POLISH CENTRE FOR
TESTING AND CERTIFICATION

CERTIFICATE

No. M - 68/5/2025

This is to certify that:

HAGMED
Sp. z o.o. Sp. komandytowa
ul. Tomaszowska 32, 96-200 Rawa Mazowiecka

(certified locations listed in Annex to the certificate)

is in conformance with

PN-EN ISO 13485:2016-04

in the following scope of activities:

design, production and sale of sterile and non-sterile medical devices intended for use in cardiology, vascular surgery, urology and bacteriology

The audit carried out by the Polish Centre of Testing and Certification has afforded evidence of the above.

This Certificate shall remain valid provided
that above standards are respected by the Organization.

This certificate is valid:

from 06.05.2025 to 05.05.2028

MEMBER OF IQNET

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019

Member of Multilateral Recognition Arrangement IAF

Issued under the Contract No. 3661/M/2/2025
Date of certification decision: 22.04.2025
Certificate bears a qualified signature.
Warsaw, 22.04.2025

Polish Centre for Testing and Certification 469 Puławska Street, 02-844 Warsaw phone: +48 22 45 46 200, pcbc@pcbc.gov.pl

POLISH CENTRE FOR
TESTING AND CERTIFICATION

ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No. M - 68/5/2025

This is to certify that the following Locations:

- **HAGMED Sp. z o.o. Sp. komandytowa**
  Head Office and Production Plant
  ul. Tomaszowska 32, 96-200 Rawa Mazowiecka
- **HAGMED Sp. z o.o. Sp. komandytowa**
  Production Plant
  ul. Krakowska 22D, 96-200 Rawa Mazowiecka

in the following scope of activities:

design, production and sale of sterile and non-sterile medical devices intended for use in cardiology, vascular surgery, urology and bacteriology

meet the requirements of the standards listed on the certificate.

MEMBER OF IQNET

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania AC 019

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POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

Warsaw, 29.04.2024

KW/MC/2024/0168

Manufacturer Name:

Hagmed sp. z o.o. Sp. k.

Adress:

Tomaszowska 32,
96-200 Rawa Mazowiecka
Poland

Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, Polish Centre for Testing and Certification, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1434 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Hagmed sp. z o.o. sp. k.
Tomaszowska 32
96-200 Rawa Mazowiecka
Poland

SRN Number: PL-MF-000021862

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement

concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Tomasz Koeber

Head of Medical Device Certification Department

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Ablation electrodes EA	Class III	Not applicable	1434-MDD-576/2019 1434-MDD-577/2019
Temporary transvenous pacing electrodes ES	Class III	Not applicable	1434-MDD-050/2019 1434-MDD-051/2019
Electrophysilogy diagnostic electrodes steerable EES and non-steerable EE	Class III	Not applicable	1434-MDD-048/2019 1434-MDD-049/2019
Resectoscope electrodes	Class IIb	Not applicable	1434-MDD-052/2019
Etension cables of electrophysiological electrodes	Class Is	Not applicable	1434-MDD-050/2020
Applicators for collecting genetic material	Class Is	Applicators for specimen collecting; Sterile cotton swabs	1434-MDD-056/2019 1434-MDD-055/2019
Embolectomy catheters	Class IIa	Not applicable	1434-MDD-053/2019

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable	Not applicable	Not applicable	Not applicable

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
15.04.2024	KW/MC/2024/0152	Initial issue
24.04.2024	KW/MC/2024/0168	Addition of Embolectomy catheters to the Table 1