



Certificate No. 2925-5-2012

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:

<u>Name of Product(s)</u>	<u>Name of Manufacturer/Distributor, Address</u>
Pulse Oximeter Sensors	BETA Biomed Services, Inc. 2804 Singleton St. Rowlett, TX 75088
See Attached List (1 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.



Ann M. Ferriter
Director
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 4 day of June month 2012 year.

CATHRYN N. MORRIS
NOTARY PUBLIC STATE OF MARYLAND
County of Montgomery
My Commission Expires January 4, 2013



Name of Product(s) <u>Pulse Oximeter Sensors</u>	Name of Manufacture/Distributor,Address BETA Biomed Services, Inc. 2804 Singleton St. Rowlett, TX 75088
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Adult Finger Pulse Oximeter Sensor

Model #'s B505-1001, 1001R, 0601, 1002, 1002N, 1003N, 1003P, 1004, 1004N, 1005, 1005N, 1006M, 1006V, 1006V-10, 1007, 1007N, 1011, 1011N, 1011P, 1013, 1013N, 1014, 1014L, 1015, 1016, 1016N, 1016R, 1017, 1018, 1019, 1020, 1020N, 1020NV, 1020PC, 1020S, 1020T, 2002, 1021, 1021B, 1024, 1027, 1028, 1031, 1032, 1033B, 1036, 1040, 1040N, 1042, 1042N, 1042V, 1043S, 1046, 1047, 1048, 1050, 1051, 1051N, 1052, 1053, 1069, 1069N, 1070, 1073, 1074, 1075, 1075C, 1300, 3100, 3305, 7600, 8300, 8302, 8400

Soft Tip Adult Sensor

Models# B510-0100, 0101, 0102, 0200, 0201, 0400, 0401, 0500, 0501, 4300, 0600, 0601, 0602, 1100, 1101, 1102, 1400, 1600, 1601, 1700

Soft Tip Pediatric Sensor

Models# B110-0100, 0101, 0102, 0200, 0201, 0400, 0401, 0500, 0501, 4300, 0600, 0601, 0602, 1100, 1101, 1102, 1400, 1600, 1601, 1700

Pediatric Finger Pulse Oximeter Sensor

Model #'s B100-1001, 1001, 1001R, 0601, 1002, 1002N, 1003N, 1003P, 1004, 1004N, 1005, 1005N, 1006M, 1006V, 1006V-10, 1007, 1007N, 1011, 1011N, 1011P, 1013, 1013N, 1014, 1014L, 1015, 1016, 1016N, 1016R, 1017, 1018, 1019, 1020, 1020N, 1020NV, 1020PC, 1020S, 1020T, 2002, 1021, 1021B, 1024, 1027, 1028, 1031, 1032, 1033B, 1036, 1040, 1040N, 1042, 1042N, 1042V, 1043S, 1046, 1047, 1048, 1050, 1051, 1051N, 1052, 1053, 1069, 1069N, 1070, 1073, 1074, 1075, 1075C, 1300, 3100, 3305, 7600, 8300, 8302, 8400

Adult Ear Pulse Oximeter Sensor

Model #'s B200-1001, 1001, 1001R, 0601, 1002, 1002N, 1003N, 1003P, 1004, 1004N, 1005, 1005N, 1006M, 1006V, 1006V-10, 1007, 1007N, 1011, 1011N, 1011P, 1013, 1013N, 1014, 1014L, 1015, 1016, 1016N, 1016R, 1017, 1018, 1019, 1020, 1020N, 1020NV, 1020PC, 1020S, 1020T, 2002, 1021, 1021B, 1024, 1027, 1028, 1031, 1032, 1033B, 1036, 1040, 1040N, 1042, 1042N, 1042V, 1043S, 1046, 1047, 1048, 1050, 1051, 1051N, 1052, 1053, 1069, 1069N, 1070, 1073, 1074, 1075, 1075C, 1300, 3100, 3305, 7600, 8300, 8302, 8400

Adult Omni-site Pulse Oximeter Sensor

Model #'s B300-1001, 1001, 1001R, 0601, 1002, 1002N, 1003N, 1003P, 1004, 1004N, 1005, 1005N, 1006M, 1006V, 1006V-10, 1007, 1007N, 1011, 1011N, 1011P, 1013, 1013N, 1014, 1014L, 1015, 1016, 1016N, 1016R, 1017, 1018, 1019, 1020, 1020N, 1020NV, 1020PC, 1020S, 1020T, 2002, 1021, 1021B, 1024, 1027, 1028, 1031, 1032, 1033B, 1036, 1040, 1040N, 1042, 1042N, 1042V, 1043S, 1046, 1047, 1048, 1050, 1051, 1051N, 1052, 1053, 1069, 1069N, 1070, 1073, 1074, 1075, 1075C, 1300, 3100, 3305, 7600, 8300, 8302, 8400

Preamp/Adaptor/Extension Cable

Model # B400-1011PA, 1001A, 1001E, 1002A, 1002E, 1003A, 1004A, 1005A, 1006A, 1006AV, 0600, 0601, 0602, 1007A, 1011E, 1011A, 1011B, 1013, 1301, 1014B, 1020A, 1020B, 1020D, 1020E, 1040A, 1020E, 2001, 2003, 1021A, 1024A, 1032A, 1033A, 1070A, 3300, 3303, 7000, 7001, 7003, 8300, 8400,

END OF PRODUCT LIST

