



EC CERTIFICATE

Dako Denmark A/S

Produktionsvej 42
DK-2600 Glostrup
Denmark

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV, section 3 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 Classification:

Annex II, list B

Device Descriptions:

Monoclonal and polyclonal antibodies to CMV and PSA

Models:

Refer to Attachment 1

File Number	A12312	Cycle Start Date	07 July 2015
Certificate No.	290.150707	Effective Date	07 July 2015
		Expiry Date	06 July 2018

Authorised by

Brian Rodgers
Certification Manager

For and on Behalf of UL International (UK) Ltd

We hereby declare that an examination of the full quality assurance system has been carried out per report 4786864801, 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 model numbers.

Notified Body

0843

00-NB-F0068 3.0

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

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

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