bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 632519**

Issued To: **SURGIVAL co. S.A.U.**
Leonardo Da Vinci 12-14
Paterna
Valencia
46980
Spain

In respect of:

The design and manufacture of screws, washers, nuts, bolts, staples, plates, nails, wires and pins for osteosynthesis, intramedullary nails for hip femoral head fractures, dynamic hip/condylar compression screw-plate systems, hip hemi-arthroplasty prosthesis and accessories for total knee replacement prosthesis

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 0086):

Digitally signed by Cobzari-Turcan Rodica
Date: 2024.02.05 11:32:57 EET
Reason: MoldSign Signature
Location: Moldova

Frank Lee, EMEA Compliance & Risk Director

First Issued: **28 April 2015** Date: **24 February 2017** Expiry Date: **24 February 2022**

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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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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