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:**
05524245001	**cobas**® 6800 System	761333601845BA
05412722001	**cobas**® 8800 System	
Including		
06379664001	**cobas**® 6800 System Fixed Platform	
06379672001	**cobas**® 6800 System Moveable Platform	
06301037001	Sample Supply Module	
09277137001	**cobas**® 6800/8800 Systems Software version: 1.4.7	
09074899001	SW **cobas**® 6800/8800 Language Packages Software version: 1.4	

Intended Purpose:

The **cobas**® 6800 and **cobas**® 8800 System is designed to run Polymerase Chain Reaction (PCR) based Nucleic Acid Testing (NAT) to be applied in diagnostic and blood screening laboratories.

The complete Intended Use is contained in the **cobas**® 6800/8800 Systems User Guide.

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).

  Starting with Serial no. 1275 (**cobas**® 6800 System), 5075 (**cobas**® 8800 System)

- 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: Tucson, AZ

Date: 21-Dec-2021

DocuSigned by:
Jeff Boone
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Jeff Boone
Vice President, Quality Management

Place: Santa Clara, CA

Date: 20-Dec-2021

DocuSigned by:
Carolyn Glickman
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Carolyn Glickman
Director, Regulatory Affairs