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

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Nathalie Pankiw
Network Lead Molecular Lab
Pre-Market Quality

Place: Pleasanton, CA

Date: 07 November 2022

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Global Head of Regulatory Affairs, Molecular Lab