# Risk Management Report
# For Medical Device

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|---|---|
| Organization's Name .....: | TRACO ELECTRONIC AG |
| Address.....: | Sihlbruggstrasse 111 CH-6340 Baar Switzerland |
| Kind of Device..... | DC-DC Converter |
| Model and/or Type Reference ..: | Model THM x-yzAz1z1z1z1z1z1z1 , where x = 3, 6 or 10 representing output power, y = 05, 12, 24 or 48, z = 10, 11, 12, 13, 15, 21, 22 or 23, z1 can be any alphanumeric or blank for marketing purpose and no impact to safety.<br>Model THM x-yzz1z1z1z1z1z1z1, where x = 3, 6 or 10 representing output power, y = 05, 12, 24 or 48, z = 10, 11, 12, 13, 15, 21, 22 or 23, z1 can be any alphanumeric or blank for marketing purpose and no impact to safety.<br>Model THM x-yzWIAz1z1z1z1z1z1z1, where x = 3, 6 or 10 representing output power, y = 24 or 48, z = 10, 11, 12, 13, 15, 21, 22 or 23, z1 can be any alphanumeric or blank for marketing purpose and no impact to safety.<br>Model THM x-yzWIz1z1z1z1z1z1z1, where x = 3, 6 or 10 representing output power, y = 24 or 48, z = 10, 11, 12, 13, 15, 21, 22 or 23, z1 can be any alphanumeric or blank for marketing purpose and no impact to safety. |
| Scope of the risk analysis.....: | 1. Intended use and identification of characteristics related to the safety of the medical power supply<br>2. Identification of hazards<br>3. Estimation of the risk for each hazardous situation<br>4. "Design, Development and Manufacture" of the product in question. |

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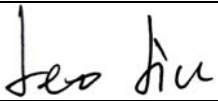
| Prepared: |  | Quality Assurance: |  |
| Safety: |  | Sales: |  |
| R&D: |  | Assigned Responsibility person: |  |

## Revisions

| Version | Description | Date |
|---|---|---|
| 1.0 | Initial | 2017-01-14 |
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# Table of Content

## 1. Introduction

This report specifies a process to identify the hazards associated with medical devices to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

Bibliography:

| Item | Standard no. |
|---|---|
| safety | IEC60601-1:2005/A1:2012<br>ANSI/AAMI ES60601-1:2005/A1<br>CAN/CSA-C22.2 No. 60601-1:14 |
| EMC | IEC 60601-1-2: 2014 |
| Quality System | ISO9001: 2015 |
| Risk Management | ISO 14971:2007 |

## 2. Risk Management Policy

Criteria for risk acceptability has defined based upon applicable national or regional regulations and relevant International Standards, and taken into account available information such as the generally accepted state of the art and known stakeholder concerns.

Based on the guidelines being set up by the company management the identified risks will be evaluated in the risk management worksheet and reported in annual risk management reports as follows (according to ISO 14971):

In determining acceptable risk, we will research pertinent regulations, standards and associated literature to identify state of the art for power supply with medical and dental equipment. The criteria of risk acceptability were according to requirement of IEC 60601-1.

## 3. Risk management process

### 3.1 Risk management process

The risk management process will be conducted follow Standard ISO 14971 clause 3.1, in figure 1 as below.

