



EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 758297 R000

Manufacturer: Argentum Medical LLC

Address:

2571 Kaneville Court
Geneva
Illinois
60134
USA

Single Registration Number: US-MF-000003391

EU Authorised Representative: Emergo Europe B.V.

Address:

Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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 Global Regulatory & Quality

First Issue Date: **2025-02-14**

Current Issue Date: **2025-02-14**

Starting Validity Date: **2025-02-14**

Expiry Date: **2030-02-13**

...making excellence a habit.™