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 Medical Devices

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

Current Issue Date: **2024-03-25**

Starting Validity Date: **2024-03-25**

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

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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

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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
Current	30116512	Supplemented – Addition of the following device categories: Amniotic membrane perforator Circumcision devices

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