

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

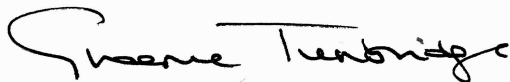
Address:

Prinsessegracht 20
2514 AP The Hague
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 and Class IIb implantable devices an 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 Issued: **2022-06-28**

Date: **2022-06-28**

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

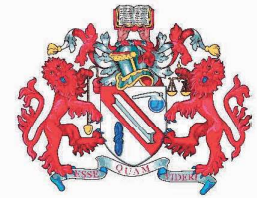


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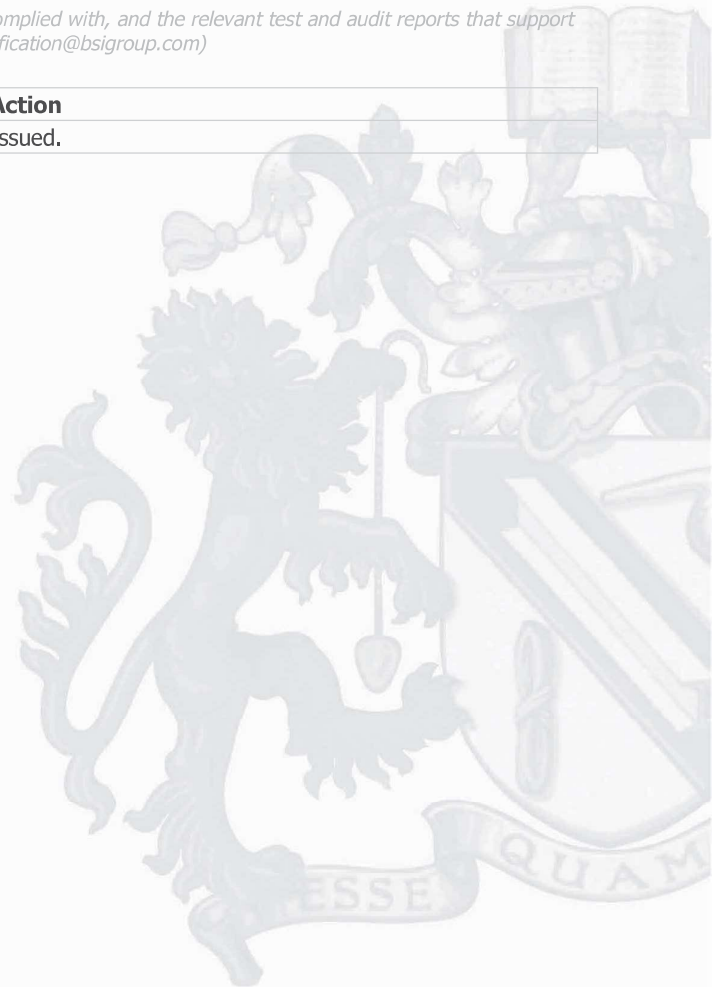
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Certificate History

(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
Current	3497508	Issued.



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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.