



Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH
certifies that

Fotona d.d.
Stegne 7
SI-1210 Ljubljana

has established and applies
a Quality Management System for

**Design and Development,
Production and Sales of
Optoelectronic and Laser Devices**

An audit was performed, Report No. **70028569**
Proof has been furnished that the requirements
according to

ISO 9001:2008

are fulfilled. The certificate is valid until **2011-07-31**

Certificate Registration No. **12 100 19832 TMS**

Munich, 2010-08-12



QMS-TGA-ZM-07-92

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICADO ◆ CERTIFICAT



Product Service

CERTIFICATE

No. Q1N 08 07 25155 013

Holder of Certificate: **Fotona d.d.**
 Stegne 7
 1210 Ljubljana
 REPUBLIC OF SLOVENIA

Facility(ies): Fotona d.d.
 Stegne 7, 1210 Ljubljana, REPUBLIC OF SLOVENIA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Sales of Medical Surgical Lasers**

Applied Standard(s): EN ISO 13485:2003/AC:2007
 Medical Devices - Quality Management Systems - Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 71336277

Valid until: 2011-07-31



Date, 2008-08-01

Hans-Heiner Junker

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TÜV SÜD Product Service GmbH
 Zertifizierstelle
 Ridlerstr. 65 · 80339 München
 Germany



Akkreditiert durch
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 ZLG-ZQ-999.98.12-46



CERTIFICATE

The Certification Body of
TÜV SÜD AMERICA INC.
Management Service Division

hereby certifies that

Fotona d.d.
Stegne 7
1210 Ljubljana - Slovenia

has implemented a Quality Management System
in accordance with:

ISO 13485:2003

The scope of this Quality Management System includes:

**Design and Development, Manufacturing
and Distribution of Medical Surgical Lasers**

Certificate Expiry Date: July 31, 2011

Certificate Registration No: S 951 03 1983

Original Issue Date: September 15, 2003

Effective Date: August 19, 2008





Gary W. Minks
VP, Regulatory Affairs



Health
Canada
CMDCAS
Recognized
Registrar



Product Service

EC-CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 07 04 25155 012

Manufacturer: **Fotona d.d.**
Stegne 7
1210 Ljubljana
REPUBLIC OF SLOVENIA

Facility(ies): Fotona d.d.
Stegne 7, 1210 Ljubljana, REPUBLIC OF SLOVENIA

Product Category(ies): **Surgical Lasers**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

Report No.: 71318845

Valid until: 2012-05-30

Date, 2007-05-31


Reiner Krumme



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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