Dolphin Medical
An OSI SYSTEMS Company

Decree of Compatibility for Dolphin 2000 SpO_2 Sensors

Dolphin 2000 SpO_2 Sensors have been found to be Substantially Equivalent to Nellcor® SpO_2 Sensors by the Food and Drug Administration since May 2003 and received a CE mark in March of 2000. Substantially equivalent means that the device manufactured must be technically equivalent to the original device. As Dolphin 2000 Sensors are substantially equivalent to Nellcor® SpO_2 sensors, the Dolphin 2000 sensors must be compatible to Nellcor® SpO_2 monitors.

Dolphin Medical makes a statement of fact that extensive clinical testing was completed prior to submission of Substantial Equivalence notification and that all testing demonstrated the compatibility of the Dolphin SpO_2 Sensors to Nellcor® Oximeter Monitors.

The manufacturing requirements for a medical device within the United States are the quality guidelines set by Congress and enforced by the Food and Drug Administration (FDA). The Good Manufacturing Practices (GMP) guidelines qualify each device manufactured is of the same quality as the next. Also under the ISO regulatory requirements similar requirements are mandated.

Dolphin Medical Inc. makes statement of fact of compliance to the Good Manufacturing Practices and ISO manufacturing guidelines.

Dolphin 2000 SpO_2 Sensors have been on the market since March of 2000 in areas around the world. During the time period from introduction of Dolphin 2000 product line to present date, ***no*** Dolphin 2000 SpO_2 Sensor has been related to a Nellcor® Oximeter Monitor failure or has caused damage to a Nellcor® Oximeter Monitor (per complaint handling process, Code of Federal Regulations Title 21: Part 820.198 and Clause 4.14 ISO 9001; part of GMP/ISO requirements).

Dolphin Medical, Inc. makes statement of fact of not receiving or processing any customer complaint related to a Dolphin 2000 SpO_2 Sensor causing the operational failure of a Nellcor® Oximeter Monitor.

As a representative of Dolphin Medical, Inc., I hereby certify the above statements to be, to the best of my knowledge accurate and true.

Don Melnikoff

Donald Melnikoff
Engineering Manager

Date August, 27 2003