

# APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by *Cesar A. Perez*

3. acting in the capacity of *Director, Office of Regulatory Programs*

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

## Certified

5. at Washington, D.C.

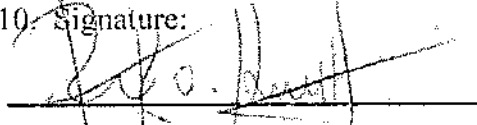
6. the *fifteenth* of June, 2020

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

8. No. *200251111*

9. *for*

10. Signature:

  
Patrick O. Hatchett



U.S. FOOD & DRUG  
ADMINISTRATION

U.S. Food and Drug Administration  
10903 Newpark Blvd., Suite 100  
San Diego, CA 92121  
(619) 291-6000

Certificate No. 6415-2-2020

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

(Four 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 March 10, 2020 to March 09, 2022.





U.S. FOOD & DRUG ADMINISTRATION

1001 15th St., N.W., Washington, D.C. 20505

Division of Regulatory Affairs  
Office of Regulatory Affairs  
Office of Regulatory Affairs  
Office of Regulatory Affairs

Certificate No. 6415-2-2020

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

Name of Manufacturer

Manufacturing Facility

3M COMPANY

601 22ND AVE. SOUTH

BROOKINGS, SD USA 57006

Legal Manufacturer

3M COMPANY

3M Center, 2510 Conway Ave.

Bldg. 275-5W-06

Saint Paul, MN USA 55144

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





Certificate No. 6415-2-2020

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 4

Name of Manufacturer

Manufacturing Facility

3M COMPANY  
601 22ND AVE. SOUTH  
BROOKINGS, SD-USA 57006

Legal Manufacturer

3M COMPANY  
3M Center, 2510 Conway Ave.  
Bldg. 275-5W-06  
Saint Paul, MN USA 55144

Name of Product(s)

3M™ Attest™ Biological Indicators for Steam - 1261, 1261P  
1261, 1261P

3M™ Attest™ Biological Indicators for Steam - 1262, 1262P  
1262, 1262P

3M™ Attest™ Biological Indicators and Test Packs for Ethylene Oxide  
1264, 1264P

3M™ Attest™ Rapid Readout Biological Monitoring System  
1291, 1292

3M™ Attest™ 1294 Rapid Readout Biological Indicator for EO  
1294

3M™ Attest™ Rapid Readout Biological Indicator  
1295

3M™ Attest™ Super Rapid Readout Biological Indicator 1491  
1491

3M™ Attest™ Super Rapid Readout Biological Indicator 1492V  
1492V, 1492VS

3M™ Blenderm™ Surgical Tape  
1525-0, 1525-1, 1525-2

3M™ Coban™ Self-Adherent Wrap  
1581, 1581B, 1582, 1582B, 1583, 1583A, 1583B, 1583G, 1583N, 1583R,  
1583S, 1583W, 1583Y, 1584, 1584B, 1584L, 1584S, 1586, 1586S

3M™ Coban™ LF Latex Free Self-Adherent Wrap  
2081, 2081S, 2082, 2083, 2083S, 2084, 2084L, 2084S, 2084K, 2086, 2086K, 2086S,  
2081C, 2081SC, 2082C, 2083C, 2084C, 2086C

3M™ Coban™ NL Non-Latex Self Adherent Wrap  
2081, 2081S, 2082, 2083, 2083S, 2084, 2084L, 2084S, 2084K, 2086, 2086K, 2086S,  
2081C, 2081SC, 2082C, 2083C, 2084C, 2086C, 2082-1X, 2083-1X, 2084-1X, 2086-1X

3M™ Coban™ 2 Two-Layer Compression System  
2094, 2094N

3M™ Coban™ 2 Lite Two-Layer Compression System  
2794, 2794N





U.S. FOOD & DRUG  
ADMINISTRATION

U.S. Food & Drug Administration  
Washington, D.C. 20204  
202-201-2099  
www.fda.gov

