EC Certificate Full Quality Assurance System: US00/51254

The management system of

Zimmer Trabecular Metal Technology, Inc.
doing business as Zimmer and Implex

10 Pomeroy Rd, Parsippany, NJ, 07054, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 13 September 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 07 December 2021
Issue 24. Certified since 17 January 2000

Certification is based on reports numbered WW/MC 200616

Authorised by

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Zimmer Trabecular Metal Technology, Inc.
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Directive 93/42/EEC
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Issue 24

Detailed scope

Sterile Trabecular Metal Acetabular Revision Shells, Sterile Primary and Revision Trabecular Metal Patella comprising Standard Patella and Augmentation Patella. Sterile NexGen Trabecular Metal Monoblock Tibial Components comprising Cruciate-Retaining (CR) and Legacy® Posterior Stabilised (LPS) Monoblock Tibia, Knee System Trials, Specialty Spine System Trials, Hip Trials, Spine System Trials, Orthopaedic Powered Instruments, Sterile Knee System Implants – Trabecular Metal Tibial and Femoral Cones and Augments, Sterile Hip System Implants: non-articulating bone filling portions of the hip implants, Sterile Trabecular Metal Spinal Devices, and Sterile PEEK Spinal System Implants.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market