

Certificate of Completion

This certificate of completion shall serve as evidence
of successful completion of training by:

Vitalie Turcanu

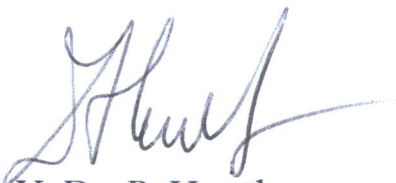


User Name: Vitalie Turcanu
Title: cobas 5800 Service Training (standardized)
Completion date: Friday, September 23, 2022

Training Location: Mannheim
Session Start Date: 9/19/2022
Session End Date: 9/23/2022
Course Duration: 40 Hours 0 Minutes

Trainee Signature

Date of Signature (dd-mmm-yyyy)



i. V. Dr. P. Henčl

Roche Diagnostics GmbH
68298 Mannheim



Declaration of Conformity

as per Annex IV of the Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 via BSI as the Notified Body (registration no. BSI-NL 2797)

Document No.: **DOC-2022-11**

Manufacturer: **Roche Molecular Systems, Inc.**
1080 US Highway 202 South
Branchburg, NJ 08876
USA

Authorized Representative: **Roche Diagnostics GmbH**
Sandhofer Strasse 116
68305 Mannheim
Germany

Name, Address and Identification number of the Notified Body: **BSI Group The Netherlands B.V.**
Notified Body Number: 2797
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam, Netherlands

Roche Molecular Systems, Inc. declares that the *in vitro* diagnostic medical device:

Product Name: **cobas® MPX**
*For use on the **cobas® 5800/6800/8800 Systems***

P/N: 09040862190: **cobas® MPX – 480**
09040846190: **cobas® MPX Control Kit**

Description:

The **cobas® MPX** test, for use on **cobas® 5800/6800/8800 Systems** is a qualitative *in vitro* test for the direct detection of Human Immunodeficiency Virus Type 1 (HIV-1) Group M RNA, HIV-1 Group O RNA, Human Immunodeficiency Virus Type 2 (HIV-2) RNA, Hepatitis C Virus (HCV) RNA, and Hepatitis B Virus (HBV) DNA in human plasma and serum.

The complete Intended Use is contained in the **cobas® MPX** Package Insert.

Complies with the requirements of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

This declaration is supported by the following certificates:

EC Certificate – Full Quality Assurance: CE 707974, first issued 2019-03-26, valid until 2025-05-26

EC Design-Examination Certificate: CE 708021, first issued 2019-03-26, valid until 2025-05-26



Declaration of Conformity

as per Annex IV of the Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 via BSI as the Notified Body (registration no. BSI-NL 2797)

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The Manufacturer agrees to develop, implement, and maintain a documented post-production monitoring process, including the notification of reportable events, under the European Medical Device Vigilance System Guidelines. As a legal manufacturer, Roche Molecular Systems, Inc., is solely responsible for the product. This declaration is issued under the sole responsibility of Roche Molecular Systems, Inc.

Place: Tucson, AZ

Date: 19-May-2022

A handwritten signature in black ink that reads "Jeff Boone".

Jeff Boone

Vice President, Quality Management

Place: Pleasanton, CA

Date: 17-May-2022

A handwritten signature in black ink that reads "Rita Hoady".

Rita Hoady

Network Lead Molecular Lab
Director, Global Regulatory Affairs



EU Declaration of Conformity

In accordance with EU Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

Manufacturer: **Roche Molecular Systems, Inc.**
1080 US Highway 202 South
Branchburg, NJ 08876
USA

Single Registration Number (SRN) **US-MF-000018066**
Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH**
Sandhofer Strasse 116
68305 Mannheim
Germany

Single Registration Number (SRN) **DE-AR-000006262**
Authorized Representative:

This declaration is issued under the sole responsibility of Roche Molecular Systems, Inc.

Product Information

Part Number:	Product Name:	Basic UDI-DI:
08707464001	cobas ® 5800 Instrument	761333602236AJ

Intended Purpose: The **cobas**® 5800 System supports an automated and integrated workflow to run Polymerase Chain Reaction (PCR) based Nucleic Acid Testing (NAT). The **cobas**® 5800 System combines the functionalities of instrumentation, consumables, reagents, and data management to provide an efficient workflow from sample processing to result interpretation.

Risk Class and Classification Rule: Class A, as per EU Regulation 2017/746, Annex VIII, Rule 5 (b)

Common Specifications: Not applicable as no Common Specifications exist for the concerned device.



Conformity of the product with EU Regulation 2017/746 and the following EU legislation, which also require an EU Declaration of Conformity, and other applicable EU legislation, has been established.

- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).
- Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment (RED).

To assess the product with regard to this EU Directive, the following relevant harmonised European standards were applied:

Safety: EN 60950-1:2005 + Amd. 1:2009 + Amd. 2:2013, EN 62368-1:2014

EMC: ETSI EN 301489-1 V2.1.1 (2017-02)

ETSI EN 301489-3 V2.1.1 (2017-03)

Radio Spectrum Matters: ETSI EN 300 330 V2.1.1 (2017-02)

On behalf of Roche Molecular Systems, Inc.

Place: Rotkreuz, Switzerland

Place: Pleasanton, CA

Date:

Date:

DocuSigned by:

Nathalie Pankiw

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Nathalie Pankiw

Network Lead Molecular Lab
Pre-Market Quality

DocuSigned by:

Rita Hoady

36040CF34A65477...

Rita Hoady

Network Lead
Global Head of Regulatory Affairs, Molecular Lab