

# EC Certificate - Full Quality Assurance

## Supplementary Information to CE 707974

Issued To:

**Roche Molecular Systems, Inc.**  
**1080 US Highway 202 South**  
**Branchburg 08876**  
**New Jersey**  
**USA**

### Annex II List A

<b>IVD0201, IVD0203</b>	cobas® MPX Test Kit – 96 Tests	See CE 708021
	cobas® MPX Test Kit – 480 Tests	
	cobas® MPX Control Kit	
	cobas® NHP Negative Control Kit	
<b>IVD0201</b>	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test v2.0 (quantitative)	See CE 708017
<b>IVD0201</b>	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test v2.0 (qualitative)	See CE 709230
<b>IVD0201</b>	cobas® HIV-1 Test	See CE 709225
<b>IVD0201</b>	cobas® HIV-1 Test (quantitative)	See CE 709229
<b>IVD0201</b>	cobas® HIV-1 Test (quantitative & qualitative)	See CE 709229
<b>IVD0203</b>	cobas® HBV Test	See CE 708019
<b>IVD0203</b>	COBAS® AmpliPrep/COBAS® TaqMan® HBV Test v2.0	See CE 709234
<b>IVD0203</b>	cobas® HCV Test	See CE 708020

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.

This certificate was issued electronically and is bound by the conditions of the contract.

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