



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 095419 0012 Rev. 02

Manufacturer: **Quanta System S.P.A.**

Via Acquedotto, 109
21017 Samarate (VA)
ITALY

SRN Manufacturer - IT-MF-000007393

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10 095419 0012 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:G10_095419_0012_Rev.02)

Report No.:	ITA1882522
Preceding Certificate No.:	G10 095419 0012 Rev. 01
Valid from:	2023-10-06
Valid until:	2026-12-13
Date of Initial Issuance:	2021-12-14

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-10-06



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlg.de
 BS-MDR-099



Product Service

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Classification: Class IIb
Device Group: Z120110 - LASER SURGERY INSTRUMENTS
Intended Purpose: Medical laser devices are used to therapeutically treat dermatological skin conditions or diseases through light-tissue interaction

Classification: Class IIb
Device Group: Z120110 - LASER SURGERY INSTRUMENTS
Intended Purpose: A surgical laser system that is used to treat soft tissue through light-tissue interaction

Classification: Class IIa
Device Group: Z12011080 - LASER SURGERY INSTRUMENTS - HARDWARE ACCESSORIES
Intended Purpose: /

Classification: Class IIb
Device Group: Z120110 - LASER SURGERY INSTRUMENTS
Intended Purpose: Surgical laser system that is used to treat soft tissue and stones through light-tissue interaction

The validity of this certificate depends on conditions and/or is limited to the following: None

Revision History:

Rev.	Dated	Report	Description
00	2021-12-14	ITA1457950	-
01	2022-12-21	ITA1976588	-
02	2023-10-06	ITA1882522	Supplemented: Device(s)/group of device(s) added