HITACHI

CÔNG TY TRÁCH NHIỆM HỮU HẠN ROCHE VIỆT NAM

Trương Thị Tố Hoa
Trưởng phòng Đăng ký,
Đối ngoại và Quản lý Chất lượng

EU Declaration of Conformity

Manufacturer: Address:	Hitachi High-Tech Corporation 1-17-1 Toranomon, Minato-ku Tokyo 105-6409, JAPAN
Single Registration Number:	JP-MF-000016991
European Representative: Address:	Roche Diagnostics GmbH Sandhofer Strasse 116, 68305 Mannheim Germany

Product Name	Basic UDI-DI	Order information	Risk Class for REGULATION (EU) 2017/746
cobas 8000 B-Gate KIT	761333601413A9	06372546001	Class A

We, Hitachi High-Tech Corporation, declare under our sole responsibility that the above listed device(s) is/are in conformity with the following European Union harmonisation legislation:

- REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances

Intended use/purpose:	The cobas 8000 B-Gate KIT is an IVD accessory used for the connection of cobas 8000 Core Unit to the Sample Pre-Analytical Module. Additionally, it is an optional accessory that is used for the connection of cobas pro sample supply unit to a bidirectional pre-analytical system.
Notified Body's name/ number (if applicable):	Not applicable
IVDR conformity assessment procedures:	Annex II and III of REGULATION (EU) 2017/746 (Class A)
Applied standards:	See Appendix I
Starting Serial No.:	See Appendix II

on behalf of the company

Date: 27. Jun. 2022

Yoshihiro Kawabe
General Manager
Medical Systems Quality Assurance Dep't
Corporate Quality Assurance Div.
Hitachi High-Tech Corporation

on behalf of the company

Date: 27 Jun 2022

Yoshitaka Kodama
General Manager
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Life & Medical Systems Business Div.
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Hitachi High-Tech Corporation

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Appendix I
List of applied standards

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU:

Standard number, year	Name of applied standard
EN ISO 13485: 2016	Medical devices – Quality management systems - Requirements for regulatory purposes
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN 62366: 2008 (for cobas 8000) EN 62366: 2008 + A1 2015 (for cobas pro)	Medical devices - Application of usability engineering to medical devices
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 18113-1: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-3: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
IEC 61010-2-101: 2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61326-2-6: 2012/ EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment

DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances:

Standard number, year	Name of applied standard
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Appendix II
List of applicable product name and starting serial number

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU:

Product name or component name	Starting serial number
cobas 8000 B-Gate KIT	Date of production from March 2022 onward

DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances:

Product name or component name	Starting serial number
cobas 8000 B-Gate KIT	Date of production from January 2021 onward

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