EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapters I and III

Registration No.:	HZ 2573835-1
Manufacturer:	ABAStroke Sp. z o.o. ul. Warszawska 3 /3 31-155 Kraków Poland
EUDAMED Single Registration No.:	PL-MF-000039172
Products:	
	Products of class IIa:
	Z129092 – VARIOUS INSTRUMENTS FOR FUNCTIONAL EXPLORATION AND THERAPEUTIC INTERVENTIONS – MEDICAL DEVICE SOFTWARE
Authorized representative(s):	Not applicable

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2025-12-23

The Notified Body hereby declares that the requirements of Annex IX, Chapter I of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	84974915-80
Effective date:	2025-12-23
Expiry date:	2030-12-22
Issue date:	2025-12-23

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This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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BS-MDR-091

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