

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. **UKCA 776646**
Issued To: **Aspen Surgical Products Inc.**
6945 Southbelt Drive, SE
Caledonia
Michigan
49316
USA

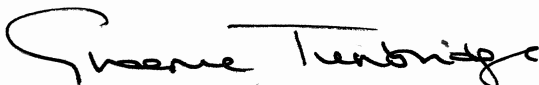
In respect of:

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, scalpel handles, scalpel handle covers, cautery tip cleaners, wound closures, surgical light handle and camera covers, general purpose probe and instrument covers, system drapes, endocavity probe covers, general purpose, 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: **2023-10-18**

Expiry Date: **2028-08-16**

...making excellence a habit.™

Page 1 of 3

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.

UKCA Certificate - Production Quality Assurance

Supplementary Information to UKCA 776646

Issued To:

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

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Sterile surgical scalpels	---
MD 0106	Non-sterile surgical scalpels	---
MD 0106	Sterile surgical blades	---
MD 0106	Non-sterile surgical blades	---
Class Is		
MD 0106	Surgical marking pens	---
MD 0106	Scalpel handles and scalpel handle covers	---
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	---
MD 0106	General Purpose Needle Guides	---
MD 0106	Endocavity Needle Guides	---

First Issued: **2023-02-24**

Date: **2023-10-18**

Expiry Date: **2028-08-16**

...making excellence a habit.™

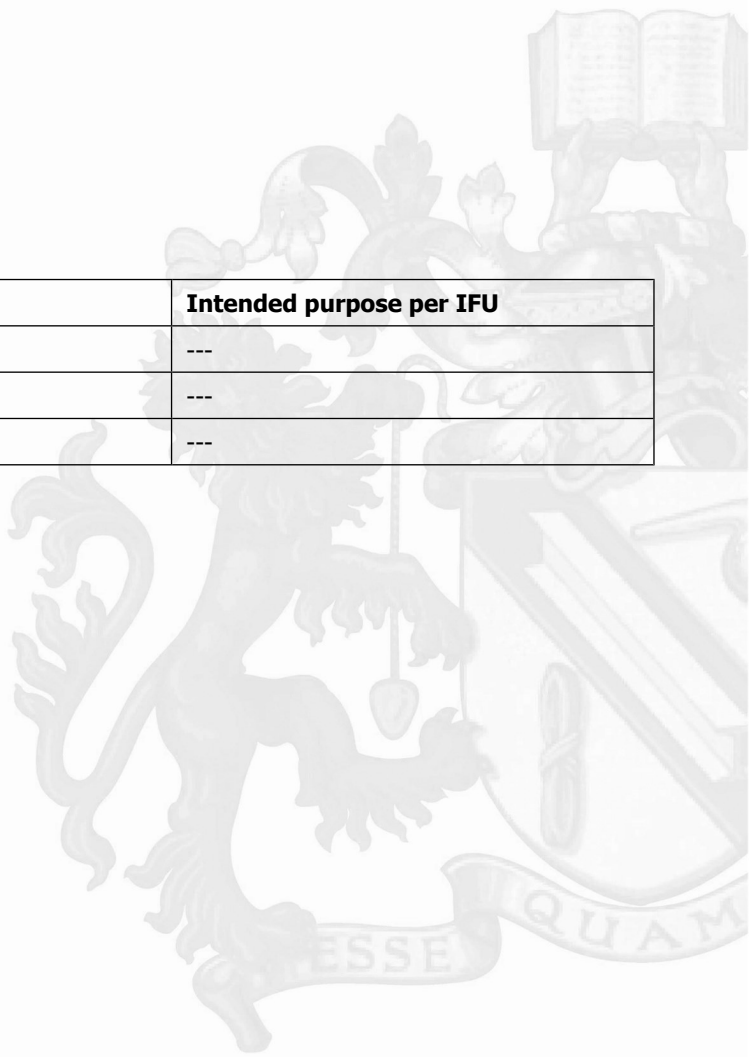
UKCA Certificate - Production Quality Assurance

Supplementary Information to UKCA 776646

Issued To:

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

Number	Device Name	Intended purpose per IFU
MD 0106	Patient Positioning	---
MD 0106	Umbilical Cord Clamps	---
MD 0106	Urine Specimen Collection bags	---



First Issued: **2023-02-24**

Date: **2023-10-18**

Expiry Date: **2028-08-16**

...making excellence a habit.™

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.

UKCA Certificate - Production Quality Assurance

Certificate History

Certificate No: **UKCA 776646**
 Date: **2023-10-18**
 Issued To: **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.
Current	30005163	Certificate Renewal

...making excellence a habit.™