

Our Ref.: SMO 3654019

29 July 2022

To whom it may concern,

BSI has initiated a renewal for ISO 13485 certificate, MD 77268, to B. Braun Medical Ltd, also trading as Aesculap, Downs Surgical and Sterilog, Thornccliffe Park, Sheffield, S35 2PW, United Kingdom.

The certification is under review and has not yet been completed by BSI. All necessary audits have been conducted, and there are no issues identified that would compromise the renewal of the above certificate.

The scope of the ISO 13485 certificate remains unchanged:

“The design development and manufacture of surgical instruments, orthopaedic implants, sterile single use surgical instruments and associated sterile products. The repair of surgical instruments. The servicing and repair of infusion pumps, power tools and dialysis machines. Sales warehousing and distribution of surgical instruments, orthopaedic implants and associated sterile products, pharmaceutical products and outpatient treatment products. Cleaning and decontamination of surgical instruments, including the processing, packaging and sterilisation of individual instruments, theatre and procedure packs”

CE certification is also supported by BSI performing regular audits of the quality management system of the listed site, in accordance with Annex II excluding section 4 (certificate CE 01356). This certificate is current and expires 26 May 2024 with scope:

“The design and manufacture of sterile and non-sterile orthopaedic and trauma implants, sterile single use surgical instruments and non-sterile Simpson pessary”

Additionally, B Braun Medical Ltd also hold an Annex V certificate (CE 78051). This certificate is current and expires 26 May 2024 with scope:

“For those aspects of Annex V related to the accuracy of metrology in the manufacture of surgical implant templates”

Please contact the undersigned if there are any further questions regarding the contents of this letter.

Yours sincerely,



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