



Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, Maryland 20993

Certificate No. 5566-8-2009

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
(2 Pages)

Name of Manufacturer, Address

Xodus Medical, Inc.
702 Prominence Drive
New Kensington, PA 15068

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.

Theresa McDonald
Chief, Regulatory Policy and Systems Branch
Division of Risk Management Operations
Office of Compliance
Center for Devices and Radiological Health

**This certificate expires 24 months
from the date notarized.**

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this 17th day of Sept month 2009 year.

MARY JO EVERETT
NOTARY PUBLIC STATE OF MARYLAND
County of Montgomery
My Commission Expires June 21, 2011



CERTIFICATE TO FOREIGN GOVERNMENT – Attachment (Page 1 of 2 Pages)

Name of Products

Cautery Tip Cleaner
30500

Surgical Light Handle Cover:
60511, 60512, 60513
60711, 60712
60881, 60882

Safety Scalpel Handles:
90000, 90001
90210, 90211, 90215

Safety Scalpel Blades:
90100, 90101, 90110
90111, 90150, 90151

Anti-fog Solution:
30900

Needle counters:
70110, 70119, 70120, 70130, 70131, 70160, 70161, 70164, 70211,
70212, 70213, 70215, 70216, 70330, 70331, 70360, 70361, 70362,
70365, 70400, 70410, 70411, 70412, 70414, 70418, 70419, 70420,
70423, 70424, 70440, 70441, 70455, 70456, 70464, 70465, 70470,
70481, 70482, 70512, 70514, 70522, 70523, 70524, 70525, 70529,
70555, 70556, 70560, 70561, 70564, 70570, 70580, 70581, 70582,
70660, 70661, 70711, 70730, 70731, 70742, 70760, 70761, 70765,
70775, 70810, 70830, 70830, 70831, 70861, 70870, 70871, 70872,
70873, 70875, 70880, 70881, 70882, 70883, 70884, 70890, 70900,
70930, 70931, 70960, 70961 :

Surgical Sponge Counter Bags:
50500, 50600, 50510, 50511, 50512

Scalpel Holder:
20220

Surgical Skin Markers:
10400, 10402, 10405, 10406, 10407, 10411, 10412, 10415, 10416,
10417, 10500, 10511, 10600, 10611, 10670, 10700, 10711, 10715,
10716, 10717, 10718, 10719, 10720, 10725, 10726, 10727, 10730,
10731, 10732, 10733, 10735, 10736, 10737

Electrosurgical Pencils/Electrodes:
20010, 20011, 20012, 20013, 20014, 20015, 20018, 20023, 20024,
20040, 20041, 20042, 20043, 20044, 20045, 20048, 20053, 20054,
20055, 20056, 20057, 20058, 20061, 20062, 20063, 20064, 20070,

END OF PAGE

Name of Manufacturer, Address

Xodus Medical, Inc.
702 Prominence Drive
New Kensington, PA 15068



CERTIFICATE TO FOREIGN GOVERNMENT – Attachment (Page 2 of 2 Pages)

Name of Products

Name of Manufacturer, Address

Electrosurgical Pencils/Electrodes cont.:

20071, 20080, 20082, 20083, 20090, 20091, 20093, 20094, 21400,
21410, 21420, 21430, 21440, 21450, 21500, 21520, 21530, 21540,
21550, 21570, 21600, 21610, 21620, 21630, 21640, 21650, 21660,
21670, 21680, 21690, 21800, 21810, 21820, 21830, 21840, 21850,
21860, 21870, 21880, 21890, 21900, 21910, 21920, 21930, 21940,
21950, 21960, 21970, 21980, 21990, 22081,

Xodus Medical, Inc
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O.R. Positioning Belts / Fetal Monitoring Straps:

30100, 30150, 30210, 30220, 30310, 30320

Patient Positioning Products:

40400, 40401, 40402, 40403, 40404, 40405, 40406, 40407, 40408, 40409,
40410, 40411, 40412, 40413, 40414, 40415, 40416, 40417, 40419, 40420,
40421, 40423, 40424, 40428, 40432, 40434, 40435, 40436, 40438, 40442,
40443, 40447, 40448, 40449, 40451, 40452, 40453, 40454, 40455, 40456,
40457, 41500, 41502, 41805, 41806, 41807, 41808, 41809, 41810, 41811,
41812, 41813, 41814, 41815, 41816, 41817, 41818, 41819, 41820, 41821,
41822, 41823, 41824, 41825, 41826, 41827, 41828, 41829, 41830, 41831,
41834, 41835

Stretcher Pads:

41601, 41602, 41603, 41604, 41605, 41606, 41607, 41608, 41609, 41610,
41611, 41612, 41613, 41614, 41615, 41616, 41617, 41618, 41619, 41620,
41621, 41622, 41623, 41624, 41625, 41626, 41801, 41802, 41803, 41804

Pre-Printed Medication Labels:

CLXXXX (part numbers are customer specific)

Suction Tube Holder:

30400, 30420

Shoulder Suspension Kit:

90403

Surgical Instrument, Transfer Zones:

80710, 80700, 80720, 80855, 80856, 80885, 80886, 80300, 80400

Surgical "Sharps" Safety Device Safe-T-Stop™:

10670

Syringe Transfer Cup:

80100

Device Cover, Foot Pedal:

50300

"END OF PRODUCT LIST"

