

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

TEKNIMED SAS
8 rue du Corps Franc-Pommiès
Vic En Bigorre
65500
France

Facility ID Number: F003472

Holds Certificate No:

MDSAP 709498

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, development, manufacture and distribution of implantable medical devices and ancillary tools for orthopaedic, spinal and dental surgery. Manufacture and distribution of material for medical use, based on calcium phosphates, polylactide.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-01-31

Effective Date: 2023-01-31

Expiry Date: 2026-01-30



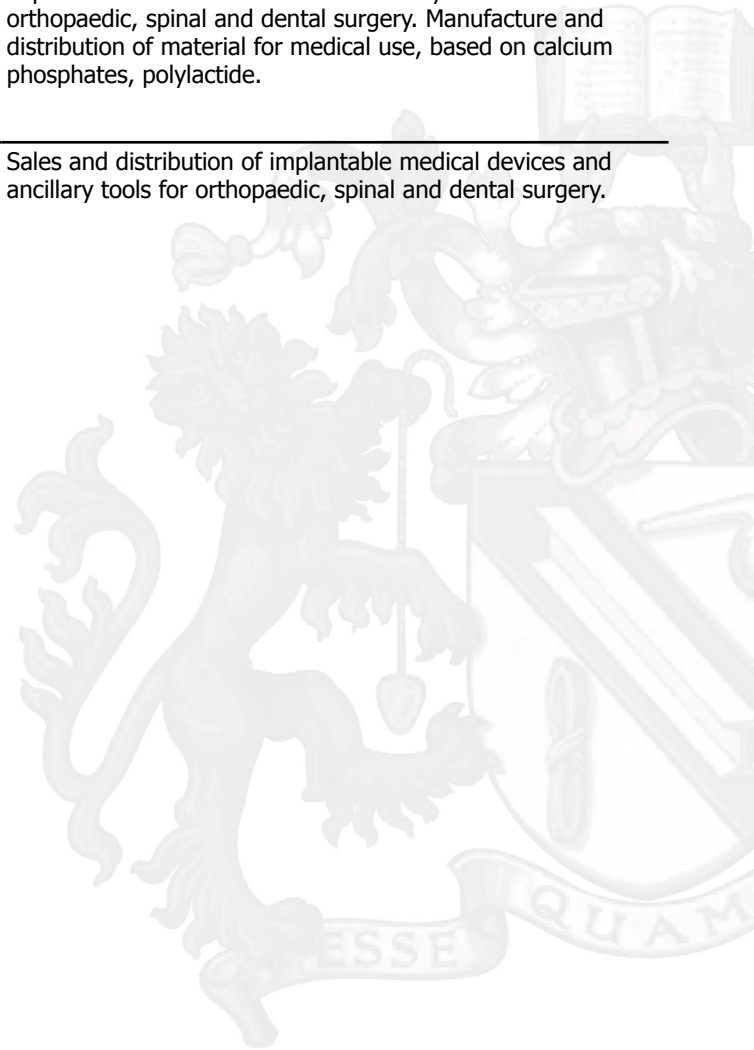
BSI Group America Inc. is an MDSAP recognised auditing organization

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Location	Registered Activities
TEKNIMED SAS 8 rue du Corps Franc-Pommiès Vic En Bigorre 65500 France Facility ID Number: F003472	Legal Manufacturer outsourcing all activities to the other sites on the certificate.
TEKNIMED SAS 11-12 rue d'Apollo L'Union 31240 France Facility ID Number: F003294	Design, development, manufacture and distribution of implantable medical devices and ancillary tools for orthopaedic, spinal and dental surgery. Manufacture and distribution of material for medical use, based on calcium phosphates, polylactide.
TEKNIMED SAS ZI de la Herry Vic en Bigorre 65500 France Facility ID Number: F003472	Sales and distribution of implantable medical devices and ancillary tools for orthopaedic, spinal and dental surgery.



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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

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