

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 783155 R000

Manufacturer: Aspen Surgical Products, Inc.

Address:

6945 Southbelt Drive, SE
Caledonia
Michigan
49316
USA

Single Registration Number: US-PR-000032443

EU Authorised Representative: Emergo Europe

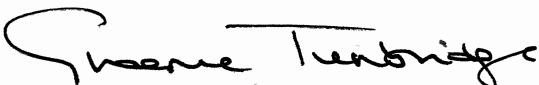
Address:

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 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: **2023-11-28**

Current Issue Date: **2023-11-28**

Starting Validity Date: **2023-11-28**

Expiry Date: **2028-11-27**

...making excellence a habit.™

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 783155 R000

Device Schedule: Article 22.3 Systems and Procedure Packs

Device(s)	Highest Risk Classification within the System or Procedure Pack
Needle Guide Kit	Class IIa
Probe Cover Kit	Class IIa

For Systems and Procedure Packs under Article 22.3, the Notified Body conformity assessment is limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged.



First Issue Date: **2023-11-28**

Current Issue Date: **2023-11-28**

Starting Validity Date: **2023-11-28**

Expiry Date: **2028-11-27**

...making excellence a habit.™

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 783155 R000

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



First Issue Date: **2023-11-28**

Current Issue Date: **2023-11-28**

Starting Validity Date: **2023-11-28**

Expiry Date: **2028-11-27**

...making excellence a habit.™

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.