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 8100 automated workflow series**

We, Hitachi High-Tech Corporation, declare under our sole responsibility that cobas 8100 automated workflow series（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:	The cobas 8100 automated workflow series is an automated, software-controlled system for processing patient samples before they go for analysis. The system is designed to centrifuge patient samples, remove and insert sample tube caps as required, apply barcode labels to secondary tubes, and prepare aliquots from primary samples. It can sort samples for online and offline analysis, and temporarily store samples. The system transports individual samples between modules, and to connected analyzers. The cobas 8100 automated workflow series is intended for use with analyzers that perform tests in the areas of immunology, clinical chemistry, coagulation, urinalysis, and hematology.
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

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Signer Name: Yoshihiro Kawabe
Signing Reason: I approve this document
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Yoshihiro Kawabe
General Manager
Medical Systems Quality Assurance Dept.
Corporate Quality Assurance Div.
Hitachi High-Tech Corporation

on behalf of the company

Date:

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Kenta Imai
Signer Name: Kenta Imai
Signing Reason: I approve this document
Signing Time: 29-May-2024 | 5:33:31 PM JST
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Healthcare Business Group Diagnostic System Business
Hitachi High-Tech Corporation

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

Appendix I

List of components for cobas 8100 automated workflow series

Product name or component name	Basic UDI-DI	Order information	Risk classification for REGULATION (EU) 2017/746
ACU for cobas 8100	761333602157AM	07123868001	Class A
AOB for cobas 8100	761333602158AP	07123914001	Class A
AQM for cobas 8100	761333602159AR	07787138001	Class A
BCL for cobas 8100	761333602160AA	07123922001	Class A
2nd BCL for cobas 8100	761333602161AC	08010595001	Class A
BRF for cobas 8100	761333602162AE	07439954001	Class A
CLO for cobas 8100	761333602163AG	07439997001	Class A
CLW for cobas 8100	761333602164AJ	07440006001	Class A
CRO for cobas 8100	761333602165AL	07440022001	Class A
CRW for cobas 8100	761333602166AN	07440049001	Class A
DSP for cobas 8100	761333602167AQ	07787146001	Class A
IPB for cobas 8100	761333602168AS	07787120001	Class A
2nd IPB for cobas 8100	761333602169AU	08015597001	Class A
OBS for cobas 8100	761333602170AD	07123892001	Class A
PXT for cobas 8100	761333602171AF	07440057001	Class A
RFX for cobas 8100	761333602173AK	07440065001	Class A
RSF for cobas 8100	761333602174AM	07123876001	Class A
RSS for cobas 8100	761333602175AP	08015589001	Class A
SCM for cobas 8100	761333602176AR	07440073001	Class A
SLL for cobas 8100	761333602177AT	07440081001	Class A
SLR for cobas 8100	761333602178AV	07440090001	Class A
TLJ300 for cobas 8100	761333602179AX	07440103001	Class A
TLJ600 for cobas 8100		07440111001	Class A
TLJ900 for cobas 8100		07440120001	Class A
TLJ1200 for cobas 8100		07440138001	Class A
TLJ1500 for cobas 8100		07440146001	Class A
TLJ1800 for cobas 8100		07441541001	Class A
TLJ2100 for cobas 8100		07441592001	Class A
TLJ2400 for cobas 8100		07441606001	Class A
TLJ2700 for cobas 8100		07441614001	Class A
TLJ3000 for cobas 8100		07441622001	Class A
UCU for cobas 8100	761333602180AG	07476124001	Class A
URF for cobas 8100	761333602181AJ	07441657001	Class A
RFU for cobas 8100	761333602959BZ	10165367001	Class A

