



# CERTIFICATE

**EC Certificate No. 1434-IVDD-074/2022**

**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

*The list of medical devices covered by this certificate is provided in the Annex 1*

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 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: 504/2022  
Certificate bears the qualified signature.  
Warsaw, 28/04/2022  
Module H6/V1

Aleksandra  
Kostrzewa

Digitally signed by  
Aleksandra  
Kostrzewa

**President**



## ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-IVDD-074/2022**

*List of medical devices covered by the certificate:*

Anti-A Monoclonal 600010  
Anti-B Monoclonal 610010  
Anti-A,B Monoclonal 620010  
Anti-D Clone 1 Monoclonal 730010  
Anti-D Clone 2 Monoclonal 710010  
Anti-D Duoclone Monoclonal 740010  
Anti-C Monoclonal 690005  
Anti-E Monoclonal 691005  
Anti-c Monoclonal 692005  
Anti-e Monoclonal 693005  
Anti-C+D+E Monoclonal 700010  
Anti-K Monoclonal 760010



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Application No: 504/2022  
Certificate bears the qualified signature.  
Warsaw, 28/04/2022

Aleksandra  
Kostrzewa  
**President**

Digitally signed by  
Aleksandra  
Kostrzewa