Compliance matrix

This document lists the compliance of the **cobas e** 411 analyzer 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)
cobas e 411 analyzer (rack system)	From 8901-01 onward
cobas e 411 analyzer (disk system)	From 8901-01 onward

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)
cobas e 411 analyzer (rack system)	From 16E3-01 and 6361-01 onward
cobas e 411 analyzer (disk system)	From 16E3-06 and 6359-01 onward

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)
cobas e 411 analyzer (rack system)	From 8845-03 onward
cobas e 411 analyzer (disk system)	From 8845-01 onward

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)
cobas e 411 analyzer (rack system)	From 16E3-01 and 6361-01 onward
cobas e 411 analyzer (disk system)	From 16E3-06 and 6359-01 onward