

# Compliance matrix

This document lists the compliance of the **cobas**<sup>®</sup> 8000 modular analyzer series to applicable directives and regulations, traceable by serial number.

The compliance is provided by means of the Declaration of Conformity.

## EU In Vitro Diagnostic Regulation (IVDR)

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	Applicable serial numbers (S/N)
<b>cobas</b> <sup>®</sup> 8000 - Core unit	From 2201-01 onward
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 701 module	From 2201-01 onward
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 702 module	From 2201-01 onward
<b>cobas e</b> 801 module	From 2201-01 to 31Z9-10 From 4201-01 onward
<b>cobas e</b> 801 analytical unit	From 2201-01 to 31Z9-10 From 4201-01 onward
<b>cobas e</b> 801 MSB/MSBL	From 2201-01 onward
<b>cobas</b> <sup>®</sup> 8000 - ISE 900 module	From 2201-01 onward
<b>cobas</b> <sup>®</sup> 8000 - ISE 1800 module	From 2201-01 onward
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 502 module	Not applicable
<b>cobas</b> <sup>®</sup> 8000 - <b>e</b> 602 module	Not applicable

## EU In Vitro Diagnostic Directive (IVDD)

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

Product	Applicable serial numbers (S/N)
<b>cobas</b> <sup>®</sup> 8000 - Core unit	Up to 21Z9-10
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 701 module	Up to 21Z9-10
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 702 module	Up to 21Z9-10
<b>cobas e</b> 801 module	Up to 21Z9-10 From 4101-01 to 41Z9-10
<b>cobas e</b> 801 analytical unit	Up to 21Z9-10 From 4101-01 to 41Z9-10
<b>cobas e</b> 801 MSB/MSBL	Up to 21Z9-10
<b>cobas</b> <sup>®</sup> 8000 - ISE 900 module	Up to 21Z9-10
<b>cobas</b> <sup>®</sup> 8000 - ISE 1800 module	Up to 21Z9-10
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 502 module	All serial numbers
<b>cobas</b> <sup>®</sup> 8000 - <b>e</b> 602 module	All serial numbers

## Restriction of Hazardous Substances (RoHS)

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	Applicable serial numbers (S/N)
<b>cobas</b> <sup>®</sup> 8000 - Core unit	From 21Y2-01 onward
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 701 module	From 20S4-01 onward
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 702 module	From 2093-01 onward
<b>cobas e</b> 801 module	From 2070-01 onward
<b>cobas e</b> 801 analytical unit	From 2070-01 onward
<b>cobas e</b> 801 MSB/MSBL	From 2004-01 onward
<b>cobas</b> <sup>®</sup> 8000 - ISE 900 module	From 20G3-08 onward
<b>cobas</b> <sup>®</sup> 8000 - ISE 1800 module	From 21G3-01 onward
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 502 module	Not applicable
<b>cobas</b> <sup>®</sup> 8000 - <b>e</b> 602 module	Not applicable

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:

Product	Applicable serial numbers (S/N)
<b>cobas</b> <sup>®</sup> 8000 - Core unit	From 16S4-01 onward
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 701 module	From 16E9-01 onward
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 702 module	From 16F9-01 onward
<b>cobas e</b> 801 module	From 1601-01 onward
<b>cobas e</b> 801 analytical unit	From 1817-01 onward
<b>cobas e</b> 801 MSB/MSBL	From 1817-01 onward
<b>cobas</b> <sup>®</sup> 8000 - ISE 900 module	From 16E1-01 onward
<b>cobas</b> <sup>®</sup> 8000 - ISE 1800 module	From 16E3-01 onward
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 502 module	From 16A8-01 onward
<b>cobas</b> <sup>®</sup> 8000 - <b>e</b> 602 module	From 15J6-01 onward

## Radio Equipment Directive (RED)

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:

Product	Applicable serial numbers (S/N)
<b>cobas</b> <sup>®</sup> 8000 - Core unit	Not applicable
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 701 module	From 16G6-01 onward
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 702 module	From 16K5-01 onward
<b>cobas e</b> 801 module	From 1748-01 onward
<b>cobas e</b> 801 analytical unit	From 1801-01 onward
<b>cobas e</b> 801 MSB/MSBL	From 1801-01 onward
<b>cobas</b> <sup>®</sup> 8000 - ISE 900 module	Not applicable
<b>cobas</b> <sup>®</sup> 8000 - ISE 1800 module	Not applicable
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 502 module	Not applicable
<b>cobas</b> <sup>®</sup> 8000 - <b>e</b> 602 module	Not applicable

## Regulation on Fluorinated Greenhouse Gases

Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006:

Product	Applicable serial numbers (S/N)
<b>cobas</b> <sup>®</sup> 8000 - Core unit	Not applicable
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 701 module	From 16G6-01 onward
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 702 module	From 16K2-01 onward
<b>cobas e</b> 801 module	From 1601-01 onward
<b>cobas e</b> 801 analytical unit	From 1817-01 onward
<b>cobas e</b> 801 MSB/MSBL	Not applicable
<b>cobas</b> <sup>®</sup> 8000 - ISE 900 module	Not applicable
<b>cobas</b> <sup>®</sup> 8000 - ISE 1800 module	Not applicable
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 502 module	From 16D1-01 onward
<b>cobas</b> <sup>®</sup> 8000 - <b>e</b> 602 module	Not applicable

### Fluorinated Greenhouse Gas<sup>1</sup>

Product	R-134a	R-1234yf
	Applicable serial numbers (S/N)	
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 701 module	Up to 21S9-05	From 21U0-01 onward
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 702 module	Up to 21S9-05	From 21B4-01 onward
<b>cobas e</b> 801 module	Up to 31Z9-10	From 4101-01 onward
<b>cobas e</b> 801 analytical unit	Up to 31Z9-10	From 4101-01 onward
<b>cobas</b> <sup>®</sup> 8000 - <b>c</b> 502 module	All serial numbers	Not applicable

<sup>1</sup> Refer to **cobas**<sup>®</sup> 8000 Operators Manual, chapter: Specifications > General Specifications > Fluorinated Greenhouse Gas