HITACHI

EU Declaration of Conformity

Manufacturer:	Hitachi High-Tech Corporation
Address:	1-17-1 Toranomon, Minato-ku, Tokyo 105-6409, Japan
Single Registration Number:	JP-MF-000016991
European Representative:	Roche Diagnostics GmbH
Address	Sandhofer Strasse 116, 68305 Mannheim, Germany
Product Name	**cobas pure integrated solutions**

We, Hitachi High-Tech Corporation, declare under our sole responsibility that **cobas pure integrated solutions**（Refer to Appendix I for the components) 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:	cobas pure integrated solutions is an automated analyzer, intended for running qualitative and quantitative clinical chemistry and immunochemistry assays as well as ion selective measurements.
Notified Body's name/ number (if applicable)	Not applicable
IVDR conformity assessment procedures:	Annex II and III of REGULATION (EU) 2017/746 (Class A)
Starting Serial No.:	See Appendix II
Applied standards:	See Appendix III

on behalf of the company

Date: 09-Feb-2023

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Signer Name: Yoshihiro Kawabe
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Medical Systems Quality Assurance Dept
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Hitachi High-Tech Corporation

on behalf of the company

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Hitachi High-Tech Corporation

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Appendix I
List of components for cobas pure integrated solutions

Product name or component name	Basic UDI-DI	Order information	Risk classification for REGULATION (EU) 2017/746
sample supply unit	761333601772B8	09031537001	Class A
cobas e 402 analytical unit	761333601773BA	09031553001	Class A
cobas c 303 analytical unit	761333601771B6	09031529001	Class A
cobas pure liquid waste container	761333601774BC	09033394001	Class A

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
sample supply unit	From 2201-01 onward
cobas e 402 analytical unit	From 2201-01 onward
cobas c 303 analytical unit	From 2201-01 onward (NAKA site shipment) From U301-01 onward (OMUTA site shipment)
cobas pure liquid waste container	Shipment 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
sample supply unit	From 2201-01 onward
cobas e 402 analytical unit	From 2201-01 onward
cobas c 303 analytical unit	From 2201-01 onward (NAKA site shipment) From U301-01 onward (OMUTA site shipment)
cobas pure liquid waste container	Shipment from March 2022 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
sample supply unit	From 2201-01 onward
cobas e 402 analytical unit	From 2201-01 onward
cobas c 303 analytical unit	From 2201-01 onward (NAKA site shipment) From U301-01 onward (OMUTA site shipment)
cobas pure liquid waste container	Shipment from March 2022 onward

Appendix III
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/A1 2015	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
IEC61010-2-101:2002	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

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