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

Product Service

EC-CERTIFICATE

Full Quality Assurance System

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

No. G1 09 12 33292 016

Manufacturer:

EKA Ges. für medizinisch-technische Geräte mbH
Isarstraße 2
82065 Baierbrunn
GERMANY

Facility(ies):

EKA Ges. für medizinisch-technische Geräte mbH
Isarstraße 2, 82065 Baierbrunn, GERMANY

Product Category(ies):

Light-Coagulators

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.

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H.-H.

Hans-Heiner Junker

TÜV 378915

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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