By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

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

Holds Certificate Number: **MD 646662**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, manufacturing, sales and distribution of implantable medical devices and ancillary tools for orthopaedic, spinal and dental surgery.
Manufacturing and sales of material for medical use, based on calcium phosphates, polylactide.
Conception, développement, fabrication vente et distribution de dispositifs médicaux implantables et instrumentations pour la chirurgie orthopédique, rachidienne et dentaire.
Fabrication et vente de matière à usage médical, à base de phosphates de calcium, de polylactide.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-09-27
Latest Revision Date: 2020-04-21

Effective Date: 2020-04-21
Expiry Date: 2023-01-30

UKAS MANAGEMENT SYSTEMS 003

Digitally signed by Iarovoi Petru
Date: 2022.03.18 10:03:20 EET
Reason: MoldSign Signature
Location: Moldova

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Certificate No: **MD 646662**

Location	Registered Activities
TEKNIMED SAS 8 rue du Corps Franc-Pommiès Vic En Bigorre 65500 France	Headquarters Siège social
TEKNIMED SAS 11-12 rue d'Apollo L'Union 31240 France	Design, development, manufacturing and sales of implantable medical devices and ancillary tools for orthopaedic, spinal and dental surgery. Manufacturing and sales of material for medical use, based on calcium phosphates, polylactide. Conception, développement, fabrication et vente de dispositifs médicaux implantables et instrumentations pour la chirurgie orthopédique, rachidienne et dentaire. Fabrication et vente de matière à usage médical, à base de phosphates de calcium, de polylactide.
TEKNIMED SAS ZI de la Herray Vic en Bigorre 65500 France	Distribution of implantable medical devices and ancillary tools for orthopaedic, spinal and dental surgery. Distribution de dispositifs médicaux implantables et instrumentations pour la chirurgie orthopédique, rachidienne et dentaire.

Original Registration Date: 2016-09-27
Latest Revision Date: 2020-04-21

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Expiry Date: 2023-01-30

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 646667**

Issued To: **TEKNIMED SAS**
8 rue du Corps Franc-Pommiès
Vic En Bigorre
65500
France

In respect of:

Design, development and manufacture of sterile surgical cements, sterile surgical cement with antibiotic and radiopaque bone cements, associated sterile mixing and injection systems and non-sterile injection syringe; sterile suture material for tendons and ligaments; sterile osseous drilling pins; sterile bio-absorbable screws and pins; sterile porcine gelatin-based bio-absorbable cement restrictors; sterile bio-absorbable suture anchors; sterile synthetic bone substitutes.
Those aspects of Annex II related to securing and maintaining sterility in the manufacture of the mixing and injection systems for bone cement.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-03-24** Date: **2021-04-06** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 646667

Issued To:

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

Number	Device Name	Intended purpose per IFU
Class III		
MD 0202 MDS 7001 MDS 7006 MDS 7009	GENTAFIX	See CE 646675; CE 681359; CE 646689; CE 646693; CE 646695; CE 646685; CE 681365; CE 681361; CE 681364; CE 681360; CE 681362; CE 646694; CE 681363; CE 681459; CE 700586; CE 700581; CE 700580; CE 700585; CE 700582; CE 740899; CE 740900; CE 740901; CE 740904; CE 740905; CE 740907
MD 0202 MDS 7002 MDS 7006 MDS 7009	CEMSTOP	See CE 646677; CE 673587; CE 673588; CE 673589; CE 673592; CE 673593; CE 740908, CE 740909, CE 740910, CE 740911, CE 740912
MD 0202 MDS 7006 MDS 7009	CERAFORM	See CE 646680; CE 678760
MD 0202 MDS 7006 MDS 7008 MDS 7009	NANOGEL	See CE 646681; CE 675260; CE 675261; CE 675262; CE 675263; CE 740914, CE 740916, CE 740918, CE 740920, CE 740921
MD 0202 MDS 7006 MDS 7009	TRIHA+	See CE 646683; CE 685550; CE 685555; CE 685559; CE 685561

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Number	Device Name	Intended purpose per IFU
Class III		
MD 0202 MDS 7006 MDS 7009	EUROSCREW / EUROSCREW TCP	See CE 646686; CE 678761
MD 0202 MDS 7006 MDS 7009	EUROSCREW NG / EUROSCREW TCP NG	See CE 646687; CE 678764; CE 678765; CE 700578; CE 740922, CE 740923, CE 740924, CE 740925
MD 0202 MDS 7006 MDS 7009	A'LINK'S	See CE 646691; CE 678758; CE 678759; CE 700577; CE 740926, CE 740927, CE 740928, CE 740929
MD 0202 MDS 7006 MDS 7009	BIORESORBABLE PIN	See CE 646688
MD 0202 MDS 7006 MDS 7009	TLS Bio-C	See CE 646690
MD 0202 MDS 7006 MDS 7009	ISOFIX+	See CE 663900

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Number	Device Name	Intended purpose per IFU
Class IIb		
35217	Surgical cement	Fixation of prostheses to living bone in orthopaedic musculoskeletal surgical procedures.
60505	Radiopaque bone cement	Fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.
13907	Suture – Tendons and ligaments reintegration	Repairing or reinforcing ligaments, closure and/or ligation of soft tissues, and tuberosity reinsertions.
Class IIa		
MD 0106	Surgical drill pin, Single-use and connected to active device	Stainless steel drilling pin to support drilling of Bioresorbable pins procedures.
MD 0106	Single-use Vacuum instrument system for bone cement	Vacuum system instrument for mixing and injection of low & medium viscosity arthroplasty bone cement.
Class Is		
MD 0106	Non-invasive sterile instruments for bone cement	Sterile instruments for mixing and injection of low & medium viscosity arthroplasty bone cements
MD 0106	Non-invasive sterile instruments for bone cement	Sterile instruments for injection of high viscosity arthroplasty bone cements

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