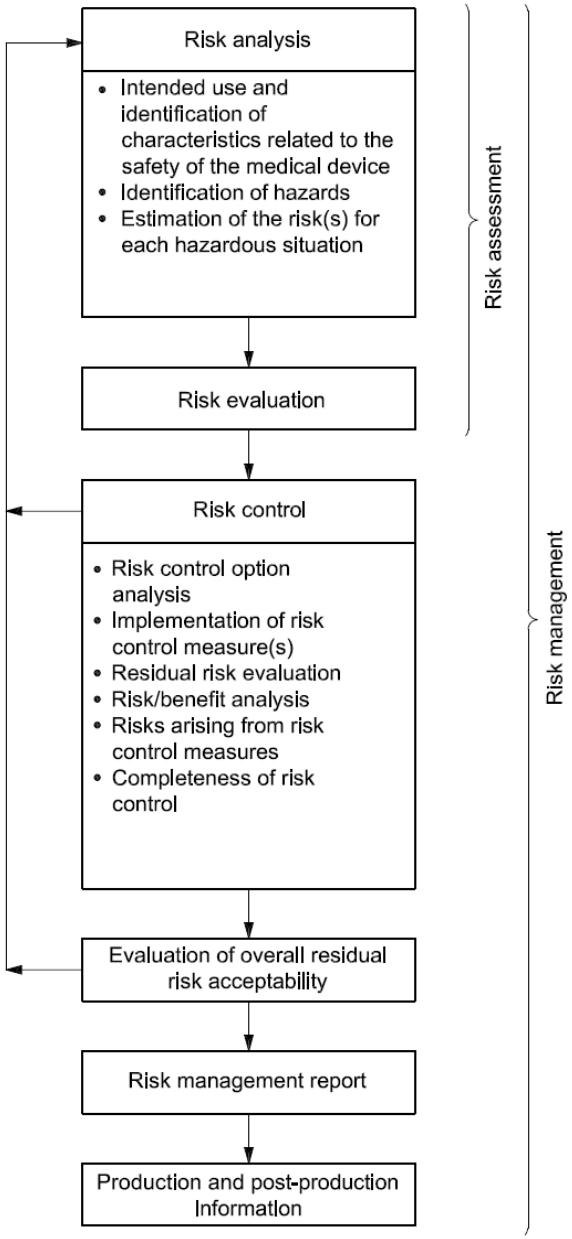


Figure 1 – A schematic representation of the risk management process

## 3.2 Management responsibilities

Top management / President opened the meeting for risk management process for following item
- Assignment of qualified personnel
- Adequate Resources
- Policy for determining criteria for risk acceptability

See “risk management plan” for details.

## 3.3 Qualification of personnel

Persons performing risk management tasks shall have the knowledge and experience appropriate to the tasks assigned to them

a) R&D department: Responsible for carrying out the RM report
(The person shall be trained ISO14971 or with related experience.)

| Assigned Responsibility person | Personnel Qualification Record Ref. No. |
|---|---|
|  | T0054 |

b) Safety section: Responsible for reviewing the RM report.
(The person shall be trained ISO14971 or with related experience.)

| Assigned Responsibility person | Personnel Qualification Record Ref. No. |
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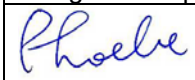
|  | T0067 |

c) Sales department: Responsible for collects data and from customer and market

| Assigned Responsibility person | Personnel Qualification Record Ref. No. |
|---|---|
|  | T0030 |

d) QA department: Responsible for document any decisions and actions taken.

| Assigned Responsibility person | Personnel Qualification Record Ref. No. |
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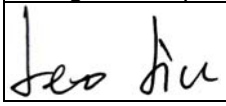
|  | T0024 |

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e) Top management: Responsibilities as below
- Defining of criteria for the acceptability of risks
- Approval of the risk management plan and report
- Ensuring the availability of appropriate resources
- Ensuring the assignment of qualified personnel for risk management
- Checking of the results of risk management activities (suitability and effectiveness)

| Assigned Responsibility person | Personnel Qualification Record Ref. No. |
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|  | T008 |

## 3.4 Risk management plan

Risk management activities was refer to Risk management plan (Document No “P1612027-1”), include the following:

a) The scope of the risk management plan is specific for the product group: DC to DC converter which could be used for medical equipment with or without patient environment. And covering the each phase identified in Risk management plan (Document No “P1612027-1”) new product development process.

b) Assignment of responsibilities and authorities; See clause 3.3 for details.

c) The review requirements of risk management activities was specified in Risk management plan (Document No “P1612027-1”).

d) The criteria for accepting risks shall considering the applicable national or regional regulations and relevant international standards, and take into account available information such as the generally accepted state of the art and known stakeholder concerns. The risk index matrix is disclosed in clause 3.4.1

e) The final verification of the risk control shall be performed on the prototype samples. The compliance reports according to IEC60601-1, IEC 60601-1-2 and qualification test report.

f) Activities related to collection and review of relevant production and post-production information.

See Attachment for Risk management plan for details.

### 3.4.1 Evaluation System

Based on the guidelines being set up by the company management the identified risks will be evaluated

A: Probability of Occurrence (Improbable/Remote/Occasional/Probable/Frequent)

| **Probability** (Likelihood of event occurrence) | | **Definition** |
|---|---|---|
| Common term | Rank (1=lowest) | |
| Frequent | 5 | With a probability of occurrence more than $10^{-3}$, or occurs more than once a month |
| Probable | 4 | With a probability of occurrence less than $10^{-3}$ but greater than $10^{-4}$, or occurs more than once a season |
| Occasional | 3 | With a probability of occurrence less than $10^{-4}$ but greater than $10^{-5}$, or occurs more than once a year |
| Remote | 2 | With a probability of occurrence less than $10^{-5}$ but greater than $10^{-6}$, or occurs more than once a product life-cycle |
| Improbable | 1 | With a probability of occurrence less than $10^{-6}$, unlikely to occur, but possible. |

B: Severity of Harm (Negligible, Minor, Serious, Critical, Catastrophic)

| **Severity** (Impact of event occurrence) | | **Definition** |
|---|---|---|
| Common term | Rank (1=lowest) | |
| Catastrophic | 5 | Could result in death, or life-threatening injury |
| Critical | 4 | Could result in permanent partial disability, injuries |
| Serious | 3 | Could result in injury requiring professional medical intervention |
| Minor | 2 | Could result in temporary injury not requiring professional medical intervention |
| Negligible | 1 | Inconvenience or temporary discomfort, these do not require any medical treatment. |

