ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Digitally signed by Antonova Anna
Date: 2021.07.23 16:20:27 EEST
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Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 18 02 02848 003

Manufacturer:

A.R.C. Laser GmbH
Bessemerstr. 14
90411 Nürnberg
GERMANY

Facility(ies):

A.R.C. Laser GmbH
Bessemerstr. 14, 90411 Nürnberg, GERMANY

Product Category(ies):

Therapeutic and surgical lasers and associated sterile laser contact probes and sterile bare fibers

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 devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713127554

Valid from: 2018-07-01
Valid until: 2023-06-30

Date, 2018-04-24

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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