

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No.

UKCA 777089

Issued To:

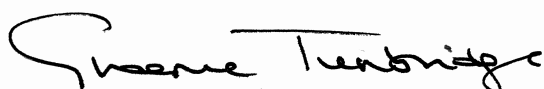
**B.Braun Medical Ltd
Also trading as Aesculap and
Downs Surgical
Thorncliffe Park
Sheffield
S35 2PW
United Kingdom**

In respect of:

The design, manufacture and final inspection of sterile orthopaedic and trauma implants, sterile single use surgical instruments and non-sterile Simpson pessary.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issued: **2024-03-25**

Date: **2026-07-14**

Expiry Date: **2031-07-24**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.
This certificate was issued electronically and is bound by the conditions of the contract.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000
Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
A member of BSI Group of Companies.

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Supplementary Information to UKCA 777089

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Device code	Device name	Intended purpose per IFU
Class IIb		
61786	Thompson Endoprotheses	Hip replacement to replace function of the head of the femur, (hemi-arthroplasty). For use when the neck of the femur has fractured due to trauma in elderly patients.
34149	Simpson Shelf Pessary (Pelvic-Organ-Supporting Pessary)	Used to relieve symptomatic prolapse of the uterus in patients where ring pessary has fallen out.
Class IIa		
34848	Burrs "Sterile single instruments connected to an active device"	---

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Certificate History

Certificate No: **UKCA 777089**
Date: **2026-07-14**
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Date	Reference Number	Action
2024-03-25	3746569	First Issue; Traceable to CE 01356
2026-07-07	30274916	Removal of • MD 0202 Austin Moore Endoprosthesis • MD 0202 Orthopaedic Bone Nail (Telescopic Rod) • MD 0202 Non-biodegradable Orthopaedic Bone Screw • MD 0402 Buttons for eyelet wiring
Current	30517659	Certificate Renewal. Addition and removal of critical subcontractors for final packaging and final cleaning. Administrative change to certificate (update the device's codes and nomenclature to align with the IFU)

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