



Certificate No. 5005-5-2016

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.

Carl Fischer, Ph.D.  
Director  
Division of International Compliance Operations  
Office of Compliance  
Center for Devices and Radiological Health

This certificate is valid from May 24, 2016 to May 23, 2018.





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

Name of Manufacturer

Legal Manufacturer

Covidien LLC  
15 HAMPSHIRE ST  
MANSFIELD, MA USA 02048

Manufacturer

Covidien  
Boulevard Insurgentes 19030 Libramiento  
TIJUANA, B.C., Mexico MEXICO 22225

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







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MANSFIELD, MA USA 02048

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Boulevard Insurgentes 19030 Libramiento

TIJUANA, B.C., Mexico MEXICO 22225

Name of Product(s)

Oximax Sensors

MAXR Adult SpO2 Nasal Sensor

MAXRI Adult SpO2 Nasal Sensor

MAXP Pediatric SpO2 Sensor

MAXPI Pediatric SpO2 Sensor

MAXP-NS Pediatric SpO2 Sensor

MAXN Neonatal-Adult SpO2 Sensor

MAXNI Neonatal-Adult SpO2 Sensor

MAXN-NS Neonatal-Adult SpO2 Sensor

SC-PR Premie SpO2 Sensor

SC-PR-I Premie SpO2 Sensor

SCNEO Neonatal SpO2 Sensor

SCNEO-I Neonatal SpO2 Sensor

SC-A Adult SpO2 Sensor

SC-A-I Adult SpO2 Sensor

MAXI Infant SpO2 Sensor

MAXII Infant SpO2 Sensor

MAXI-NS Infant SpO2 Sensor

MAXFAST Forehead SpO2 Sensor

MAXFASTI Forehead SpO2 Sensor

MAXAL Adult XL SpO2 Sensor

MAXALI Adult XL SpO2 Sensor

MAXAL-NS Adult XL SpO2 Sensor

MAXA Adult SpO2 Sensor

MAXAI Adult SpO2 Sensor

MAXA-NS Adult SpO2 Sensor

MAXPAC Adult Sensor Pack

MAXPACI Adult Sensor Pack

RS10 Forehead SpO2 Sensor

Reusable Sensors

OXI-A/N Adult-Neonatal SpO2 Sensor with Wraps

OXI-P/I Pediatric-Infant SpO2 Sensor with Wraps

D-YS SpO2 Sensor

D-YSE SpO2 Ear Sensor Clip

D-YSPD Pediatric SpO2 Sensor Clip

DS100A Adult SpO2 Sensor

DS100A-1 Adult SpO2 Sensor

ADH-P/I Pediatric/Infant Adhesive Sensor Wrap

Oxicliq Sensors

N Neonatal/Adult SpO2 Sensor

NI Neonatal/Adult SpO2 Sensor

P Pediatric SpO2 Sensor

PI Pediatric SpO2 Sensor

A Adult SpO2 Sensor

AI Adult SpO2 Sensor

I Infant SpO2 Sensor





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**II Infant SpO2 Sensor**

**Inspiratory/Expiratory Bacterial Filters**

4-010793-00 Main Flow Bacteria Filter

4-006306-00 Main Flow Bacteria Filter

4-006308-00 Main Flow Bacteria Filter

4-070305-00 Re/X800 Expiratory Filter

4-000618-00 Flex Tube

4-000057-00 Flex Tube

4-000613-00 Flex Tube

4-000616-00 Flex Tube

4-000614-00 Flex Tube

4-003791-00 Nebulizer Filter

4-011905-00 Bacteria Filter Assembly

4-076887-00 D/X800 Expiratory Filter

4-003443-00 Coupling Bacteria Filter

4-074613-00 Drain Port Cap

4-074647-00 Exhalation Filter

4-070311-00 Exhalation Filter Seal

4-018510-00 Adult Breathing Circuit

4-018743-00 Adult Breathing Circuit

G-060525-00 Re/X700 Reusable Expiratory Filter

G-061455-00 Silicone Tube Kit

**Patient Warming Blankets**

5030810 Full-Body /Multi Access Blanket

5030840 Pediatric Blanket

5030850 Pediatric Surgical Blanket

5030860 Cardiac Blanket

5030870 Upper Body Blanket

5030880 Lower Body Blanket

5030890 Surgical Access Blanket

5030900 Torso Blanket

**ADAM Interface System**

Y-101826-00 Soft Headgear CPAP Interface Circuit Kit

Y-100874-00 Soft Headgear CPAP Interface Circuit Kit

Y-100873-00 Soft Headgear CPAP Interface Circuit Kit

Y-100872-00 Soft Headgear CPAP Interface Circuit Kit

Y-100871-00 Soft Headgear CPAP Interface Circuit Kit

Y-101824-00 Soft Headgear CPAP Interface Circuit Kit

Y-101825-00 Soft Headgear CPAP Interface Circuit Kit

Y-101827-00 Soft Headgear CPAP Interface Circuit Kit

Y-101828-00 Nasal CPAP Mask

Y-133283-00C Nasal Ventilation Circuit

**Breeze SleepGear CPAP Interface**

Y-101976-00 Tubing (15 mm) and Swivel Adapter (15 mm / 22 mm)

