

EC Declaration of Conformity

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

Device category:	Sterile optical fibers for surgical laser devices
Model name	OAF series
Part number	OAF002001, OAF002011, OAF002091, OAF002701, OAF002711, OAF002791, OAF003601, OAF003611, OAF003691, OAF005501, OAF005511, OAF005591, OAF006001, OAF006011, OAF006091, OAF008001, OAF008011, OAF008091, OAF009901, OAF009911, OAF009991, OAF402001, OAF402011, OAF402091, OAF402701, OAF402711, OAF402791, OAF403601, OAF403611, OAF403691, OAF702701, OAF702711, OAF702791, OAF703601, OAF703611, OAF703691, OAF302711, OAF102711, OAF102791, OAF103611, OAF103691, OAF002003, OAF002013, OAF002093, OAF002703, OAF002713, OAF002793, OAF003603, OAF003613, OAF003693, OAF005503, OAF005513, OAF005593, OAF006003, OAF006013, OAF006093, OAF008003, OAF008013, OAF008093, OAF009903, OAF009913, OAF009993, OAF402003, OAF402013, OAF402093, OAF402703, OAF402713, OAF402793, OAF403603, OAF403613, OAF403693, OAF702703, OAF702713, OAF702793, OAF703603, OAF703613, OAF703693, OAF102713, OAF102793, OAF103613, OAF103693, OAF002005, OAF002015, OAF002095, OAF002705, OAF002715, OAF002795, OAF003605, OAF003615, OAF003695, OAF005505, OAF005515, OAF005595, OAF006005, OAF006015, OAF006095, OAF008005, OAF008015, OAF008095, OAF009905, OAF009915, OAF009995
Registration number (if applicable)	
Customer part number (if applicable)	
UDI-DI (if applicable)	
Class - Rule:	IIA- rule 7
Serial number/Lot Number:	xxxxxxxx
Year of manufacturing:	xxxxxxxx
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

Samarate,
Italy, 27/11/2019



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