

# EC Certificate - Full Quality Assurance System

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

**No.** CE 694363  
**Issued To:** **Neosteo**  
**Malleve 2 A**  
**1 Boulevard Jean-Moulin**  
**Nantes**  
**44100**  
**France**

In respect of:

**Design and Manufacture of Implants and Accessories, including devices connected to an active device, for orthopaedic trauma and correction.**

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: **2020-12-14**

Date: **2020-12-14**

Expiry Date: **2024-05-26**

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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.

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## Supplementary Information to CE 694363

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Number	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
61669	Staples	Fixation of Akin type osteotomy in foot surgery
61669	Superelastic Staples	Fixation of Akin type osteotomy in foot surgery - Metatarsophalangeal joint fusion - Fixation of midfoot arthrodesis
46646 61688	Screws	Fixation of bone fractures Bone Reconstruction in the hand and forefoot Tibial and femoral osteotomies Treatment of bone deformities Fractures Malalignment
61688	Osteotomy Plates	Implants are intended for tibial and Femoral osteotomies. Treatment of bone and joint deformities Fractures Malalignment caused by injury or disease such as osteoarthritis
<b>Class IIa</b>		
MD 0106	Single use Instruments and instruments connected to an active device	NEOSTEO ancillaries are instruments which can only be used for orthopedic or trauma surgery, during the insertion of NEOSTEO osteosynthesis implants.

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