DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Certificate No. 8240-4-2017

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)	**Name of Manufacturer/Distributor, Address**
See Attached List	See Attached List
(One Page)	(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 device product(s) may be marketed in, and legally exported from, the United States of America at this time. While the manufacturing plant(s) in which the device product(s) is produced is subject to inspection, FDA does not routinely inspect manufacturing firms that only make Class 1 medical devices. However, the firm has certified that it is currently operating in substantial compliance with current good manufacturing practice requirements for the device product(s) listed above.

Robin W. Newman

Robin W. Newman MSN EdD CPNP
Director
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from April 14, 2017 to April 13, 2019.

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

Name of Owner Operator

NORTH AMERICAN BRACES LLC
2888 LOKER AVENUE EAST
210 G
Carlsbad, CA USA 92010

Name of Manufacturer

NORTH AMERICAN BRACES LLC
2888 LOKER AVENUE EAST
210 G
Carlsbad, CA USA 92010

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

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Name of Product(s)

WIRE CLAMPS
EXPANSION SCREW
ALIGNERS
BAND MATERIAL
PLIERS
BAND PUSHER
ORTHODONTIC BRACKETS
BAND DRIVER
SPRINGS
ORTHODONTIC TUBES
PREFORMED BANDS
ORTHODONTIC WIRES
BAND SETTER
ELASTIC BAND
LIGATURE TUCKING

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