

# 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

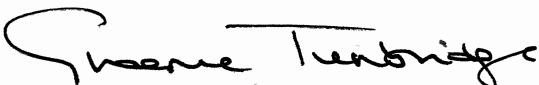
**Address:**

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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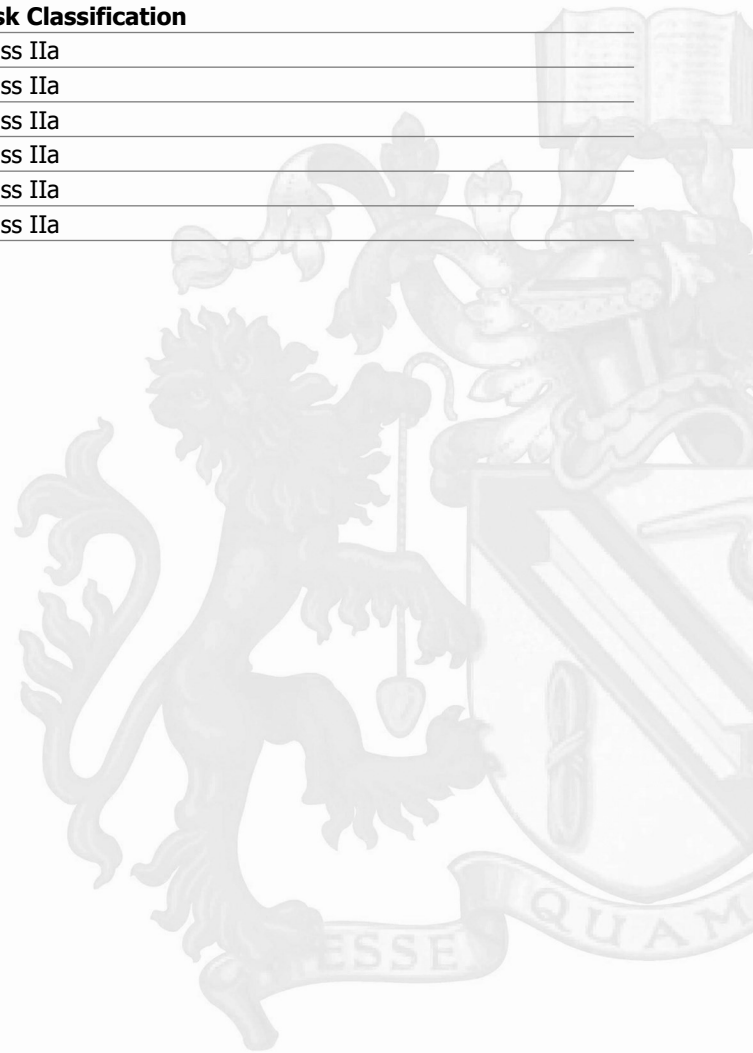
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### Device Schedule: Class IIa, Custom-made and other devices

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](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
2022-06-28	3497508	Issued.
Current	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



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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.