

Cobas e411



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Certificate No. 1524-3-2014

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(One Page)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Leila M. Lawrence
Chief, Export Branch
Division of International Compliance Operations
Office of Compliance
Center for Devices and Radiological Health

This certificate is valid from March 19, 2014 to March 18, 2016.





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Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer

ROCHE DIAGNOSTICS GMBH
SANDHOFER STRASSE 116
MANNHEIM, Baden-Wurtemberg GERMANY D-68305

Name of Distributor

ROCHE DIAGNOSTICS OPERATIONS INC
9115 Hague Rd
Indianapolis, IN USA 46250

---END OF MANUFACTURER/DISTRIBUTOR LIST---





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Name of Product(s)

cobas e 411 Analyzer 04775279001

cobas c 311 Analyzer 04826876001

-----END OF PRODUCT LIST-----

