CERTIFICATE

EC Certificate No. 1434-IVDD-130/2022

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:

Agilent Technologies Singapore (International) Pte Ltd.

No. 1 Yishun Avenue 7
Singapore, 768923

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

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

complies 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 02.05.2022 to 27.05.2025

The date of issue of the Certificate: 02.05.2022

The date of the first issue of the Certificate: 28.10.2020

CE 1434

Issued under the Contract No. MD-006/2022
Application No: 506/2022
Certificate bears the qualified signature.
Warsaw, 02/05/2022
Module H7

Aleksandra Kostrzewa
President

Digitally signed by Aleksandra Kostrzewa

ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-130/2022

List of medical devices covered by the certificate:

M0854 Monoclonal Mouse Anti-Cytomegalovirus, Clones CCH2 + DDG9

IR752 FLEX Monoclonal Mouse Anti-Cytomegalovirus, Clones CCH2 + DDG9, Ready-to-Use (Link)

IS752 FLEX Monoclonal Mouse Anti-Cytomegalovirus, Clones CCH2 + DDG9, Ready-to-Use, (Dako Autostainer / Plus)

GA752 FLEX Monoclonal Mouse Anti-Cytomegalovirus, Clones CCH2 + DDG9, Ready-to-Use (Dako Omnis)

M0750 Monoclonal Mouse Anti-Human Prostate-Specific Antigen, Clone ER/PR8

CE 1434

Issued under the Contract No. MD-006/2022
Application No: 506/2022
Certificate bears the qualified signature.
Warsaw, 02/05/2022

Aleksandra Kostrzewa
President

Digitally signed by Aleksandra Kostrzewa