HITACHI

EU Declaration of Conformity

Manufacturer:	Hitachi High-Tech Corporation
Address:	1-17-1 Toranomon, Minato-ku Tokyo 105-6409, JAPAN
Single Registration Number:	Not available yet
European Representative:	Roche Diagnostics GmbH
Address:	Sandhofer Strasse 116, 68305 Mannheim, Germany

Product name	Basic UDI-DI	Order information	Risk Class for REGULATION (EU) 2017/746
cobas e 411 analyzer (rack system)	7613336013209Z	04775201001	Class A
cobas e 411 analyzer (disk system)	761333601321A3	04775279001	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 e 411 analyzer (rack system) and the cobas e 411 analyzer (disk system) are automated analyzers including software, intended for running qualitative, semi-quantitative and quantitative immunochemistry assays.
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: 7. July. 2021

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

on behalf of the company

Date: 7th July 2021

Yoshitaka Kodama
General Manager
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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 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

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 e 411 analyzer (rack system)	From 8901-01 onward
cobas e 411 analyzer (disk system)	From 8901-01 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 e 411 analyzer (rack system)	From 8845-03 onward
cobas e 411 analyzer (disk system)	From 8845-01 onward

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