



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 034111 0014 Rev. 00

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 manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: 713141094

Valid from: 2019-01-09
Valid until: 2024-01-08

Date, 2018-12-27

Stefan Preiß

Page 1 of 1
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