ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD 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 04 84462 012

Manufacturer:

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
GERMANY

Facility(ies):

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34, 78532 Tuttlingen, GERMANY

Product Category(ies):

- **medical and surgical instruments**
- **active surgical instruments**
- **implantable clamps for ligation of tubings and vessels**
- **bone implants (non active)**
- **rigid and flexible endoscopes for diagnostics and therapy**
- **active medical devices and surgical auxiliary devices**
- **cameras, devices and auxiliary devices for imaging procedure with non ionizing radiation**
  [for a detailled list of product groups class II a and higher we refer to the KARL STORZ internal document C2.3.1 (in the current updated version)]

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.: 713129927

Valid from: 2018-07-17
Valid until: 2023-07-16

Date, 2018-07-03

Stefan Preiß

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