cobas® 8000 modular analyzer series

Addendum 1.0 to Operator's Manual version 5.2

Publication information

Publication version	Revision date	Change description
1.0	2018-07	First version

Revision history

Edition notice

This addendum contains supplementary information for operators of the **cobas**® 8000 modular analyzer series. It is meant to complement the Operator's Manual Version 5.2.

Trademarks

The following trademarks are acknowledged:

COBAS, COBAS C, COBAS E, COBAS INTEGRA, and LIFE NEEDS ANSWERS are trademarks of Roche.

All other trademarks are the property of their respective owners.

Approvals

The **cobas**® 8000 modular analyzer series meets the requirements laid down in:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.
To view the full text of the 2014/53/EU declaration of conformity, go to the Roche DiaLog Global Web Site (*https://dialog1.roche.com/*) and choose the eLabDoc link.
If you are unable to access Roche DiaLog, contact a Roche Service representative.

The full text of the 2014/53/EU declaration of conformity is available at the following internet address:
http://e-labdoc.roche.com

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Compliance is provided by means of the Declaration of Conformity.

The following marks demonstrate compliance:

For *in vitro* diagnostic use.

Complies with the IVD directive 98/79/EC on *in vitro* diagnostic medical devices

Issued by Intertek for Canada and the US.

Contact addresses

Inside the European Union and EFTA member states

Manufacturer of the instrument	Hitachi High-Technologies Corporation 1-24-14 Nishi-Shimbashi Minato-ku Tokyo 105-8717 Japan
Manufacturer of **cobas**® 8000 data manager	Roche Diagnostics GmbH Sandhofer Strasse 116 D-68305 Mannheim Germany
Authorized representative	Roche Diagnostics GmbH Sandhofer Strasse 116 D-68305 Mannheim Germany

Outside the European Union and EFTA member states

Manufactured by:	Hitachi High-Technologies Corporation
Manufactured for:	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim Germany

Table of contents

Revision 1: Instrument approvals

This addendum includes changes concerning section *Instrument approvals*.

The following standards have been deleted in section *Instrument approvals*:

- IEC 61010-2-081
- UL 61010-1
- CAN/CSA C22.2 No. 61010-1
- CAN/CSA C22.2 No. 61010-2-101
- CAN/CSA C22.2 No. 61010-2-081

Instrument approvals

Furthermore, the instrument is manufactured and tested according to the following international safety standards:

- IEC 61010-1
- IEC 61010-2-101

The instrument complies with the emission and immunity requirements described in standard IEC 61326-2-6/EN 61326-2-6.

Revision 1: Instrument approvals