OPTOTEK
medical

EC DECLARATION OF CONFORMITY

Declaration No.: **01-2017**

Manufacturer:	**OPTOTEK d.o.o.** Tehnološki park 21 1000 Ljubljana, Slovenia
Product Name:	Medical therapeutic laser device
Model/Type:	OptoYag M, Opto SLT M, OptoYag&SLT M
Classification:	IIb (Annex IX, Rule 9)
GMDN Code:	35940

OPTOTEK d.o.o. HEREBY STATES THAT THE ABOVE MENTIONED PRODUCTS COMPLY WITH THE ESSENTIAL REQUIREMENTS OF THE COUNCIL DIRECTIVE 93/42/EEC, FOR MEDICAL DEVICES.

OPTOTEK d.o.o. HEREBY STATES THAT THE ABOVE MENTIONED PRODUCTS ARE IN CONFORMITY WITH DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF JUNE 2011 ON THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT.

The product was a subject of conformity assessment procedure described in Annex II (Full Quality Assurance System), excluding Section 4.

Standards Applied:	EN 60601-1:2006 + A11:2011 EN 60601-1-2:2007 EN 60601-2-22:2013 EN 62304:2006 EN 60825-1:2007 EN 62366:2008 EN ISO 15004-1:2006; EN ISO 15004-2:2007 EN ISO 10939:2007 EN ISO 14971:2012 EN ISO 10993-1:2009
Notified Body:	SIQ, Slovenian Institute of Quality and Metrology Tržaška cesta 2 1000 Ljubljana, Slovenia Notified Body No. 1304
EC Certificate:	No: MDD-005 Issued: 04/2017-07-11 Valid until: 2020-09-03

Name: Iztok Dvoraček
Position: Optotek CEO&CFO

Signature:

OPTOTEK d.o.o. Ljubljana 2016

ISO 13485 M-003

Highest Creditworthiness Rating
OPTOTEK d.o.o.
Company ID: 5326389
Bisnode d.o.o., 21.12.2016

Place and Date: Ljubljana, 17.07.2017

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VAT ID No.: SI72584106
Registered by: Okrožno sodišče v Ljubljani, Registry entry: 1/04147/00
Co. Registration No.: 5326389000, Share capital: 71.278,01 EUR