Y-102640-00 CPAP Interface Headgear for Nasal Mask or Nasal Pillows

Y-102950-00 CPAP Interface Cradle

Y-103059-00A CPAP Interface with Nasal Cushion Assembly

Y-102617-00 Nasal Mask CPAP Interface

Y-102620-00 Nasal Mask CPAP Interface

Y-103060-00A Nasal Mask CPAP Interface

Y-103075-00A Nasal Mask CPAP Interface

Y-102639-00 Nasal Mask CPAP Interface

Y-102622-00 Nasal Shell CPAP Interface with Vent

Y-101975-00 CPAP Interface Straps

Y-102833-00 Hose Guide with Clip and Straps

Y-101400-00 CPAP Interface with Nasal Pillows Assembly

Y-103074-00A Y-103074-00A CPAP Interface with Shallow Nasal Cushion Assembly

Y-102616-00 CPAP Interface with Nasal Cushion Assembly







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Y-101400-01 CPAP Interface without Nasal Pillows Assembly  
Y-103061-00A Nasal Mask CPAP Interface Front Assembly  
Y-102444-00 Nasal Airway Assembly without pillows  
Y-101974-00 Nasal Pillows Exhalation Vent  
Y-101987-00 Nasal Pillows Shell with Pressure Tap  
Y-101699-00 Nasal Pillows Shell with Vent  
Y-102637-00 Nasal Shell CPAP Interface with Pressure Tap  
DreamFit Nasal Mask  
DF301 Nasal Mask CPAP Interface  
DF303 Nasal Mask CPAP Interface  
DF302 Nasal Mask CPAP Interface  
10002002 Replacement Hose with Swivel  
10002003 Replacement Silicone Parts Kit  
10001994 Strap Kit  
10001990 Cushion Adapter Kit  
CPAP Interface  
S-231703-00C Nasal Ventilation Shell  
S-231702-00B Calibration Shell  
S-133250-00D Soft Headgear CPAP Interface Circuit  
S-133350-00B Flex Tube Assembly  
S-232101-00B Narrow CPAP Shell  
S-232100-00B Narrow Vent Shell  
S-232102-00B Narrow Shell Assembly  
S-231701-00B Shell with Pressure Port  
S-231699-00B Shell and Thermometer Ports  
S-231700-00B Shell with Velcro Patch Assembly  
S-616329-00B Swivel Adapter  
S-133294-00B Soft Headgear CPAP Interface Circuit with Pressure Port  
S-616323-00A Flexible Nasal Pillow, Small  
S-616324-00C Flexible Nasal Pillow, Medium  
S-616324-01C Bulk Flexible Nasal Pillow, Medium  
S-616325-00A Flexible Nasal Pillow, Large  
S-616325-01A Bulk Flexible Nasal Pillow, Large  
S-616355-00C Nasal Dilator, Pillow Small  
S-616356-00C Nasal Dilator, Pillow Medium  
S-616357-00C Nasal Dilator, Pillow Large  
Y-101969-00 Nasal Pillow, X-Large  
Y-103076-00A Nasal Mask CPAP Interface Front Assembly  
Ventilator Mask  
4-005251-00 Adult Mask, Small  
4-005252-00 Adult Mask, Medium  
4-005253-00 Adult Mask, Large  
4-005281-00 Infant Mask, Size 1  
4-005282-00 Infant Mask, Size 2  
4-005283-00 Infant Mask, Size 3  
4-005284-00 Infant Mask, Size 4  
4-000730-00 Mouthpiece Seal Assembly  
4-018011-00 Adult Breathing Circuit  
4-020740-00 Adult Breathing Circuit  
4-002536-00 Mask with Harness, Small  
4-001085-00 Harness  
Ventilator Accessories  
4-015254-00 Adult Breathing Circuit  
4-018744-00 Adult Breathing Circuit  
4-018052-00 Adult Breathing Circuit  
4-018062-00 Adult Breathing Circuit  
D20 Pediatric SpO2 Sensor  
D25 Adult SpO2 Sensor





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D25L Adult XL SpO2 Sensor

I20 Infant SpO2 Sensor

N25 Neonatal/Adult SpO2 Sensor

901-A Adult SpO2 Sensor

902-I Infant SpO2 Sensor

903-P Pediatric SpO2 Sensor

904-N Neonatal/Adult SpO2 Sensor

PEDICAP/EASYCAP

PEDICAP Pediatric Colorimetric CO2 Detector

PEDICAP 6 Pediatric Colorimetric CO2 Detector

EASYCAP II Adult Colorimetric CO2 Detector

EASYCAP II 6 Adult Colorimetric CO2 Detector

Other Accessories

10063031 Puritan Bennett Condensate Vial, Reusable

10043551 Puritan Bennett Pediatric-Adult Expiratory Filtration System, Disposable

10068119 Nellcor Adult Respiratory Sensor SpO2, RR

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

