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	Basic UDI-DI	Order information	Risk Class for REGULATION (EU) 2017/746
cobas e 411 analyzer Instrument Software Version 03-02	761333601991BN	09390090001	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

Intended use/purpose:	The cobas e 411 analyzer Instrument Software is an IVD accessory used for driving the cobas e 411 analyzer for in-vitro determinations. The cobas e 411 analyzer language pack is an IVD accessory used for translation of the user interface of the cobas e 411 analyzer into different languages. See the list of the cobas e 411 analyzer language packs 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.:	Not applicable

on behalf of the company

Date: DocuSigned by:

Signer Name: Yoshihiro Kawabe
Signing Reason: I approve this document
Signing Time: 01-6-2022 | 10:09:38 午前 JST
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Yoshihiro Kawabe
General Manager
Medical Systems Quality Assurance Dep't
Corporate Quality Assurance Div.
Hitachi High-Tech Corporation

on behalf of the company

Date: DocuSigned by:

Kazuhiro Nakamura

Signer Name: Kazuhiro Nakamura
Signing Reason: I approve this document
Signing Time: 01-6-2022 | 10:46:56 午前 JST
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Kazuhiro Nakamura
General Manager
Medical Systems Design 2nd Dep't.
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

The list of cobas e 411 analyzer language packs

Name of cobas e 411 analyzer language pack	Update	Order information	Basic UDI-DI
cobas e 411 analyzer Language Pack - French Version 3.2.1.fr	---	09388079001	7613336020049T
cobas e 411 analyzer Language Pack - German Version 3.2.1.de	---	09313893001	
cobas e 411 analyzer Language Pack - English Version 3.2.1.en	---	09313907001	
cobas e 411 analyzer Language Pack - Spanish Version 3.2.1.es	---	09313915001	
cobas e 411 analyzer Language Pack - Portuguese Version 3.2.1.pt	---	09313923001	
cobas e 411 analyzer Language Pack - Italian Version 3.2.1.it	---	09309403001	
cobas e 411 analyzer Language Pack - Bulgarian Version 3.2.1.bg	(*1)	09650571001	
cobas e 411 analyzer Language Pack – Czech Version 3.2.1.cs	(*1)	09309489001	
cobas e 411 analyzer Language Pack - Danish Version 3.2.1.da	(*1)	09309497001	
cobas e 411 analyzer Language Pack– Greek Version 3.2.1.el	(*1)	09742263001	
cobas e 411 analyzer Language Pack– Hungarian Version 3.2.1.hu	(*1)	09742913001	
cobas e 411 analyzer Language Pack– Latvian Version 3.2.1.lv	(*1)	09742956001	
cobas e 411 analyzer Language Pack– Lithuanian Version 3.2.1.lt	(*1)	09742999001	
cobas e 411 analyzer Language Pack – Estonian Version 3.2.1.et	(*1)	09743049001	
cobas e 411 analyzer Language Pack - Norwegian Version 3.2.1.no	(*1)	09743103001	
cobas e 411 analyzer Language Pack – Polish Version 3.2.1.pl	(*1)	09309446001	
cobas e 411 analyzer Language Pack – Romanian Version 3.2.1.ro	(*1)	09650580001	
cobas e 411 analyzer Language Pack – Slovak Version 3.2.1.sk	(*1)	09743146001	
cobas e 411 analyzer Language Pack - Swedish Version 3.2.1.sv	(*1)	09743227001	
cobas e 411 analyzer Language Pack – Turkish Version 3.2.1.tr	(*1)	09743251001	
cobas e 411 analyzer Language Pack - English Version 3.2.2.en	(*1)	09650598001	
cobas e 411 analyzer Language Pack – French Version 3.2.2.fr	(*1)	09650601001	
cobas e 411 analyzer Language Pack – German Version 3.2.2.de	(*1)	09650610001	
cobas e 411 analyzer Language Pack – Spanish Version 3.2.2.es	(*1)	09650628001	
cobas e 411 analyzer Language Pack – Italian Version 3.2.2.it	(*1)	09650636001	
cobas e 411 analyzer Language Pack – Portuguese Version 3.2.2.pt	(*1)	09650644001	
cobas e 411 analyzer Language Pack– Japanese Version 3.2.1.ja_WXP	(*1)	09611029001	

cobas e 411 analyzer Language Pack - Japanese Version 3.2.1.ja_W10	(*1)	09309438001	
cobas e 411 analyzer Language Pack – Chinese Version 3.2.1.zh_WXP	(*1)	09611886001	
cobas e 411 analyzer Language Pack – Chinese Version 3.2.1.zh_W10	(*1)	09309462001	
cobas e 411 analyzer Language Pack – Russian Version 3.2.1.ru	(*1)	09309454001	

(*1) Additional declaration of Language Pack(s) in this DoC

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

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