69131 : STD - RISK MANAGEMENT AND QUALITY MANAGEMENT SYSTEMS POLICY FOR MEDICAL POWER SUPPLIES

Introduction:
TDK-Lambda UK Ltd designs and manufactures power supplies for use in medical and IVD devices, both of which have requirements for risk management. This document provides customers with information regarding the approach of TDK-Lambda UK Ltd to the risk management process. It also describes the quality management systems that TDK-Lambda UK Ltd has in place for medical power supplies.

Compliance Overview:
For end products which need to comply with the Medical Devices Directive, our medical power supplies are approved to both IEC/EN 60601-1 Edition 2 and 3 with current amendments*. These products are listed below:

Alpha 400 Series
Alpha 800/1000 Series
Vega AC Series (450W, 550W, 650W, 750W and 900W)
NV175 Series
NVM175 Series
NV300 Series
NV350 Series
NV700 Series
EFE300M Series
EFE400M Series
CFE400M Series
ZMS100 Series
XMS Series
QM Series.

As these products are not medical devices, they cannot be CE marked for the Medical Devices Directive. They are however CE marked for the Low Voltage Directive and are approved to IEC/EN 60950-1 Edition 2 with current amendments*.

For end products which need to comply with the In-vitro Diagnostic Devices Directive, our IVD power supplies are approved to IEC/EN 61010-1 Edition 3 with current amendments*. Again, they cannot be CE marked for the In-vitro Diagnostic Devices Directive because they are not In-vitro Diagnostic devices. These products are listed below:

Vega AC Series (450W, 550W, 650W, 750W and 900W)
NV175 Series
NV350 Series
NV700 Series
EFE300M Series
EFE300 Series
EFE400 Series

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In addition to the above approvals, the power supplies are also approved to UL/CSA versions of the standards described. All products have a CB Report and certificate, and UL/CSA Reports.

TDK-Lambda UK Ltd has BSI Certification to ISO 9001 (FM13021), ISO 14001 (EMS 518156). ISO 13485/ EN ISO 13485 (MD 601259) and OHSAS 18001 (OHS 609627).

Risk Management:
It should be noted that ISO 13485 calls for a Risk Management process to be put in place but does not mandate that it complies with ISO 14971. IEC 60601-1/EN 60601-1/ CAN/CSA C22.2 No. 60601-1/ANSI/AAMI ES60601-1 mandate a Risk Management process that complies with ISO 14971, but the IECEE Medical Electrical Equipment Task Force issued a decision which exempted component power supplies from this requirement. Having said this, TDK-Lambda UK Ltd will provide the customer with all requested information relating to risks arising from our products and the implementation of them in medical devices or systems on request, but subject to appropriate Non-Disclosure Agreements being signed between TDK-Lambda UK Ltd and the customer.

For non-standard products and custom products, risk management requirements for a customer can be agreed as part of the Contract Review Process. For standard products, and since changes to manufacturing processes and to the design of a product can have an effect on the risk management of end products or systems, such changes shall be notified to our customers via our Change Control Process. Further, any field problems relating to the safety of our products shall be reported to our customers via our Global Quality Risk Management Process (Recall Process).

This risk management policy is detailed in TLUK procedures and provides the customer with a reference covering the risks associated with our products and how these are mitigated.

** For details of the amendments, please contact TDK-Lambda UK Ltd or refer to website www.uk.tdk-lambda.com under 'Technical Centre' - Safety Certification'*

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