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POLISH CENTRE FOR
TESTING AND CERTIFICATION

CERTIFICATE

No. M - 38/10/2025

This is to certify that:

HYDREX DIAGNOSTICS
SPÓŁKA Z OGRANICZONĄ ODPOWIEDZIALNOŚCIĄ
al. Stanów Zjednoczonych 61a, 04-028 Warszawa

(certified locations listed in Annex to the certificate)

is in conformance with

PN-EN ISO 13485:2016-04

in the following scope of activities:

- **manufacture, sales, installation and servicing of in vitro diagnostic medical devices (for self-testing and professional use)**
- **distribution of non-sterile Class I and Class II medical devices with and without a measuring function, and in vitro diagnostic medical devices**

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 standard are respected by the Organization.

This certificate is valid:

from 12.05.2025 to 05.05.2028

MEMBER OF IQNET

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019

Member of Multilateral Recognition Arrangement IAF

Aleksandra Kostmeva
President

Issued under the Contract No. 1719/JM/8/2025
Date of certification decision: 12.05.2025
Certificate bears a qualified signature.
Warsaw, 12.05.2025

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POLISH CENTRE FOR
TESTING AND CERTIFICATION

ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No. M - 38/10/2025

This is to certify that the following Locations:

- **HYDREX DIAGNOSTICS SPÓŁKA Z OGRANICZONĄ ODPOWIEDZIALNOŚCIĄ al. Stanów Zjednoczonych 61a, 04-028 Warszawa**
  in the following scope of activities:
  - **manufacture, sales, installation and servicing of in vitro diagnostic medical devices (for self-testing and professional use)**
  - **distribution of non-sterile Class I and Class II medical devices with and without a measuring function, and in vitro diagnostic medical devices**
- **HYDREX DIAGNOSTICS SPÓŁKA Z OGRANICZONĄ ODPOWIEDZIALNOŚCIĄ Magazyn i Konfekcja - ul. Odlewnicza 7, 03-231 Warszawa**
  in the following scope of activities:
  - **manufacture, sales, installation and servicing of in vitro diagnostic medical devices (for self-testing and professional use)**
  - **distribution of non-sterile Class I and Class II medical devices with and without a measuring function, and in vitro diagnostic medical devices**
- **HYDREX DIAGNOSTICS SPÓŁKA Z OGRANICZONĄ ODPOWIEDZIALNOŚCIĄ Produkcja - ul. Jagiellońska 88, 00-992 Warszawa**
  in the following scope of activities:
  manufacture, sales, installation and servicing of in vitro diagnostic medical devices (for self-testing and professional use)

meet the requirements of the standard listed on the certificate.

MEMBER OF IQNET

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019

Member of Multilateral Recognition Arrangement IAF

Aleksandra Kostmerva
President

Issued under the Contract No. 1719/JM/8/2025
Date of certification decision: 12.05.2025
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Warsaw, 12.05.2025

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

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