Teknimed S.A.S.
Biomaterials innovation

EC Certification / Certification CE

We, TEKNIMED S.A.S located ZI de Montredon – rue d'Apollo – 31240 L'Union – France, hereby declare that:

Nous, TEKNIMED SAS, domicilié ZI de Montredon – rue d'Apollo – 31240 L'Union – France, déclarons par la présente que :

All products manufactured and marketed by Teknimed are EC certified by the notified body BSI as evidenced by the certificate number CE 646667 valid from July 06th presented in the Appendix below.

L'ensemble des produits fabriqués et commercialisés par Teknimed sont couverts par le marquage CE délivré par l'organisme notifié BSI comme en atteste le certificat numéro CE 646667 émis le 06 juillet 2017 présentés en annexe ci-après.

RÉPUBLIQUE FRANÇAISE
LÉGALISATION
(DECRET N° 2007 - 1205 DU 10 AOUT 2007)
DESTINATION DE L'ACTE (PAYS OU AUTORITE)
VIETNAM
DATE : 26 NOV. 2018
NOM ET QUALITE DE L'AGENT : S. DAVID
BUREAU DES LEGALISATIONS
SIGNATURE
ET CACHET OBLIGATOIRE :

L'Union (France), November, 09th 2018.

Vu pour certification matérielle de la signature de M. S. SALLES
171

Stéphanie SALLES
Regulatory Affairs manager
Responsable affaires réglementaires

F. FERRAND
13 NOV. 2018

ĐẠI SỨ QUÁN CHXHCNVN TẠI CH PHÁP
AMBASSADE DE LA R.S DU VIETNAM EN REPUBLIQUE FRANCAISE

CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ
Certificat/Légalisation consulaire

1. Quốc gia **VIỆT NAM**
   Pays

Giấy tờ tài liệu này
Ce (ces) document (s)

2. Do Ông (bà) **Sylvain DAVID**
   ký
   a été signé par
3. Với chức danh **CÁN BỘ NGOẠI GIAO**
   en tant que
4. Và con dấu của **BỘ NGOẠI GIAO PHÁP**
   avec le tampon de
   Được chứng nhận/hợp pháp hóa lãnh sự
   a été (ont été) cerrtifié (s)/légalisé (s)
5. Tại. **PARIS** 6. Ngày **07/12/2018**
   à le
7. Cơ quan cấp **ĐSQ VIỆT NAM TẠI PHÁP**
   par
8. Số **518/2018/DAV**
   N°

T/L ĐẠI SỨ/*P. O. DE L'AMBASSADEUR*
BÍ THƯ THỨ HAI/ LE DEUXIÈME SECRÉTAIRE

Ngô Quốc Cường

bsi.

By Royal Charter

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):

Albert Roossien, Regulatory Lead

First Issued: **2017-03-24** Date: **2018-12-07** Expiry Date: **2022-05-01**

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