



U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

JAN 27 2019

Mike Flis
Regulatory Director
Roche Diabetes Care, Inc.
9115 Hague Rd
Indianapolis, IN 46256

Dear Mr. Mike Flis,

This is in response to your Certificate of Exportability Section 801(e)(1) request. This Certificate of Exportability Section 801(e)(1) only attests to the status of your product under the Federal Food, Drug, and Cosmetic Act. You are responsible for assuring that your product, when exported to these countries, is in compliance with all other US laws and regulations regarding export of such products to these specific countries. Enclosed are the certificates that you requested. If you have any additional questions, please let us know.

Export Branch
Division of International Compliance Operations
Office of Compliance
Center for Devices and Radiological Health
301-796-7400
exportcert@cdrh.fda.gov

Enclosure:

1 Certificate(s)
4068-1-2019



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Certificate No. 4068-1-2019

CERTIFICATE OF EXPORTABILITY SECTION 801(e)(1)

The Food and Drug Administration certifies that the product(s) described below is subject to its jurisdiction under the Federal Food, Drug, and Cosmetics Act (the Act). The products described below may not be sold or offered for sale in the United States. The company has certified to the Food and Drug Administration that:

- * the product(s) accords to the specifications of the foreign purchaser;
- * the product(s) is not in conflict with the laws of the country to which it is intended for export;
- * the shipping package for the product(s) is labeled on the outside that it is intended for export;
and
- * the product(s) is not sold or offered for sale in the United States.

Based on the information above, the product(s) listed below may be exported pursuant to Section 801(e)(1) of the Act.

Name of Product(s)

See Attached List
(One Page)

Name of Company, Address

ROCHE DIABETES CARE, INC.
9115 Hague Road
Indianapolis, IN USA 46250

CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from January 22, 2019 to January 21, 2021.





**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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Certificate No. 4068-1-2019

Certificate of Exportability Section 801(e)(1) - Name of Product(s) Attachment Page 1 of 1

Name of Company, Address

ROCHE DIABETES CARE, INC.
9115 Hague Road
Indianapolis, IN USA 46250

Name of Product(s)

Accu-Chek Instant x25 strips, 07819374023

Accu-Chek Instant x50 strips, 07819382023

Accu-Chek Instant meter, 07819323036

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

