



# CERTIFICATE

**EC No 1434-IVDD-136/2019**  
**Full Quality Assurance System**

**Directive 98/79/EC on 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 devices  
List A

**Products list in attachments: 1**

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

Validity of Certificate: from 10.04.2019 to 07.03.2022

The date of issue of the Certificate: 10.04.2019

The date of the first issue of the Certificate: 10.04.2019



Application No: 650/2019  
Module: H7

  
mgr Anna Wyroba  
Vice-President



Certificate No **1434-IVDD-136/2019**  
Issued under the Contract No **MD-59/2019**  
Bears the PCBC hologram.  
Warsaw, 10.04.2019



**ANNEX 1 TO CERTIFICATE**  
**VALID ONLY WITH CERTIFICATE**  
**No 1434-IVDD-136/2019**

The products detailed below are covered under the scope of this certificate:

**Name:**

**GMDN code:**

**Monoclonal Rh Control - 640010**

**52705**

**Monoclonal D Negative Control - 650010**

**52705**



  
mgr Anna Wyroba  
Vice-President



Annex 1 to certificate No. **1434-IVDD-136/2019**  
Issued under the Contract No. **MD-59/2019**  
Bears the PCBC hologram.  
Warsaw, 10.04.2019