

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by CDR Cesar A. Perez, PhD, Director

3. acting in the capacity of DRP2: Division of Establishment Support

4. bears the seal/stamp of U. S. Department of Health and Human Services

Certified

5. at Washington, D.C.

6. the twenty-eighth of January, 2020

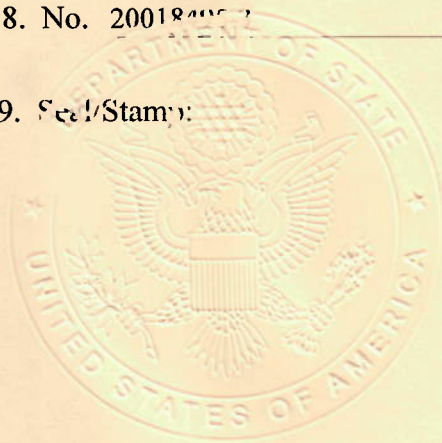
7. by *Assistant Authentication Officer, United States Department of State*

8. No. 200182252

9. Seal/Stamp:

10. Signature:

Sonya N. Johnson





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

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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

Certificate No. 3854-1-2020

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

(Two Pages)

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.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from January 09, 2020 to January 08, 2022.





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

Name of Manufacturer

Legal Manufacturer

3M COMPANY

3M Center, 2510 Conway Ave.

Bldg. 275-5W-06

Saint Paul, MN USA 55144

Manufacturing Facility

3M CANADA CO.

400 RT. 100

MORDEN, Manitoba CANADA R6M 1Z9

Name of Distributor

Distributor

3M COMPANY

806 W. CRYSTAL LAKE RD.

FOREST CITY, IA USA 50436

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





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3M CANADA CO.
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MORDEN, Manitoba CANADA R6M 1Z9

Name of Distributor

Distributor

3M COMPANY
806 W. CRYSTAL LAKE RD.
FOREST CITY, IA USA 50436

Name of Product(s)

3M™ Double-Stick Discs
2181

3M™ Red Dot™ Monitoring Electrode with Foam Tape
2228, 2228-3, 2228-5, 2228BA

3M™ Red Dot™ Monitoring Electrode
2230, 2235, 2237, 2237-3, 2237-5, 2238, 2238-3, 2238-5, 2239
2245-50, 2248-50, 2249, 2249-50, 2255-50, 2259-50
2270-5, 2270-50, 9642

3M™ Red Dot™ Diaphoretic Monitoring Electrode
2231, 2271-50

3M™ Red Dot™ Trace Prep
2236

3M™ Red Dot™ Radiolucent Monitoring Electrode with Foam Tape
2244

3M™ Red Dot™ Wet Gel Monitoring Electrode
2256-50

3M™ Red Dot™ ECG Monitoring Electrode
2268-3, 2268-5

3M™ Red Dot™ Neonatal Monitoring Electrode with Pre-Attached Lead Wire
2269T

3M™ Red Dot™ Prewired Monitoring Electrode
2289PA, 2289PAL, 2289T

3M™ Red Dot™ Monitoring Electrode with Foam Tape and Sticky Gel
2560, 2560-3, 2560-5

3M™ Red Dot™ Radiolucent Monitoring Electrode with Foam Tape,
Sticky Gel and Abrader Pad
2570, 2570-3, 2570-5





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Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 2

3M™ Red Dot™ Repositionable Monitoring Electrode

2660-3, 2660-5, 2670-3, 2670-5

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

