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POLISH CENTRE FOR
TESTING AND CERTIFICATION

CERTIFICATE

No. M - 139/2/2023

This Certificate cancels and replaces Certificate No. M - 139/1/2023.

This is to certify that:

OASIS Diagnostics S.A.
8/10 Czerska St., suite 313, 00-732 Warsaw

is in conformance with

PN-EN ISO 13485:2016-04

in the following scope of activities:

design, production and sales of active medical devices intended to detect obstetric anal sphincter injuries in women after vaginal delivery using impedance spectroscopy supported by machine learning methods

The audit carried out by the Polish Centre for 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 24.11.2023 to 23.11.2026

MEMBER OF IQNET

PCA POLSKIE CENTRUM AKREDYTACJI CERTYFIKACJA SYSTEMÓW ZARZĄDZANIA
AC 019

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

President

Issued under the Contract No. 3977/M/2023
Date of certification decision: 24.11.2023
Certificate bears a qualified signature.
Warsaw, 28.12.2023

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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