

# 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]

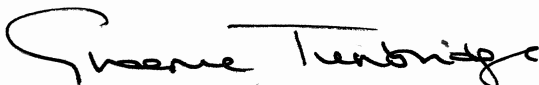
**No.** UKCA 777089  
**Issued To:** **B.Braun Medical Ltd**  
**Also trading as Aesculap and Downs Surgical**  
**Thornccliffe Park**  
**Sheffield**  
**S35 2PW**  
**United Kingdom**

In respect of:

**The design, manufacture and final inspection of sterile and non-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 Medical Devices

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

Date: **2024-03-25**

Expiry Date: **2026-07-24**

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## Supplementary Information to UKCA 777089

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Device code	Device name	Intended purpose per IFU
<b>Class IIb</b>		
MD 0202	Austin Moore Endoprosthesis	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
MD 0202	Thompson Endoprosthesis	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
MD 0202	Orthopaedic Bone Nail	For the surgical treatment of osteogenesis imperfecta of the long tubular bones
MD 0202	Non-biodegradable Orthopaedic Bone Screw	Arthrodesis of the Sacroiliac joint and trans sacral fusion, for pain proven to derive from that joint
MD 0204	Pelvic-Organ-Supporting Pessary	Used to relieve symptomatic prolapse of the uterus in patients where ring pessary has fallen out.
<b>Class IIa</b>		
MD 0106	Sterile single use instruments connected to an active device	---
MD 0402	Buttons for eyelet wiring	---

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## Certificate History

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Date	Reference Number	Action
Current	3746569	First Issue; Traceable to CE 01356

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