By Royal Charter

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 728701 R000

Manufacturer: Smith & Nephew, Inc.

Address:
Endoscopy
150 Minuteman Road
Andover
Massachusetts
01810-1031
USA

Single Registration Number: US-MF-000019138

EU Authorised Representative: Smith & Nephew Operations B.V.

Address:
Bloemlaan 2
2132 NP Hoofddorp
Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

[redacted]

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-05-26**

Current Issue Date: **2023-09-05**

Starting Validity Date: **2023-09-05**

Expiry Date: **2026-05-25**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Reusable instruments 'Orthopaedic Instruments'	Class Ir
'Orthopaedic Instruments' with a measuring function	Class Im
Sterile Instruments	Class Is
Fluid Management, Motor Drive and Electronic Control Units	Class IIa
Fluid Management System Tube Sets	Class IIa
Arthroscopes and Laparoscopes	Class IIa
Orthopaedic and Arthroscopic Surgical Instruments	Class IIa

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing, and maintaining sterile conditions.
For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.
For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
2021-05-26	3204843	Issued.
2023-01-16	3746663	Amended – Approval of significant subcontractors Amended – Addition of Single Registration Number Supplemented – Addition of device group Dyonics Fluid Management Control System Unit Supplemented – Addition of device group Dyonics Fluid Management Tube Sets Supplemented - Addition of device group Sterile Instruments
Current	30001240	Amended – Approval of significant subcontractors for manufacturing Amended – Approval of significant subcontractor for E-Beam sterilization Supplemented – Addition of Class IIa device group Arthroscopes and Laparoscopes Amended – Removal of 'Dyonics 25 Fluid Management System Control Unit' device description Supplemented – Addition of Class IIa device group Fluid Management, Motor Drive and Electronic Control Units Supplemented – Addition of Class IIa device group Orthopaedic and Arthroscopic Surgical Instruments Amended – Replace device description 'Dyonics 25 Fluid Management System Tube Sets' with 'Fluid Management System Tube Sets'

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