HITACHI

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:	**cobas® 8000 modular analyzer series**

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
- DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC

Intended use/purpose:	The cobas® 8000 modular analyzer series is a fully automated random-access software-controlled system for immunoassays and photometric analysis intended for qualitative and quantitative in vitro determinations using a wide variety of tests. See the configurable device list on page 2 for details.
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
Life & Medical Systems Center
Life & Medical Systems Business Div.
Analytical & Medical Solution Business Group
Hitachi High-Tech Corporation

Contact address:
Hitachi High-Tech Corporation
1-17-1 Toranomon, Minato-ku Tokyo 105-6409, JAPAN

Configurable device list of cobas® 8000 modular analyzer series

Product name or component name	Basic UDI-DI	Order information	Risk Class for REGULATION (EU) 2017/746
cobas 8000 Core Unit	761333601370AG	05641446001	Class A
cobas 8000 c 701 Module	761333601371AJ	05641489001	Class A
cobas 8000 c 702 Module	761333601421A8	06473245001	Class A
cobas e 801 MSB/MSBL	761333601562AT	08459606001	Class A
cobas 8000 ISE 900 Module	761333601394AW	05641497001	Class A
cobas 8000 ISE 1800 Module	761333601372AL	05964075001	Class A
cobas 8000 Transport Line	761333601373AN	05641519001	Class A

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 62304: 2006 / AC: 2008	Medical device software - Software life-cycle processes
EN 62366: 2008	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

DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC:

Standard number, year	Name of applied standard
EN 300 330 V2.1.1	Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz
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
EN 62479:2010:	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
EN 301 489-1 V1.9.2:	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
EN 301 489-3 V1.6.1:	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electro-Magnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz

Appendix II
List of applicable product name and 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 Core Unit	From 2201-01 onward
cobas 8000 c 701 Module	From 2201-01 onward
cobas 8000 c 702 Module	From 2201-01 onward
cobas e 801 MSB/MSBL	From 2201-01 onward
cobas 8000 ISE 900 Module	From 2201-01 onward
cobas 8000 ISE 1800 Module	From 2201-01 onward
cobas 8000 Transport Line	From 2201-01 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 Core Unit	From 21Y2-01 onward
cobas 8000 c 701 Module	From 20S4-01 onward
cobas 8000 c 702 Module	From 2093-01 onward
cobas e 801 MSB/MSBL	From 2004-01 onward
cobas 8000 ISE 900 Module	From 20G3-08 onward
cobas 8000 ISE 1800 Module	From 20G3-01 onward
cobas 8000 Transport Line	From 20X5-01 onward

DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC:

Product name or component name	Starting serial number
cobas 8000 c 701 Module	From 16G6-01 onward
cobas 8000 c 702 Module	From 16K5-01 onward
cobas e 801 MSB/MSBL	From 1801-01 onward

End of the document