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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

Digitally signed by Lazari Cristina
Date: 2024.11.08 09:20:41 EET
Reason: MoldSign Signature
Location: Moldova

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)

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

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

Jeff Boone

Jeff Boone
Vice President, Quality Management

Place: Pleasanton, CA

Date: 17-May-2022

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) Manufacturer:	**US-MF-000018066**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**
Single Registration Number (SRN) Authorized Representative:	**DE-AR-000006262**

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

Date: 08 November 2022

DocuSigned by:
Nathalie Pankiw
4AE3D64FEAD7483...

Nathalie Pankiw
Network Lead Molecular Lab
Pre-Market Quality

Place: Pleasanton, CA

Date: 07 November 2022

DocuSigned by:
Rita Hoady
36040CF34A65477...

Rita Hoady
Network Lead
Global Head of Regulatory Affairs, Molecular Lab