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

Jonathan M. Wall

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

Page 1 of 2





This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/ferms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at http://www.sgs.com/en/certified-dients-dar-products/certified-dients-directory. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest.

SGS

EC Certificate Full Quality Assurance System: Certificate US00/51254, continued

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

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

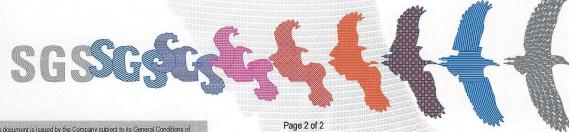
Issue 24

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





This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/ferms_and_conditions.htm.
Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at http://www.sgs.com/en/certified-clients-and-products/certified-client-directory.

Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest