

EU Quality Management System Certificate

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

MDR 765498 R000

Manufacturer: ASEPTICO INC.

Address:

8333 216th Street SE
Woodinville
Washington
98072
USA

Single Registration Number: US-MF-000014012

EU Authorised Representative: Advena Ltd.

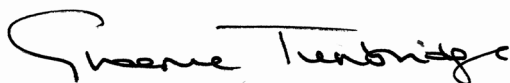
Address:

Tower Business Centre
2nd Flr.
Tower Street
Swatar
BKR 4013
Malta

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: **2023-12-04**

Current Issue Date: **2023-12-04**

Starting Validity Date: **2023-12-04**

Expiry Date: **2028-12-03**

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Device Schedule: Class IIa

Device(s)	Risk Classification
Gutta Percha Delivery System	Class IIa

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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	3620139	Issued

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