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

Digitally signed by Iarovoi Petru
Date: 2021.06.28 14:27:02 EEST
Reason: MoldSign Signature
Location: Moldova

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