bsi.



EU Technical Documentation Assessment Certificate

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

MDR 758298 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

Starting Validity Date: 2025-02-14

Current Issue Date: 2025-02-14

Expiry Date: 2030-02-13

...making excellence a habit."

Page 1 of 3

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. A Member of the BSI Group of Companies.