

POLISH CENTRE FOR
TESTING AND CERTIFICATION

No. 1434-MDR-019/2025

**of the EU technical documentation assessment with the requirements
of Chapter II of Annex IX to the Regulation (EU) 2017/745
issued for medical devices manufactured by:**

HAGMED Sp. z o.o. Sp. komandytowa
96-200 Rawa Mazowiecka, ul. Tomaszowska 32
Single Registration Number (SRN): PL-MF-000021862

Polish Centre for Testing and Certification S.A. (Notified Body no. 1434) certifies that the technical documentation of the medical devices covered by this certificate complies with the requirements specified in Annexes II and III to the Regulation (EU) 2017/745. Details of the devices covered by this certificate are described on the following pages. The technical documentation report referenced below summarises the result of the assessment and includes reference to the relevant common specifications, harmonized standards and test reports.

Report no.: **S/039/BM/2023**

Validity of the Certificate: from 10.10.2025 to 09.10.2030

The date of issue of the Certificate: 10.10.2025

Certificate bears the qualified signature PCBC S.A.
Warsaw, 10.10.2025

FBM-R-24-MDR-E/8 of 05.08.2025

Page 1 of 2

CERTIFICATE

No. 1434-MDR-019/2025

Size of electrode		Number of electrode diagnostic poles		Configuration of electrode distal end		Spacing of electrode diagnostic poles	
Symbol	Description	Symbol	Description	Symbol (color ID)	Description	Symbol	Description
6	6F	Q	Four (Quadrapolar)	B (yellow)	Reach: 50 mm Min. diameter: 22 mm	222	2-2-2 mm
7	7F			S (red)	Reach : 57 mm Min. diameter: 26 mm	252	2-5-2 mm
8	8F			M (white)	Reach : 63 mm Min. diameter: 30 mm	141	1-4-1 mm
				L (green)	Reach : 70 mm Min. diameter: 36 mm	162	1-6-2 mm
				X (black)	Reach : 76 mm Min. diameter: 41 mm		

Page 1 of 2

Size of stabilizing system		Configuration of stabilizing system distal end		Type of stabilizing system steerability		Length of stabilizing system working part	
Symbol	Description	Symbol	Description	Symbol	Description	Symbol	Description
8	8.5F / 11.5F	S	Reach: 25 mm Bending radius: 18 / 18 mm	U	Unidirectional	72	72 cm
		M	Reach: 29.5 mm Bending radius: 13.5 / 22.5 mm	B	Bidirectional		
		L	Reach: 57 mm Bending radius: 25 / 50 mm				