Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 095419 0005 Rev. 02

Manufacturer:

Quanta System S.P.A.
Via Acquedotto, 109
21017 Samarate (VA)
ITALY

Facility(ies):

Quanta System S.P.A.
Via Acquedotto, 109, 21017 Samarate (VA), ITALY

Product Category(ies):

Surgical and therapeutic laser devices, therapeutic intense pulsed light devices, combined therapeutic laser and intense pulsed light devices, handpieces for therapeutic laser and intense pulsed light devices, sterile optical fibers for surgical laser devices, Urological morcellator and related accessories

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: ITA9727932S

Valid from: 2019-10-07
Valid until: 2024-05-26

Date, 2019-10-07

Stefan Preiß
Head of Certification/Notified Body

Digitally signed by Apostol Eduard
Date: 2021.07.23 11:30:08 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany