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, suture retrievers, amniotic membrane perforators, circumcision devices, and those aspects of manufacturing relating to obtaining sterility in the assembly of procedure packs in accordance with Regulation 14 of the UK MDR 2002.

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: **2024-03-25** Expiry Date: **2028-08-16**

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Supplementary Information to UKCA 776645

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Device code	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	---
MD 0106	Amniotic membrane perforator	---
MD 0106	Circumcision devices	---

First Issued: **2023-03-22** Date: **2024-03-25** Expiry Date: **2028-08-16**

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UKCA Certificate - Full Quality Assurance System Certificate History

Certificate No: **UKCA 776645**
Date: **2024-03-25**
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Date	Reference Number	Action
2023-03-22	3736149	First Issue; Traceable to CE 612363 and MDR 755273 R000.
2023-10-18	30004799	Certificate Renewal
2023-11-28	30050669	Addition of procedure packs to scope
2024-02-06	30103844	Addition of sterilization subcontractor site
Current	30116644	Addition of the following device groups: Amniotic membrane perforator Circumcision devices

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