



CERTIFICATE

EC Certificate No. 1434-IVDD-526/2019

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:

Dako Denmark ApS

Produktionsvej 42

Glostrup DK-2600 DENMARK

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 25.10.2019 to 06.07.2023


The date of issue of the Certificate: 25.10.2019

The date of the first issue of the Certificate: 08.05.2019

CE 1434

Application No: 838/2019

Module H7


mgr Anna Wyroba
Vice - President



Certificate No. **1434-IVDD-526/2019**
Issued under the Contract No. **MD-222/2019**
Bears the PCBC hologram
Warsaw, 25.10.2019



**ANNEX No. 1 TO CERTIFICATE
VALID ONLY WITH CERTIFICATE
No. 1434-IVDD-526/2019**

List of in vitro diagnostic 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**

**GA514 FLEX Polyclonal Rabbit Anti-Human Prostate-Specific
Antigen Ready-to-Use (Dako Omnis)**




mgr Anna Wyroba
Vice - President



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