List of optional components for cobas 8100 automated workflow series

Product name or component name	Basic UDI-DI	Order information	Risk classification for REGULATION (EU) 2017/746
BCL Screw Top Tube Modification Kit	761333602183AN	07123957001	Class A
Connection kit STA-R	761333602184AQ	07474687001	Class A
cobas 6500 URF Modification Kit	761333602185AS	08260125001	Class A
Signal Tower	761333602186AU	07474652001	Class A
c8100 HHT 1 tray IPB/OBS mod kit	761333602187AW	08137536001	Class A
c8100 HHT 2 tray IPB/OBS mod kit	761333602187AW	08137579001	Class A
c8100 HHT +1 tray IPB/OBS mod kit	761333602187AW	08137595001	Class A
c8100 Sysmex Tray OBS mod kit	761333602187AW	08137633001	Class A
c8100 100 pos Tray IPB/OBS mod kit	761333602187AW	08137200001	Class A
c8100 HHT/Sysmex TrayLane Arm cover	761333602188AY	08137218001	Class A
Laser BCR modification kit for BRF	761333602189B2	08433020001	Class A
Laser BCR modification kit for URF	761333602189B2	08433038001	Class A
Laser BCR modification kit for RFX	761333602189B2	08433046001	Class A
Laser BCR modification kit for ACU	761333602189B2	08433054001	Class A
Laser BCR modification kit for AOB	761333602189B2	08433062001	Class A
Laser BCR modification kit for OBS	761333602189B2	08433089001	Class A
Laser BCR modification kit for UCU	761333602189B2	08433097001	Class A
HHT-LLD SCM retrofit kit	761333602798BZ	09968563001	Class A
c8100 MSC modification kit	761333602960BJ	10165375001	Class A
Single Tube Holder (Slim)	761333602961BL	10165391001	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
ACU for cobas 8100	ACB: From 2201-01 onward ACU: From 2201-01 onward
AOB for cobas 8100	From 2201-01 onward
AQM for cobas 8100	From 2201-01 onward
BCL for cobas 8100	From 2201-01 onward
2nd BCL for cobas 8100	From 2201-01 onward
BRF for cobas 8100	From 2201-01 onward
CLO for cobas 8100	From 2201-01 onward
CLW for cobas 8100	From 2201-01 onward
CRO for cobas 8100	From 2201-01 onward
CRW for cobas 8100	From 2201-01 onward
DSP for cobas 8100	From 2201-01 onward
IPB for cobas 8100	From 2201-01 onward
2nd IPB for cobas 8100	From 2201-01 onward
OBS for cobas 8100	From 2201-01 onward
PXT for cobas 8100	From 2201-01 onward
RFX for cobas 8100	From 2201-01 onward
RSF for cobas 8100	From 2201-01 onward
RSS for cobas 8100	From 2201-01 onward
SCM for cobas 8100	From 2201-01 onward
SLL for cobas 8100	From 2201-01 onward
SLR for cobas 8100	From 2201-01 onward
TLJ300 for cobas 8100	From 2203-001 onward
TLJ600 for cobas 8100	From 2206-001 onward
TLJ900 for cobas 8100	From 2209-001 onward
TLJ1200 for cobas 8100	From 2212-001 onward
TLJ1500 for cobas 8100	From 2215-001 onward
TLJ1800 for cobas 8100	From 2218-001 onward
TLJ2100 for cobas 8100	From 2221-001 onward
TLJ2400 for cobas 8100	From 2224-001 onward
TLJ2700 for cobas 8100	From 2227-001 onward
TLJ3000 for cobas 8100	From 2230-001 onward
UCU for cobas 8100	From 2201-01 onward
URF for cobas 8100	From 2201-01 onward
RFU for cobas 8100	From 2401-01 onward
BCL Screw Top Tube Modification Kit	Shipment from March 2022 onward
Connection kit STA-R	Shipment from March 2022 onward
cobas 6500 URF Modification Kit	Shipment from March 2022 onward
Signal Tower	Shipment from March 2022 onward
c8100 HHT 1 tray IPB/OBS mod kit	Shipment from March 2022 onward
c8100 HHT 2 tray IPB/OBS mod kit	Shipment from March 2022 onward
c8100 HHT +1 tray IPB/OBS mod kit	Shipment from March 2022 onward

Product name or component name	Starting serial number
c8100 Sysmex Tray OBS mod kit	Shipment from March 2022 onward
c8100 100 pos Tray IPB/OBS mod kit	Shipment from March 2022 onward
c8100 HHT/Sysmex TrayLane Arm cover	Shipment from March 2022 onward
Laser BCR modification kit for BRF	Shipment from March 2022 onward
Laser BCR modification kit for URF	Shipment from March 2022 onward
Laser BCR modification kit for RFX	Shipment from March 2022 onward
Laser BCR modification kit for ACU	Shipment from March 2022 onward
Laser BCR modification kit for AOB	Shipment from March 2022 onward
Laser BCR modification kit for OBS	Shipment from March 2022 onward
Laser BCR modification kit for UCU	Shipment from March 2022 onward
HHT-LLD SCM retrofit kit	Shipment from June 2023 onward
c8100 MSC modification kit	Shipment from March 2024 onward
Single Tube Holder (Slim)	Shipment from March 2024 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
ACU for cobas 8100	ACB:20C3-01 onward ACU:2091-01 onward
AOB for cobas 8100	20B7-02 onward
AQM for cobas 8100	2094-01 onward
BCL for cobas 8100	2084-02 onward
2nd BCL for cobas 8100	2106-01 onward
BRF for cobas 8100	20P0-01 onward
CLO for cobas 8100	2106-01 onward
CLW for cobas 8100	2129-01 onward
CRO for cobas 8100	2128-01 onward
CRW for cobas 8100	20A8-01 onward
DSP for cobas 8100	20C1-01 onward
IPB for cobas 8100	20B9-01 onward
2nd IPB for cobas 8100	2104-01 onward
OBS for cobas 8100	20E6-01 onward
PXT for cobas 8100	2121-01 onward
RFX for cobas 8100	2136-01 onward
RSF for cobas 8100	20A6-03 onward
RSS for cobas 8100	2132-01 onward
SCM for cobas 8100	2063-02 onward
SLL for cobas 8100	2115-01 onward
SLR for cobas 8100	2115-01 onward
TLJ300 for cobas 8100	2103-001 onward
TLJ600 for cobas 8100	2106-001 onward
TLJ900 for cobas 8100	2109-001 onward
TLJ1200 for cobas 8100	2112-001 onward
TLJ1500 for cobas 8100	2115-001 onward
TLJ1800 for cobas 8100	2118-001 onward

