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Subject: New Third Edition Medical Evaluation

Dear Valued Customer:

Thank you for choosing Intertek to evaluate your product to the third edition of the medical standard: 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety and Essential Performance.

The third edition of 60601-1 requires the manufacturer of a medical product to have a robust Risk Management File which complies with the process standard ISO 14971. To evaluate your product to these standards, we have provided several checklists that must be completed prior to the start of your project with Intertek:

- ISO 14971 2007-Checklist.doc
- Checklist RMF, IEC 60601-1 ed. 3, rev. June 2011.doc
- Checklist PEMS, Clause 14, rev.1.doc
- IEC 60601-1-6 – 2010-Checklist.doc
- Additional Supporting Information

These checklists are a resource for our engineers to accurately find and evaluate information within your Risk Management File as it relates to the particular requirements of the standard.

ISO 14971 2007-Checklist.doc
This checklist regards the application of risk management to medical devices and compliance with this ISO process standard. (To better understand the clauses and their requirements, view the IECEE guidance document)

To complete this checklist, please begin at clause 3 “General Requirements for Risk Management” and fill out the “Result-Remark” column with an indication of where in your risk management file the appropriate information or documentation can be found. At the end of this checklist is a table: “Risk Management Files.” Please reference each file that is part of the RMF on a separate line along with the current reference number and date of revision.

Checklist RMF, IEC 60601-1 ed. 3, rev. June 2011.doc
This checklist assists our engineers in understanding how your medical product complies with the requirements of the standard. There are many risk-management related clauses in this version of 60601-1, as well as some specific tests which are directly dependant on your Risk Management File and its contents.

Just like the ISO 14971 checklist, please fill out the “Location in the RMF” column with an indication of where in your risk management file the appropriate information or document can be found. If a particular clause does not apply to your particular style of product, please indicate with “NA” and a justification of why. For example, if your product does not produce microwave radiation, clause: “0.3 Microwave radiation” can be listed as “NA” with the comment: “Product does not produce or emit microwave radiation.”

Checklist PEMS, Clause 14, rev.1.doc
Any product that contains one or more central processing units is identified as a Programmable Electrical Medial System (PEMS) and needs to be evaluated to Clause 14 of 60601-1. Provided is a checklist to reference the information in your Risk Management File concerning the development and risk management of the PEMS. Please fill this out in similar fashion to the “Checklist RMF.”

IEC 60601-1-6 2010 - Checklist.doc
If your project's quotation includes evaluation to the Usability standard, then the checklist for linking the requirements of the standard to your Usability Engineering File needs to be completed. To complete this checklist, please begin at clause 4 "General Requirements" and fill out the "Result-Remark" column with an indication of where in your Risk Management File the appropriate information or document can be found.

All documents referenced in these checklists need to be provided so the engineer can verify that the information required by the clause is adequately addressed by the referenced material.

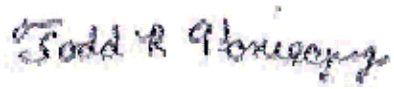
Additional Supporting Information
In addition to the completed checklists, additional information and documents are required to begin the evaluation of your product to the third edition medical standard:

- Isolation Diagram
    - Please provide a diagram showing the Means of Protection provided by your equipment to the patient and operator for protection against electric shock. These means of protection, defined MOOP for "Means Of Operator Protection" and MOPP for "Means Of Patient Protection" should show the various insulation systems that are used to protect the operator and patients against hazardous voltages and/or energies. These means could be (and are not restricted to):
        - ✓ Certified Medical Power Supplies
        - ✓ Air-gaps
        - ✓ Solid Insulation (such as plastics / polymeric parts)
        - ✓ Means of Grounding
        - ✓ Digital and Optical Isolators
        - ✓ Isolation Transformers
- Critical Component list and datasheets / agency approval information
    - Any component that is relied on for the safety of the product can be considered a critical component. These components provide a certain degree of protection to the people and environment in which a medical product operates. We highly encourage the use of certified components as it may reduce or alleviate the need for additional testing of the product and its sub-components. Please be advised that use of any non-certified critical components may result in additional testing to the relevant component standard for use of the item in the medical product. For components that are recognized, please provide the "conditions of acceptability" as provided by the manufacturer of this component.

Thank you for choosing Intertek. We look forward to examining and evaluating your product and working with you to achieve compliance to the standards.

If you have any questions or concerns, please feel free to contact me or your Intertek Account Representative.

Sincerely,



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