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

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 13 11 34111 010

Manufacturer:

C. Bruno Bayha GmbH
Dr. Karl-Storz-Str. 14
78532 Tuttlingen
GERMANY

Facility(ies):

Ernst H. Bayha GmbH
Dr.-Karl-Storz-Straße 14, 78532 Tuttlingen, GERMANY

C. Bruno Bayha GmbH
Dr. Karl-Storz-Str. 14, 78532 Tuttlingen, GERMANY

Product Category(ies):

Sterile Surgical Blades - single use

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.: 713031906

Valid from: 2014-01-09
Valid until: 2019-01-08

Date, 2013-12-18

Hans-Heiner Junker

604502

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

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