By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 512804**

Issued To: **Smith & Nephew, Inc.**
1450 Brooks Rd.
Memphis
Tennessee
38116
USA

Digitally signed by Belous Ilona
Date: 2022.10.28 14:18:53 EEST
Reason: MoldSign Signature
Location: Moldova

In respect of:

Design, development and manufacture of orthopaedic joint replacement implants, orthopaedic trauma implants, associated trial prostheses, single use instrumentation, non-medicated bone cement and accessories, irrigation devices, reusable instruments for connection to active devices, and image-guided surgical systems.

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):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2007-02-20** Date: **2018-08-16** Expiry Date: **2023-08-23**

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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
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

bsi.

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 512806**

Issued To: **Smith & Nephew, Inc.**
Orthopaedic Division
1450 E Brooks Rd.
Memphis
Tennessee 38116
USA

In respect of:

Those aspects relating to metrology in the manufacture of measurement gauges, goniometers and callipers. Those aspects relating to securing and maintaining sterility in the manufacture of drill guides, saw blades, guide rods, inserters, extractors, medullary tubes, bone graft delivery systems, cement preparation pressurization and delivery instruments. Those aspects relating to the manufacturing of active ultrasonic fracture healing systems

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2007-02-20** Date: **2018-08-16** Expiry Date: **2023-08-23**

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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.
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