ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ 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 15 02 52905 105

Manufacturer:

Mathys AG Bettlach
Mathys Ltd Bettlach
Mathys SA Bettlach
Robert Mathys Strasse 5
2544 Bettlach
SWITZERLAND

Facility(ies):

Mathys AG Bettlach Mathys Ltd Bettlach Mathys SA Bettlach
Robert Mathys Strasse 5, 2544 Bettlach, SWITZERLAND

Mathys Orthopädie GmbH
An den Trillers Büschen 2, 07646 Mörsdorf, GERMANY

Mathys Orthopädie GmbH
Michael-Faraday-Straße 5, 07629 Hermsdorf, GERMANY

Product Category(ies):

Non active instruments and implants for orthopaedics, sports medicine and bone replacement according to the attachment

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.: 713055010

Valid from: 2015-03-02
Valid until: 2020-02-21

Date, 2015-03-03

Hans-Heiner Junker

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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Product Service

Attachment to Certificate no G1 15 02 52905 105
dated 2015-03-02

Implants for orthopaedics (Class IIb, III):

Implants for the hip
Implants for the knee
Upper limb implants
Implants for the sport medicine

Bone replacement Products (Class III)

Instruments (Class IIa):

General instruments
Instruments for the hip
Instruments for the knee
Upper limb instruments
Instruments for the sport medicine
Instruments for bone replacement products

Munich, CRT2, 2015-03-03

Hans-Heiner Junker

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