By Royal Charter

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 776645**

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

In respect of:

Design, manufacture and final inspection of sterile surgical needles, endoscopic fog inhibitors and surgical probe covers, sterile and non-sterile suture boots, vessel loops and suture retrievers.

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: **2023-03-22** Date: **2023-10-18** Expiry Date: **2028-08-16**

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Supplementary Information to UKCA 776645

Issued To:

Aspen Surgical Products Inc.
6945 Southbelt Drive, SE
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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Sterile surgical needles	---
MD 0106	Sterile endoscopic fog inhibitors	---
MD 0106	Sterile suture boots	---
MD 0106	Non-sterile suture boots	---
MD 0106	Sterile vessel loops	---
MD 0106	Non-sterile vessel loops	---
MD 0106	Sterile surgical probe covers	---
MD 0106	Suture Retriever	---

First Issued: **2023-03-22** Date: **2023-10-18** Expiry Date: **2028-08-16**

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UKCA Certificate - Full Quality Assurance System Certificate History

Certificate No: **UKCA 776645**
Date: **2023-10-18**
Issued To: **Aspen Surgical Products Inc.**
6945 Southbelt Drive, SE
Caledonia
Michigan
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Date	Reference Number	Action
2023-03-22	3736149	First Issue; Traceable to CE 612363 and MDR 755273 R000.
Current	30004799	Certificate Renewal

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