Product name or component name	Starting serial number
TLJ2100 for cobas 8100	2121-001 onward
TLJ2400 for cobas 8100	2124-001 onward
TLJ2700 for cobas 8100	2127-001 onward
TLJ3000 for cobas 8100	2130-001 onward
UCU for cobas 8100	2128-01 onward
URF for cobas 8100	2035-02 onward
RFU for cobas 8100	2401-01 onward
BCL Screw Top Tube Modification Kit	Shipment from January 2021 onward
Connection kit STA-R	Shipment from January 2021 onward
cobas 6500 URF Modification Kit	Shipment from January 2021 onward
Signal Tower	Shipment from January 2021 onward
c8100 HHT 1 tray IPB/OBS mod kit	Shipment from January 2021 onward
c8100 HHT 2 tray IPB/OBS mod kit	Shipment from January 2021 onward
c8100 HHT +1 tray IPB/OBS mod kit	Shipment from January 2021 onward
c8100 Sysmex Tray OBS mod kit	Shipment from January 2021 onward
c8100 100 pos Tray IPB/OBS mod kit	Shipment from January 2021 onward
c8100 HHT/Sysmex TrayLane Arm cover	Shipment from January 2021 onward
Laser BCR modification kit for BRF	Shipment from January 2021 onward
Laser BCR modification kit for URF	Shipment from January 2021 onward
Laser BCR modification kit for RFX	Shipment from January 2021 onward
Laser BCR modification kit for ACU	Shipment from January 2021 onward
Laser BCR modification kit for AOB	Shipment from January 2021 onward
Laser BCR modification kit for OBS	Shipment from January 2021 onward
Laser BCR modification kit for UCU	Shipment from January 2021 onward
HHT-LLD SCM retrofit kit	Shipment from June 2023 onward
c8100 MSC modification kit	Shipment from March 2024 onward
Single Tube Holder (Slim)	Shipment from March 2024 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
ACU for cobas 8100	ACB:1740-05,1741-01 onward ACU: not applicable
AOB for cobas 8100	1752-01 onward
AQM for cobas 8100	1738-01 onward
BCL for cobas 8100	1730-01 onward
2nd BCL for cobas 8100	1702-01 onward
BRF for cobas 8100	1786-02,03,04,05,1788-01 onward
CLO for cobas 8100	1702-01 onward
CLW for cobas 8100	1713-01 onward
CRO for cobas 8100	1713-01 onward
CRW for cobas 8100	1736-01 onward
DSP for cobas 8100	1742-01 onward
IPB for cobas 8100	1745-01 onward

Product name or component name	Starting serial number
2nd IPB for cobas 8100	1701-01 onward
OBS for cobas 8100	1747-01 onward
RFX for cobas 8100	1713-01 onward
RSF for cobas 8100	1738-01 onward
RSS for cobas 8100	1703-01,1704-01 onward
SCM for cobas 8100	1724-01 onward
SLL for cobas 8100	1706-01 onward
SLR for cobas 8100	1705-02 onward
TLJ300 for cobas 8100	1703-023 onward
TLJ600 for cobas 8100	1706-011 onward
TLJ900 for cobas 8100	1709-006 onward
TLJ1200 for cobas 8100	1712-008 onward
TLJ1500 for cobas 8100	1715-010 onward
TLJ1800 for cobas 8100	1718-013 onward
TLJ2100 for cobas 8100	1721-021 onward
TLJ2400 for cobas 8100	1724-006 onward
TLJ2700 for cobas 8100	1627-017,1727-001 onward
TLJ3000 for cobas 8100	1730-001 onward
UCU for cobas 8100	1707-01 onward
URF for cobas 8100	1611-05,1718-01 onward
RFU for cobas 8100	2401-01 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: 2019/A11:2021	Medical devices - Application of risk management to medical devices
IEC 62304: 2006 +AMD1:2015	Medical device software - Software life-cycle processes
IEC 62366-1:2015 + AMD 1:2020	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 15223-1:2021	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 Or IEC 61010-2-101:2018	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 Or IEC 61326-2-6:2020	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 Or IEC 61010-2-101:2018	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 V2.2.3	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
EN 301 489-3 V2.1.1	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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