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By Royal Charter

EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

No. **CE 707974**

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

In respect of:

Design and manufacture of nucleic acid test kits for Donor Screening for HBV, HCV and HIV.
Design and manufacture of nucleic acid test kits to aid in the diagnosis and management of disease status for HBV, HCV or HIV infected individuals.
Design and manufacture of nucleic acid test kits to aid in the diagnosis and management of Cytomegalovirus in transplant patients and for detection of HCV, HBV, HIV-1, HIV-2 and Chlamydia Trachomatis.

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-03-26** Date: **2019-06-17** Expiry Date: **2024-03-25**

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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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

Digitally signed by Lazari Cristina
Date: 2022.07.25 11:25:00 EEST
Reason: MoldSign Signature
Location: Moldova

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Supplementary Information to CE 707974

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Annex II List A		
IVD0201, IVD0203	cobas® MPX Test Kit – 96 Tests (6800/8800 Systems)	See CE 708021
	cobas® MPX Test Kit – 480Tests (6800/8800 Systems)	
	cobas® MPX Control Kit (6800/8800 Systems)	
	cobas® NHP Negative Control Kit (6800/8800 Systems)	
IVD0201, IVD0203	cobas® TaqScreen MPX Test v2.0 (s 201 system)	See CE 709224
	cobas® TaqScreen MPX Control Kit v2.0 (s 201 system)	
IVD0201	COBAS® AmpliPrep/COBAS® TaqMan HIV-1 Test v2.0 (quantitative)	See CE 708017
IVD0201	COBAS® AmpliPrep/COBAS® TaqMan HIV-1 Test v2.0 (qualitative)	See CE 709230
IVD0201	cobas® HIV-1 Test (6800/8800 Systems)	See CE 709225
IVD0201	cobas® HIV-1 Test (quantitative, 4800 System)	See CE 709229
IVD0201	cobas® HIV-1 Test (quantitative & qualitative. 4800 System)	See CE 709229
IVD0203	cobas® HBV Test (6800/8800 Systems)	See CE 708019

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