TDK-Lambda Europe GmbH
Karl Bold Str. 40
D-77855 Achern
Tel: +49 (0)7841 666 0
Fax: +49 (0)7841 5000
https://www.emea.lambda.tdk.com/de

RISK MANAGEMENT AND QUALITY MANAGEMENT SYSTEMS POLICY FOR TDK-LAMBDA POWER SUPPLIES USED BY MEDICAL DEVICE MANUFACTURERS

Introduction:
TDK-Lambda designs and manufactures power supplies for use, as a 'component', in Medical and IVD devices, manufactured by Medical Device Manufacturers (MDM), both of which have requirements for risk management. **TDK-Lambda does not design, manufacture or supply medical devices.**

This document provides customers with information regarding the approach of TDK-Lambda to the risk management process. It also describes the quality management systems that TDK-Lambda has in place for its power supplies.

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

Alpha1000	CUS150M1	HWS100/ME	NV350
Alpha400	CUS200M	HWS1000/ME	NV700
Alpha800	CUS250M	HWS1000L (SWS1000L)	NVM175
CFE400M	CUS30M	HWS100A/ME	QM
CME100A	CUS350M	HWS150/ME	RWS1000B/ME
CME1500A	CUS350MP-1000	HWS1500/ME	RWS1500B/ME
CME150-24	CUS400M	HWS150A/ME	Vega450
CME150A	CUS500M1	HWS30/ME	Vega650
CME200A	CUS600M	HWS300/ME	Vega900
CME240P-24	CUS600M1	HWS30A/ME	WMM30
CME30A	CUS60M	HWS50/ME	XMS
CME350A	CUS850M	HWS50A/ME	ZMS100
CME350P-1000	CUT35	HWS600/ME	
CME500A	CUT35J	MU Series	
CME600A	CUT75	MV450	
CME60A	CUT75J	MV650	
CUS100MB	EFE300M	MWS65	
(Excluding CUS100MB/RB, CUS100MB/HB)	EFE400M	NV175	
CUS1500M	GXE600	NV300	

As these products are not medical devices, they cannot be CE/UKCA marked for the Medical Devices Directive (MDD). They are however CE/UKCA marked for the Low Voltage Directive and are approved to IEC/EN 62368-1 Edition 2 with current amendments*

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

CUS250M Series EFE300 Series EFE300M Series EFE400 Series MU Series	NV175 Series NV350 Series NV700 Series Vega AC Series (450W, 550W, 650W, 750W and 900W)

In addition to these 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 is certified to the following management system standards ISO 9001, ISO 14001, ISO 13485 and ISO 45001.

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.

The IECEE Medical Electrical Equipment Task Force issued a decision which exempted component power supplies from this requirement. However, TDK-Lambda will on request provide the customer with all required information relating to risks arising from our products and the implementation of them in medical devices or systems, subject to appropriate Non-Disclosure Agreements being signed between both parties.

Whilst these medical power supplies** are tested to IEC/EN 60601-1, and can be used for powering electrical medical equipment, it should be noted at this point that the power supply is only considered in the overall medical system as a tested component. The MDM should seek approval of the components prior to their use in its medical electrical device, to meet the demands placed on it by risk management in terms of the standard.

Important note for MDM's.
The power supply has been tested by verified to be single fault safe as required by 60601-1.
When classifying power supplies manufactured by TDK-Lambda, whilst the MDM may list the power supply in their safety file, **it should <u>not</u> be listed as a safety critical device / component with respect to the end user (the patient).** IEC/EN 60601 applies to the end equipment therefore to meet these requirements, the MDM will undertake a risk assessment against ISO 14971 during the design and development stages of the medical device, to ensure that if a fault occurred with the power supply then a safe situation exists.

For non-standard and custom products, risk management requirements for a customer can be agreed upon as part of the contract review process. Since changes to manufacturing processes and design of products have effects on risk management of end products or systems, such changes shall be notified to our customers via our change control process. Any field problems relating to the safety of our products shall be reported to our customers via our Global Quality Risk Management Process.

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

** For details the risk management policy and / or amendments, please refer to your local TDK-Lambda representatives website or contact your local TDK-Lambda representative.*

****These products are not authorised as critical components within life support systems.***