Certificate No. 6415-2-2020

Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 4

3M™ Comply™ Indicator Tape  
1228

3M™ Defib Pads  
2345N, 2346N

3M™ Durapore™ Surgical Tape  
1538S-1, 1538S-2, 1538-0, 1538-1, 1538-2, 1538-3

3M™ Ioban™ 2  
6635, 6640, 6640EZ, 6640EZSB, 6648, 6648EZ, 6648EZSB, 6650, 6650EZ, 6650EZSB  
6651, 6651EZ, 6651EZSB, 6651EZ

3M™ Kind Removal Silicone Tape  
2770S-1, 2770S-2

3M™ Medipore™ H Soft Cloth Surgical Tape  
2860S-1, 2860S-2, 2860S-4, 2860S-6, 2861, 2862, 2862S, 2863, 2864, 2864S,  
2866, 2866S, 2868

3M™ Medipore™ Soft Cloth Pre-cut Dressing Covers  
2954, 2955, 2956, 2957, 2958

3M™ Medipore™ Soft Cloth Surgical Tape  
2961, 2962, 2962S, 2963, 2964, 2964S, 2966, 2966S, 2968

3M™ Medipore™ +Pad Soft Cloth Adhesive Wound Dressing  
3562, 3564, 3566, 3568, 3569, 3570, 3571, 3573

3M™ Microfoam™ Surgical Tape  
1528-1, 1528-2, 1528-3, 1528-4

3M™ Micropore™ Surgical Tape  
1530-0, 1530-1, 1530-2, 1530-3, 1530S-1, 1530S-2, 1533-0, 1533-1, 1533-2,  
1535-0, 1535-1, 1535-2, 1535-3

3M™ Reston™ Self-Adhering Foam Pads & Rolls  
1560M, 1561H, 1563L, 2851H

3M™ Reusable Cold/Hot Pack  
1570

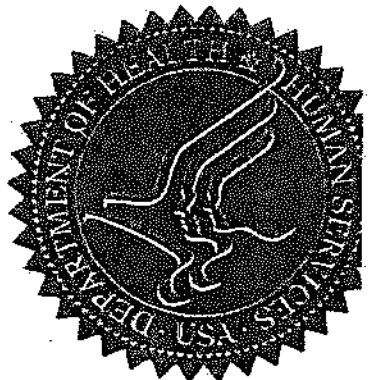
3M™ Sten-Drape™  
1000, 1000NSD, 1000DISP, 1000NSR, 1010, 1010NSD, 1015, 1015NSD, 1020, 1021, 1030,  
1033, 1040, 1050, 1051, 1060, 1061, 1071, 1115, 2037, 2040, 2045, 2050, 2051

3M™ Steri-Strip™ Antimicrobial Skin Closures (Reinforced)  
A1840, A1841, A1842, A1846, A1847, A1848

3M™ Steri-Strip™ Blend Tone Skin Closures  
B1550, B1551, B1553, B1557, B1559

3M™ Steri-Strip™ Compound Benzoin Tincture  
C1544

3M™ Steri-Strip™ Elastic Skin Closures  
E4540, E4541, E4542, E4546, E4547, E4548, E4549





U.S. FOOD & DRUG

ADMINISTRATION

112 2nd Street, N.W.  
Washington, D.C. 20540  
202-205-2000  
www.fda.gov

Certificate No. 6415-2-2020

Certificate to Foreign Government - Name of Product(s) Attachment Page 3 of 4

3M™ Steri-Strip™ Skin Closures (Reinforced)

