cobas® 8000 modular analyzer series
Addendum 1.0 to Operator’s Manual version 5.2
Publication information

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<th>Publication version</th>
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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.

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


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


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  
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- **Manufacturer of **cobas®** 8000 data manager**: Roche Diagnostics GmbH  
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**Outside the European Union and EFTA member states**

- **Manufactured by**: Hitachi High-Technologies Corporation

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  Germany
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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

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.