EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 755274 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 XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X 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: **2024-03-19**

Starting Validity Date: **2024-03-19**

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

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

Device(s)	Risk Classification
Surgical marking pens	Class Is
Wound Closures	Class Is
Cautery Tip Cleaners	Class Is
Surgical Light Handle and OR Camera Covers	Class Is
General Purpose Probe and Instrument Covers	Class Is
System drapes	Class Is
Endocavity Probe Covers	Class Is
General Purpose Needle Guides	Class Is
Endocavity Needle Guides	Class Is
Patient Positioning	Class Is
Umbilical Cord Clamps	Class Is
Urine Specimen Collection bags	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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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	30035289	Supplemented – Addition of the following device groups: Patient Positioning Umbilical Cord Clamps Urine Specimen Collection bags Amended – Change of subcontractor for sterilization of devices listed in device schedule Amended – Removal of subcontractors from certificate
2024-02-06	30103845	Amended – Addition of sterilization subcontractor site
Current	30090833	Supplemented – Removal of Scalpel Handles and Handle Covers no longer placed on the market.

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