# 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: **2024-01-16**

Starting Validity Date: **2024-01-16**

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 |

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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. |
| Current | 30035623 | Supplemented – Addition of the following device group:<br>Sterile Suture Boots<br>Non-Sterile Suture Boots<br>Sterile Suture Retrievers<br>Non-Sterile Suture Retrievers<br>Amended – Change of subcontractor for sterilization of devices listed in device schedule<br>Amended – Removal of subcontractors from certificate |

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