DLS ELECTRONIC SYSTEMS, INC.

1250 PETERSON DRIVE, WHEELING, IL 60090-6454 • PHONE 847-537-6400 • FAX 847-537-6488 • www.dlsemc.com

CE Mark "Step By Step" Procedure

MEDICAL DEVICES

The EU Medical Device Directive, Regulations 2017/745 and 2017/746 for In Vitro Devices, are the formal requirement for compliance for most medical devices and equipment, accessories and other medical related electrical apparatus which may be susceptible to unwanted electromagnetic phenomena or may cause interference to other medical devices and related equipment, and includes product safety requirements for patients, doctors, nurses, and other equipment operators, users, and caregivers.

The MDRs have published harmonized standards that outline specific tests for electromagnetic compatibility and electrical product safety. These standards have been recently updated to include more stringent levels of susceptibility and more stringent testing requirements based on specific features, location and intended use, such as devices that are used in home health care or have alarms. Specific ancillary standards have been established to address specific requirements based on the unique application of a medical device.

Medical devices and equipment that have been enhanced with wireless capabilities, such as pre-approved wireless modules, will have to meet requirements of the Radio Equipment Directive, (RED) 2014/53/EU.

Your first step is to call us at 1-847-537-6400.

At our laboratory we will help you:

1. Determine the specific standards your product will be tested to and will need to meet to show compliance to the MDD
2. Test and achieve compliance to:
   a. EMC-Emissions and Immunity EN 60601-1-2 EN 60601-1-XXXX
   b. Product Safety EN 60601-1-1 EN 60601-2-XXXX
   c. Wireless/Transmitter (If applicable)
   d. RoHS

You receive from D.L.S.: Test reports to cover all testing.

You will need to:

Issue the Declaration of Conformity: You will then issue your DoC and have it signed by you, the manufacturer of the product, and/or your legal representative in Europe. It will need to be kept on file with your legal representative in Europe to be made available to the authorities if required.

Place the CE mark on your product: The CE mark will need to be affixed visibly, legibly and indelibly on the product indicating all requirements have been met.

Market your product in Europe: You are now allowed to sell and place your product on the market throughout the entire European Union.

Please understand that the EU EMC requirements for your product and the interpretations of the requirements may change. Please check with D.L.S for latest updates. These potential changes create risk, but we believe that your greatest risk would be to do nothing.

Call D.L.S. Electronic Systems, Inc. at 1-847-537-6400 for any questions you have about EU testing, scheduling and cost. We will be most happy to assist you. Visit our Website at **www.dlsemc.com** or Email us at **jblack@dlsemc.com** 4/2019