



# CERTIFICATE

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**EC Certificate No. 1434-IVDD-025/2022**

**EC Design-examination  
Directive 98/79/EC concerning  
*in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies  
that manufactured by:

**Lorne Laboratories Ltd**

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

i.e. *in vitro* diagnostic medical devices  
List A

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

in terms of design documentation, comply with requirements  
of Annex IV (Section 4) 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: 575/2021  
Certificate bears the qualified signature.  
Warsaw, 03/03/2022  
Module H6/V1

**President**