



UKCA Certificate - Production Quality Assurance

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

No.

Issued To:

UKCA 776646

Aspen Surgical Products Inc. 6945 Southbelt Drive, SE Caledonia Michigan 49316 USA

In respect of:

Manufacture and final inspection of sterile and non-sterile surgical blades and surgical scalpels.

Those aspects of Annex V relating to securing and maintaining sterility of surgical marking pens, cautery tip cleaners, wound closures, surgical light handle and camera covers, general purpose probe and instrument covers, system drapes, endocavity probe covers, general purpose needle guides, endocavity needle guides, patient positioning, umbilical cord clamps and urine specimen collection bags.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex V [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 IIb and class III products an Annex III certificate (modified as described above) 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: 2023-02-24

Date: 2024-03-19

Expiry Date: 2028-08-16

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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 389 Chiswick High Road, London, W4 4AL, UK. A member of BSI Group of Companies.





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Supplementary Information to UKCA 776646

Issued To:

Aspen Surgical Products Inc. 6945 Southbelt Drive, SE Caledonia Michigan 49316 USA

Device code	Device name	Intended purpose per IFU
Class IIa		Now an Esta
MD 0106	Sterile surgical scalpels	
MD 0106	Non-sterile surgical scalpels	
MD 0106	Sterile surgical blades	
MD 0106	Non-sterile surgical blades	
Class Is	2.	
MD 0106	Surgical marking pens	
MD 0108	Cautery Tip Cleaners	
MD 0301	Wound Closures	
MD 0106	Surgical Light Handle and Camera Covers	
MD 0106	General Purpose Probe and Instrument Covers	
MD 0106	System drapes	
MD 0106	Endocavity Probe Covers	ESSE
MD 0106	General Purpose Needle Guides	

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Device code	Device name	Intended purpose per IFU
MD 0106	Endocavity Needle Guides	A A A A A A A A A A A A A A A A A A A
MD 0106	Patient Positioning	
MD 0106	Umbilical Cord Clamps	
MD 0106	Urine Specimen Collection bags	

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UKCA Certificate - Production Quality Assurance Certificate History

Certificate No: Date:

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UKCA 776646 2024-03-19 Aspen Surgical Products Inc. 6945 Southbelt Drive, SE Caledonia Michigan 49316 USA

Date	Reference Number	Action
2023-02-24	3736149	First Issue; Traceable to CE 571159, CE 612364 and MDR 755274 R000.
2023-10-18	30005163	Certificate Renewal
2024-02-06	30103846	Addition of sterilization subcontractor site
Current	30090835	Restricted – Removal of Scalpel Handles and Handle Covers no longer placed on the market.

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