



# POLISH CENTRE FOR TESTING AND CERTIFICATION

# CERTIFICATE

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

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# **CERTIFICATE**

**No. 1434-MDR-019/2025**

## **of the Assessment of the technical documentation with the requirements of Chapter II of Annex IX to the Regulation (EU) 2017/745**

## Devices covered by the certificate: Ablation electrodes EA

## Risk Classification: III

**Basic Code UDI-DI: 590067269EAUJ**

**Intended purpose: Ablation electrodes are used for RF cardiac ablation in patients over 18 years old diagnosed with supraventricular cardiac arrhythmias.**

Certificate validity conditions and/or limitations: n/a

Revision History including Changes: 1 / 10.10.2025 / S/039/BM/2023

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Warsaw, 10.10.2025

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# ANNEX TO THE CERTIFICATE

**VALID ONLY WITH CERTIFICATE  
No. 1434-MDR-019/2025**

## **List of medical devices covered by the certificate:**

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 (Quadrupolar)	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		

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Warsaw, 10.10.2025



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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
			Reach: 29.5 mm Bending radius: 13.5 / 22.5 mm		Bidirectional		
		L	Reach: 57 mm Bending radius: 25 / 50 mm				

Certificate bears the qualified signature.

Warsaw, 10.10.2025