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: **2024-01-16**

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

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

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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.

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

Device(s)	Risk Classification
Scalpel handles and scalpel handle covers	Class Is
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
Current	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

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