

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**

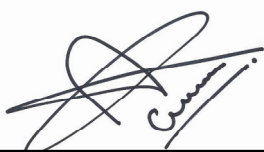
In respect of:

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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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.