



EU DECLARATION OF CONFORMITY (DoC)

Product Family: HQ-20 - SOLTIVE™ SuperPulsed Laser System
Product codes: Refer to Attachment 1
Product classification: Refer to Attachment 1
Manufacturer: Gyrus ACMI
9600 Louisiana Ave. North,
Brooklyn Park, MN 55445

Other facilities/subcontractors:
Gyrus ACMI, Inc. IPG Medical Linemaster Switch Corporation
9600 Louisiana Ave. North 377 Simarano Drive 29 Plaine Hill Road
Brooklyn Park, MN 55445 Marlborough, MA 01752 Woodstock, CT 06281
USA USA USA
(Fibers) (Generators, Footswitch, Fiber assembly) (Footswitch subassembly)

Authorized Rep: OLYMPUS EUROPA SE & CO. KG
Wendenstraße 14 - 18, 20097 Hamburg, Germany
Postfach 10 49 08, 20034 Hamburg, Germany

CE marking: CE0344, DEKRA Certification B.V. Arnhem, The Netherlands

EC Certification No: 76997CE18

Manufacturer's single registration number: N/A

The conformity with the directive is given by the following standards: Refer to Standards Listing SL-HQ-20

This declaration is based on: 93/42/EEC of 14 June 1993 Council Directive, concerning medical devices
The application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the EU-Medical Device Directive
The conformity assessment based on a quality management system and on assessment of technical documentation set out in Annex IX
RoHs directive 2011/65/EU applies

We hereby declare that the distributed CE marked products, specified in the Device Listing, is in conformity with the Directive EU 93/42/EEC and covered by the "CE Marking of Conformity Certificate" or are self-declared as indicated in the product list. The devices meet the provisions of the EU directives that apply to them based on the classification of the devices.

This declaration was issued under the sole responsibility of the manufacturer. This declaration is supported by the Quality Management System and certification based on the harmonized standard ISO 13485 Quality System Certificate issued by DEKRA Certification, B.V.

Date of issue: 5/7/2020 | 4:41 PM EDT
Signature: 
Name: Todd Vesty
Title: Sr. Manager, Regulatory Compliance

Item		Device Class	ROHS Applies	ROHS Compliant	ROHS Rationale	Actual Approval Date	Inactive Flag - Old	Inactive Date	Region
TFL-AFSW	TFL Laser Footswitch - Wired	IIB	Y	Y	GA SPEC	13-May-2020	N		European Union - Generic
TFL-AFSWL	TFL Laser Footswitch - Wireless	IIB	Y	Y	GA SPEC	13-May-2020	N		European Union - Generic
TFL-FBX150BS	150 Micron TFL Ball Tip Single Use Fiber, 5/Box	IIB	Y	Y	GA SPEC	13-May-2020	N		European Union - Generic
TFL-FBX150S	150 Micron TFL Single Use Fiber, 5/Box	IIB	Y	Y	GA SPEC	13-May-2020	N		European Union - Generic
TFL-FBX200BS	200 Micron TFL Ball Tip Single Use Fiber, 5/Box	IIB	Y	Y	GA SPEC	13-May-2020	N		European Union - Generic
TFL-FBX200S	200 Micron TFL Single Use Fiber, 5/Box	IIB	Y	Y	GA SPEC	13-May-2020	N		European Union - Generic
TFL-FBX365S	365 Micron TFL Single Use Fiber, 5/Box	IIB	Y	Y	GA SPEC	13-May-2020	N		European Union - Generic
TFL-FBX550S	550 Micron TFL Single Use Fiber, 5/Box	IIB	Y	Y	GA SPEC	13-May-2020	N		European Union - Generic
TFL-FBX940S	940 Micron TFL Single Use Fiber, 5/Box	IIB	Y	Y	GA SPEC	13-May-2020	N		European Union - Generic