

EC Certificate No. 1434-IVDD-412/2019
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:

## **Cellabs Pty Ltd**

## Unit 7, 27 Dale Street, PO Box 421 Brookvale, New South Wales 2100 AUSTRALIA

for the design, manufacture and final inspection of *in vitro* diagnostic medical devices, List B

List of devices covered by this certificate is given in the Annex no. 1

comply 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 15.08.2019 to 14.08.2024

The date of issue of the Certificate: 14.08.2019

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Application No: 950/2019 Module H7 Michał Pachowski, PhD President



Certificate No. 1434-IVDD-412/2019 Issued under the Contract No. MD-189/2019 Bears the PCBC hologram Warsaw, 14.08.2019



## ANNEX No. 1 TO CERTIFICATE VALID ONLY WITH CERTIFICATE No. 1434-IVDD-412/2019

List of in vitro diagnostic medical devices covered by the certificate

Chlamydia Cel IFA Kit - KC1

Chlamydia Cel Pn IFA Kit - KC3

Chlamydia Cel IFA Reagent - RC1

Chlamydia Cel Pn MAb Reagent - RC3

Chlamydia trachomatis Positive Control Slide - C

Anti-mouse FITC Reagent - RM

Mounting Fluid - RMF

Chlamydia pneumoniae Positive Control Slide - TW

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Michał Pachowski, PhD
President



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