EC Declaration of Conformity

According to Annex II of 93/42 EEC Directive, excl. (4)

Device category:	Surgical laser device
Model name	Laserlith i-dust
Part number	
Registration number (if applicable)	
Customer part number (if applicable)	
UDI-DI (if applicable)	
Class - Rule:	II b – Rule 9
Serial number/Lot Number:	xxxxx
Year of manufacturing:	xxxxx
Country of destination	
Manufactured by:	Quanta System S.p.A. Via Acquedotto, 109 21017 Samarate (VA), Italy

Quanta System S.p.A. on the basis of EC Quality Assurance System Certificate No. G1 095419 0005 rev.02 issued by TÜV Sud Product Service GmbH Ridlerstrasse 65 – 80339 München - Germany declaring compliance with the applicable requirements of Annex II of 93/42 EEC Directive, excl. (4)
declares, under its sole responsibility, that the above-mentioned device conforms to the applicable requirements and regulations stated in this declaration.

The device above mentioned has been marked CE-0123

Moreover, Quanta System S.p.A. declares that the device is in compliance with Directive 2014/53/EU (transposed in Italy by D. Lgs. n. 128 of 22/06/2016).]

Samarate,
Italy, 27/11/2019

Francesco Dell'Antonio
V.P. Regulatory Affairs and QA

Digitally signed by Apostol Eduard
Date: 2021.07.23 11:29:58 EEST
Reason: MoldSign Signature
Location: Moldova