



EC CERTIFICATE

Dako Denmark A/S

Produktionsvej 42
Glostrup DK-2600 DENMARK

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV (excluding sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Scope of Certificate:

The design and manufacture of in vitro diagnostic devices for determining prostate-specific antigen and cytomegalovirus by immunohistochemistry and immunoprecipitation techniques

Device Classifications:

Annex II List B

Device Descriptions and Model Type:

Please refer to Attachment: 1

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 98/79/EC, Annex IV, Section 5. For Annex II, List A devices where they are covered by this certificate, an EC Design Examination certificate according to 98/79/EC, Annex IV, Section 4 is required. This certificate is issued with 1 attachment listing product references.

File Number A12312
Certificate Number 290.180808
Initial Issue Date August 22, 2003

Cycle Start Date July 7, 2018
Effective Date August 8, 2018
Expiry Date July 6, 2023

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd



Check Certificate
Status: [here](#)

Notified Body
0843

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00-MB-A0043 Issue: 15.0

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom



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Attachment 1 of 1

The products detailed below are covered under the scope of this certificate:

Model/Type	Classification	G/UMDN Code
M0854 Monoclonal Mouse Anti-Cytomegalovirus, Clones CCH2 + DDG9	Annex II List B	62756
IR752 FLEX Monoclonal Mouse Anti-Cytomegalovirus, Clones CCH2 + DDG9, Ready-to-Use (Link)	Annex II List B	62756
IS752 FLEX Monoclonal Mouse Anti-Cytomegalovirus, Clones CCH2 + DDG9, Ready-to-Use, (Dako Autostainer / Plus)	Annex II List B	62756
GA752 FLEX Monoclonal Mouse Anti-Cytomegalovirus, Clones CCH2 + DDG9, Ready-to-Use (Dako Omnis)	Annex II List B	62756
A0562 Polyclonal Rabbit Anti-Human Prostate-Specific Antigen	Annex II List B	63066
M0750 Monoclonal Mouse Anti-Human Prostate-Specific Antigen, Clone ER/PR8	Annex II List B	63066
IR514 FLEX Polyclonal Rabbit Anti-Human Prostate-Specific Antigen, Ready-to-Use (Link)	Annex II List B	63066
IS514 FLEX Polyclonal Rabbit Anti-Human Prostate-Specific Antigen, Ready-to-Use (Dako Autostainer / Plus)	Annex II List B	63066
GA514 FLEX Polyclonal Rabbit Anti-Human Prostate-Specific Antigen Ready-to-Use (Dako Omnis)	Annex II List B	63066

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