



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 Starting Validity Date: 2024-03-25

Current Issue Date: **2024-03-25** Expiry Date: **2027-06-27**

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Page 1 of 3

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. A Member of the BSI Group of Companies.





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

Device(s)	Risk Classification		1000
Surgical probe covers	Class IIa		117575
Surgical needles	Class IIa		
Sterile Suture Boots	Class IIa		
Non-Sterile Suture Boots	Class IIa		TAS
Sterile Suture retrievers	Class IIa		199
Non-Sterile Suture retrievers	Class IIa		Alexa
Amniotic membrane perforator	Class IIa	My ART B	
Circumcision devices	Class IIa	AR BALES	

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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 3003	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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Page 3 of 3

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