



February 17, 2012

To Whom It May Concern:

The following application is for the ClearCount Medical Solutions, Inc. SmartSponge Flex Model A04 system. This application is for original certification of FCC ID: WWQCCMS004 to FCC rule part 15.225.

The SmartSponge Flex Model A04 incorporates a high frequency radio frequency identification (RFID) radio, model Medio L40. The radio transmit frequency is 13.56 MHz and it operates to the ISO15693 standard.

The frequency stability information required by FCC rule part 15.225(e) is incorporated by reference to the report for Medio L40 radio, FCC ID: QHKGEDIOL40. A copy of this report is submitted with this application.

The SmartSponge Flex Model A04 is a specially designed cart mounted device containing a microcontroller unit with specialized software designed for data collection. Integrated RFID technology allows capture of the information coded on the unique RFID tag on the sponges, pads and towels. The microcontroller unit counts the initial number of sponges introduced into a surgical case, and using the custom software program, reports the total sponges discarded at the end of the procedure, and compares that number to the original. By providing a count of the items entered into surgery, and a count of those discarded and removed permanently from the surgical field, personnel can be alerted to sponges that may still remain in the surgical field prior to closing the patient.

A Detection Wand is an additional antenna that is tethered by a cable to the SmartSponge Flex Model A04. It is powered and controlled by the SmartSponge Flex Model A04. The antenna functions as an additional RFID antenna to the system, functioning in an identical manner to the SmartSponge Flex Model A04 internal antennas. By using a keypad the user may select to activate the Detection Wand antenna. When in Detection Wand mode, the system uses the Wand antenna to recognize RFID-tagged items that may be inside the surgical site.

The ClearCount Medical Solutions SmartSponge Flex Model A04® System is indicated for use in counting and recording the number of RFID-tagged surgical sponges, laparotomy sponges and towels used during surgical procedures, as well as for providing a non-invasive means of locating retained RFID-tagged surgical sponges, towels, and other tagged items within a surgical site.

Sincerely,

A handwritten signature in black ink that reads "Jeff Wolfgang".

Jeff Wolfgang  
VP of QA/RA and Service