



CERTIFICATE

EC Certificate No. 1434-IVDD-390/2020
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 I to EC Design-examination Certificate No. 1434-IVDD-390-2020

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 01.12.2020 to 06.07.2023

The date of issue of the Certificate: 28.10.2020



Issued under the Contract No. MD-107/2020
Application No: 586/2020
Certificate bears the qualified signature.
Warsaw, 28.10.2020
Module H7

Anna
Małgorzata
Wyroba
Vice-President

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2020.10.28
11:28:31 +01'00'



ANNEX I TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-390/2020

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 / 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

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Warsaw, **28.10.2020**

Anna
Małgorzata
Wyroba
Vice-President

Elektronicznie
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