



# cobas<sup>®</sup> 8000 modular analyzer series

Addendum 1.0 to Operator's Manual, Version 5.8  
Software version 06-10

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**cobas<sup>®</sup>**  
*Life needs answers*

## Publication information

Publication version	Software version	Revision date	Change description
1.0	06-10	2023-09	EU legal manufacturer change

y Revision history

### **Edition notice**

This addendum contains supplementary information for users of the cobas® 8000 modular analyzer series.

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# Revision: EU legal manufacturer change

Added references related to the manufacturer inside the EU and EFTA member states.

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## Contact addresses - software

Inside the European Union and EFTA member states

	Manufacturer of the instrument	Hitachi High-Tech Corporation 1-17-1 Toranomon, Minato-ku, Tokyo, 105-6409 Japan
<div><div>EC</div><div>REP</div><div></div></div>	Authorized representative and Importer	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim Germany

Outside the European Union and EFTA member states

Manufactured by:	Hitachi High-Tech Corporation
Manufactured for:	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim Germany
Distributed in USA by:	Roche Diagnostics 9115 Hague Road Indianapolis, Indiana, USA

## Contact addresses - instrument

The manufacturer roles inside the EU and EFTA member states for Roche Diagnostics GmbH and Hitachi High-Tech Corporation have changed.

This change does not impact the U.S. registration status. There is no impact to the product's name, material number, design, and specifications resulting from the change in the manufacturer roles. The contacts for incident reporting remain unchanged.

The manufacturer of specific instruments is provided by means of the Declarations of Conformity. Check the serial number of the instruments to identify the manufacturer information.

All documents are available under eLabDoc on the Roche DiaLog global website (<https://dialog.roche.com>).

If you are unable to access Roche DiaLog, contact your Roche Service representative.

### Previous roles and responsibilities

Inside the European Union and EFTA member states



Manufacturer of the instrument

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



Authorized representative

Roche Diagnostics GmbH  
Sandhofer Strasse 116  
68305 Mannheim  
Germany



Outside the European Union and EFTA member states

Manufactured by:

Hitachi High-Tech Corporation

Manufactured for:

Roche Diagnostics GmbH  
Sandhofer Strasse 116  
68305 Mannheim  
Germany

Distributed in USA by: Roche Diagnostics  
9115 Hague Road  
Indianapolis, Indiana, USA

### New roles and responsibilities



Manufacturer of the instrument Roche Diagnostics GmbH  
Sandhofer Strasse 116  
68305 Mannheim  
Germany

Distributed in USA by: Roche Diagnostics  
9115 Hague Road  
Indianapolis, Indiana, USA

### Roche affiliates

A list of all Roche affiliates can be found at:

[www.roche.com/about/business/roche\\_worldwide.htm](http://www.roche.com/about/business/roche_worldwide.htm)

### eLabDoc

Electronic user documentation can be downloaded using the eLabDoc e-service from the Roche DiaLog portal:

<https://dialog.roche.com>

For more information, contact your local affiliate or Roche Service representative.