



CERTIFICATE

EC No 1434-IVDD-135/2019
EC Design-Examination

Directive 98/79/EC on 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**

in vitro diagnostic medical devices
List A

Products list in attachments: 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 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: H6


mgr Anna Wyroba
Vice-President



Certificate No **1434-IVDD-135/2019**
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-135/2019

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-135/2019**
Issued under the Contract No. **MD-59/2019**
Bears the PCBC hologram.
Warsaw, 10.04.2019