



Product Service

CERTIFICATE

No. B 057396 0537 Rev. 00

Conditions of Acceptability:

- a) The output was not evaluated as patient connected circuits.
- b) Compliance with the requirements for EMC shall be evaluated for the end use product.
- c) These products have been investigated only as a component part for use in equipment where the suitability of the combination is subject to end product investigation.
- d) The leakage current test shall be checked in end product.
- e) Clearance/creepage distance and dielectric strength were evaluated and fulfilled the requirements for MOPP.
- f) When the product is placed on the market, it must be accompanied with safety instructions written in official language of the country. The instructions shall give information regarding safe operation, installation and maintenance.
- g) According to the EU directives which have been aligned with EU NLF (new legislative framework), both of manufacturer and importer's name and address shall be affixed on the product or, where that is not possible, on its packaging or in a document accompanying the product before the product is placed on the EU market.
- h) The manufacturer/ Importer has to ensure the appliance placing on the EU market conforms to the applicable EU directives which provide the affixing of the CE marking, such as LVD, EMC, RoHS, ErP and so on.
- i) When installing the equipment, all requirements of the mentioned standard must be fulfilled.
- j) See also Engineering Conditions of Acceptability in UL CB Test Report No.: E321744-D1019-1/A0/C0-CB.

Tested according to: EN 60601-1:2006/A1:2013
 EN 60601-1:2006/A12:2014

Production Facility(ies): 003227, 071712, 089850

TÜV SÜD
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