By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 755273 R000

Manufacturer: Aspen Surgical Products Inc.

Address:
6945 Southbelt Drive, SE
Caledonia
Michigan
49316
USA

Single Registration Number: US-MF-000008255

EU Authorised Representative: Emergo Europe

Address:
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2022-06-28**

Current Issue Date: **2024-09-06**

Starting Validity Date: **2024-09-06**

Expiry Date: **2027-06-27**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Surgical probe covers	Class IIa
Surgical needles	Class IIa
Sterile Suture Boots	Class IIa
Non-Sterile Suture Boots	Class IIa
Sterile Suture retrievers	Class IIa
Non-Sterile Suture retrievers	Class IIa
Amniotic membrane perforator	Class IIa
Circumcision devices	Class IIa
Sterile Endoscopic Fog Inhibitor	Class IIa
Sterile Vessel Loops	Class IIa
Non-sterile Vessel Loops	Class IIa
Skin Marker	Class Is
Eye Bubble	Class Is
Tubes, Adapters and Hoses	Class Is
Sharp Instruments, Reusable	Class Ir
Suture Supporting Instruments, Reusable	Class Ir
General Surgical Instruments, Reusable	Class Ir
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions. For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-06-28	3497508	Issued.
2024-01-16	30035623	Supplemented – Addition of the following device group: Sterile Suture Boots Non-Sterile Suture Boots Sterile Suture Retrievers Non-Sterile Suture Retrievers Amended – Change of subcontractor for sterilization of devices listed in device schedule Amended – Removal of subcontractors from certificate
2024-02-06	30103843	Amended – Addition of sterilization subcontractor site
2024-03-25	30116512	Supplemented – Addition of the following device categories: Amniotic membrane perforator Circumcision devices

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Date	Reference Number	Action
Current	30162325	Supplemented – Addition of the following device categories: Sterile Endoscopic Fog Inhibitor Sterile Vessel Loops Non-sterile Vessel Loops Skin Marker Eye Bubble Tubes, Adapters and Hoses Sharp Instruments, Reusable Suture Supporting Instruments, Reusable General Surgical Instruments, Reusable

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