



# CERTIFICATE

**EC Certificate No. 1434-IVDD-075/2022**

**Full Quality Assurance System  
Directive 98/79/EC concerning  
*in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies  
that the quality assurance system in the organization:

**Lorne Laboratories Ltd  
Unit 1 Cutbush Park Industrial Estate  
Danehill  
Lower Earley  
Berkshire RG6 4UT, UNITED KINGDOM**

for the design, manufacture and final inspection of *in vitro* diagnostic medical device  
List A

*The list of medical devices covered by this certificate is provided  
in the Annex 1 to EC Design-examination Certificate No. 1434-IVDD-074/2022*

complies with requirements  
of Annex IV (excluding Section 4, 6) to Directive 98/79/EC (as amended)  
implemented into Polish law,  
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 28.04.2022 to 27.05.2025

The date of issue of the Certificate: 28.04.2022

The date of the first issue of the Certificate: 10.04.2019



Issued under the Contract No. MD-004/2022  
Application No: 505/2022  
Certificate bears the qualified signature.  
Warsaw, 28/04/2022  
Module H7

**President**