R1540, R1541, R1541NS, R1542, R1546, R1547, R1547NS, R1548, R1549

3M™ Steri-Strip™ Wound Closure System

W8512, W8514, W8516

3M™ Tegaderm™ +Pad

Film Dressing with Nonadherent Pad

3582, 3584, 3586, 3587, 3588, 3589, 3590, 3591, 3593

3M™ Tegaderm™ Hydrocolloid

Hydrocolloid Dressing

90001, 90002, 90003, 90004, 90005, 90007

3M™ Tegaderm™ Hydrocolloid THIN

Thin Hydrocolloid Dressing

90021, 90022, 90023, 90024

3M™ Tegaderm™ Foam

High Performance Foam Non-Adhesive Dressing

90600, 90601, 90602, 90603, 90604, 90605

3M™ Tegaderm™ Foam Adhesive

High Performance Foam Adhesive Dressing

90610, 90611, 90612, 90613, 90614, 90616, 90619

3M™ Tegaderm™ Foam Adhesive Dressing with Soft Cloth Border

90615

3M™ Tegaderm™ Absorbent Clear Acrylic Dressing

90800, 90801, 90802, 90803, 90805, 90807, 90815, 90817

3M™ Tegaderm™ HP

HP Transparent Film Dressing Frame Style

9519HP, 9534HP, 9536HP, 9543HP, 9545HP, 9546HP, 9548HP, 9519NS, 9534NS, 9536NS, 9546NS, 9634HP

3M™ Tegaderm™ IV

IV Transparent Film Dressing with Border

9525HP, 9525NS, 9634HP

3M™ Tegaderm™ I.V.

I.V. Transparent Film Dressing with Border

1610, 1610NS, 1650, 1650NS, 1655, 1655NS

3M™ Tegaderm™ Film

Transparent Film Dressing with Border

1614, 1614NS, 1616, 1616NS

3M™ Tegaderm™ Transparent Film Dressing with Label

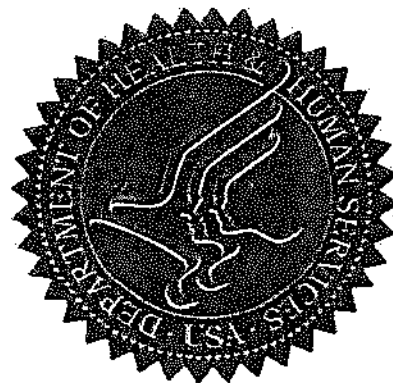
1620, 1620NS, 1621, 1621NS

3M™ Tegaderm™ Film

Transparent Film Dressing Frame Style

1622W, 1624W, 1624WNS, 1626, 1626W, 1626WNS, 1627, 1628, 1628NS, 1629, 1630, 1630NS, 1634, 9505W, 9506W

3M™ Tegaderm™ CHG





U.S. FOOD & DRUG

ADMINISTRATION

File name: 6415-2-2020  
Product name: 1657-0, 1657-1, 1657-2, 1657-3, 1657S-1, 1657S-2  
Date: 06/01/2020

Certificate No. 6415-2-2020

Certificate to Foreign Government - Name of Product(s) Attachment Page 4 of 4

Chlorhexidine Gluconate IV Securement Dressing

1657, 1658, 1659, 1660, 1657R, 1658R, 1659R, 1660R

3M™ Tegaderm™ Diamond Film

Diamond Pattern Film Dressing

1674, 1675, 1679, 1679NS, 1684, 1684NS, 1686, 1686NS

3M™ Tegaderm™ I.V. Advanced

Advanced Securement Dressing

1680, 1681, 1682, 1683, 1683NS, 1685, 1685NS, 1688, 1688NS, 1689, 1689NS, 1699, 1882, 1882NS

3M™ Tegaderm™ I.V. Transparent Film Dressing with Adhesive-Free Window

1668, 1668NS

3M™ Tegaderm™ Silicone Foam Border Dressing

90640, 90641, 90642, 90643, 90646, 90647, 90648

3M™ Tegaderm™ Silicone Foam Dressing

90631, 90632

3M™ Transpore™ Surgical Tape

1527-0, 1527-1, 1527-2, 1527-3, 1527S-1, 1527S-2

3M™ Transpore™ White Surgical Tape

1534S-1, 1534S-2

END OF PRODUCT LIST

