



CERTIFICATE

EC Certificate No. 1434-IVDD-026/2022

**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

**Monoclonal Rh Control - 640010
Monoclonal D Negative Control - 650010**

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 **08.03.2022** to **27.05.2025**

The date of issue of the Certificate: **03.03.2022**

The date of the first issue of the Certificate: **10.04.2019**



Issued under the Contract No. MD-173/2021
Application No: 576/2021
Certificate bears the qualified signature.
Warsaw, 03/03/2022
Module H7

President