



# Certificate

Certificate No.: MD 2573835-1-1  
Manufacturer: **ABAStroke Sp. z o.o.**  
ul. Warszawska 3 /3  
31-155 Kraków  
Poland  
REPs Facility ID: F008454  
Certification criteria: ISO 13485:2016  
United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –  
Subparts A to D

Scope: Design and development, manufacture, maintenance and distribution of medical device software used in neurorehabilitation.

TÜV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 84974915-80  
Issue Date: 2025-10-17  
Effective Date: 2025-10-17  
Expiry Date: 2028-10-16

Certification officer: Marek Ochocki  
TÜV Rheinland of North America, Inc.

The validity of the certificate can be verified on <https://www.certipedia.com>  
or calling 1-888-743-4652.