The Hague,Netherlands.
Tel: +31645171879(English),
+31626669008(Dutch)
Email: peter@lotusnl.com

We, the manufacturer, herewith declare that the products

Name: Medical diode laser systems

TYPE: TETHYS-10D10H

GMDN-Code/Preferred Terms: 60341

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIb according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

**TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany**

Certificate No.: HD 60126612 0001

Issue date: 2018.04.07

Expiry date: 2023.04.06

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Wuhan Gigaa Optronics Technology Co.,Ltd.
Address: 5, 6/F, Unit A, B, Building B8, Hi-Tech Medical Device Industrial Park, #818 Gaoxin
Avenue, East Lake Development Zone,
Wuhan 430206,China

Wuhan, China, 2019.02.27

Place, date

**EC Declaration of Conformity
GA/QRCE-04**

Legally binding signature, Function

