

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® pro integrated solutions**

We, Hitachi High-Tech Corporation, declare under our sole responsibility that cobas® pro 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

Intended use/purpose: cobas® pro integrated solutions is an automated analyzer, intended for running qualitative, semi-quantitative and quantitative clinical chemistry and immunochemistry assays as well as ion selective measurements.

Notified Body's name/number (if applicable) See the configurable device list on page 2 for details.
IVDR conformity assessment procedures: Not applicable
Starting Serial No.: Annex II and III of REGULATION (EU) 2017/746 (Class A)
Applied standards: See Appendix II
See Appendix III

on behalf of the company

Date: 28-Oct-2022

DocuSigned by:
Yoshihiro Kawabe

 Signer Name: Yoshihiro Kawabe
Signing Reason: I approve this document
Signing Time: 28-10-2022 | 4:30:41 午後 JST
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on behalf of the company

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Takayuki Noda
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Appendix I
List of components for cobas® pro integrated solutions

Product name or component name	Basic UDI-DI	Order information	Risk classification for REGULATION (EU) 2017/746
cobas pro SSU	761333601776BG	09205632001	Class A
cobas pro SB	761333601777BJ	09205675001	Class A
cobas pro SBL c 503	761333601779BN	09205691001	Class A
cobas pro SBL e 801	761333601781B9	09211888001	Class A
cobas pro transport line	761333601778BL	09205683001	Class A
cobas pro Transport Belt (2 AU, 2 ISE)	761333602140A4	09205713001	Class A
cobas pro Transport Belt (3 AU, 2 ISE)		09205721001	Class A
cobas pro Transport Belt (4 AU, 2 ISE)		09205730001	Class A
cobas pro B-Gate Upgrade Kit	761333601780B7	09205756001	Class A
cobas pro B-Gate update kit	761333601609AU	08763640001	Class A
cobas pro liquid waste container	761333601610AD	08763704001	Class A
cobas pro A-Gate Upgrade Kit	761333602670B6	09813799001	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
cobas pro SSU	From 2201-01 onward (Japan shipment) From C201-01 onward (China shipment)
cobas pro SB	From 2201-01 onward (Japan shipment) From C201-01 onward (China shipment)
cobas pro SBL c 503	From 2201-01 onward (Japan shipment) From C201-01 onward (China shipment)
cobas pro SBL e 801	From 2201-01 onward (Japan shipment) From C201-01 onward (China shipment)
cobas pro transport line	From 2201-01 onward (Japan shipment) From C201-01 onward (China shipment)
cobas pro Transport Belt (2 AU, 2 ISE)	Shipment from March 2022 onward
cobas pro Transport Belt (3 AU, 2 ISE)	
cobas pro Transport Belt (4 AU, 2 ISE)	
cobas pro B-Gate Upgrade Kit	
cobas pro B-Gate update kit	
cobas pro liquid waste container	Shipment from November 2022 onward
cobas pro A-Gate Upgrade Kit	

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 pro SSU	From 2001-06 onward (Japan shipment) Shipment from July 2021 onward (China shipment)
cobas pro SB	From 2001-06 onward (Japan shipment) Shipment from July 2021 onward (China shipment)
cobas pro SBL c 503	From 2001-01 onward (Japan shipment) Shipment from July 2021 onward (China shipment)
cobas pro SBL e 801	From 2001-01 onward (Japan shipment) Shipment from July 2021 onward (China shipment)
cobas pro transport line	From 2001-01 onward (Japan shipment) Shipment from July 2021 onward (China shipment)
cobas pro Transport Belt (2 AU, 2 ISE)	Shipment from March 2021 onward
cobas pro Transport Belt (3 AU, 2 ISE)	
cobas pro Transport Belt (4 AU, 2 ISE)	
cobas pro B-Gate Upgrade Kit	From 211523-01 onward
cobas pro B-Gate update kit	From 210744-01 onward
cobas pro liquid waste container	Shipment from March 2021 onward
cobas pro A-Gate Upgrade Kit	Shipment from November 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 62304: 2006 / AC: 2008	Medical device software - Software life-cycle processes
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

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