**The acceptance criteria are as following:**

Risk Index Matrix

| Severity rank / Probability rank | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| **5** | Unacceptable, moderate risk | Unacceptable, moderate risk | Unacceptable, high risk | Unacceptable, extreme risk | Unacceptable, extreme risk |
| **4** | Acceptable, Insignificant risk | Unacceptable, moderate risk | Unacceptable, high risk | Unacceptable, high risk | Unacceptable, extreme risk |
| **3** | Acceptable, Insignificant risk | Acceptable, Insignificant risk | Unacceptable, moderate risk | Unacceptable, high risk | Unacceptable, high risk |
| **2** | Acceptable, Insignificant risk | Acceptable, Insignificant risk | Acceptable, Insignificant risk | Unacceptable, moderate risk | Unacceptable, moderate risk |
| **1** | Acceptable, Insignificant risk | Acceptable, Insignificant risk | Acceptable, Insignificant risk | Acceptable, Insignificant risk | Unacceptable, moderate risk |
| **Risk (index) acceptability level .....** | Risk=Severity x probability<br>Result: Risk=1~4, acceptable; 5~25, unacceptable | | | | |

## 3.5 Risk management file

Records of risk management activities, including any significant changes, are maintained according to quality system process.

# 4. Risk analysis

## 4.1 Risk analysis process

Risk analysis was performed for DC to DC converter building in medical power supply as described in chapter 4.2 to 4.4.

## 4.2 Intended use and identification of characteristics related to the safety of the medical device

**(a) Questions:** The following questions can aid the person in identifying all the characteristics of the medical device that could affect safety. (Which according to ISO 14971, Annex C.2)

| Item | Questions | Answer / Comments |
|---|---|---|
| C.2.1 | What is the intended use and how is the medical device to be used? | DC to DC converter, it could be used for medical equipment. See Chapter 4.2 (b) for details. |
| C.2.2 | Is the medical device intended to be implanted? | No, they are not intended to be implanted. |
| C.2.3 | Is the medical device intended to be in contact with the patient or other person? | Yes, DC to DC converter is intended to be used for medical device including type B, BF or CF equipment or patient environment. However, it shall be evaluated in the final system. |
| C.2.4 | What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device? | Power supply |
| C.2.5 | Is energy delivered to or extracted from the patient? | No, they are not. |
| C.2.6 | Are substances delivered to or extracted from the patient? | No, they are not. |
| C.2.7 | Are biological materials processed by the medical device for sub-sequent re-use, transfusion or transplantation? | No, they are not. |
| C.2.8 | Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable? | No, they are not. |
| C.2.9 | Is the medical device intended to be routinely cleaned and disinfected by the user? | No, they are not. |
| C.2.10 | Is the medical device intended to modify the patient environment? | No, they are not. |
| C.2.11 | Are measurements taken? | No, they are not. |
| C.2.12 | Is the medical device interpretative? | No, they are not. |
| C.2.13 | Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies? | Power supply equipment, it shall be connect to other medical devices. |

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| C.2.14 | Are there unwanted outputs of energy or substances? | Yes, they will bring about high temperature, leakage current and EMC. |
| C.2.15 | Is the medical device susceptible to environmental influences? | Yes, they may influence by temperature, humidity, vibrations. |
| C.2.16 | Does the medical device influence the environment? | Yes, they may influence temperature and EMC |
| C.2.17 | Are there essential consumables or accessories associated with the medical device? | No |
| C.2.18 | Is maintenance or calibration necessary? | No |
| C.2.19 | Does the medical device contain software? | No |
| C.2.20 | Does the medical device have a restricted shelf life? | No |
| C.2.21 | Are there any delayed or long-term use effects? | No |
| C.2.22 | What mechanical forces will the medical device be subjected to? | No |
| C.2.23 | What determines the lifetime of the medical device? | The service life is based on previous records and feedback of marketing in previous models. |
| C.2.24 | Is the medical device intended for single use? | No, DC to DC converter only transfers DC to DC and providing the power source for medical device. |
| C.2.25 | Is safe decommissioning or disposal of the medical device necessary? | End of life cycle, DC to DC converter building in medical power supply don't throw into general trash, it must be handed over to the local recycle system. |
| C.2.26 | Does installation or use of the medical device require special training or special skills? | No, it shall be evaluated in the final system. |
| C.2.27 | How will information for safe use be provided? | Product specification or product data sheet |
| C.2.28 | Will new manufacturing processes need to be established or introduced? | No |
| C.2.29 | Is successful application of the medical device critically dependent on human factors such as the user interface? | No, it shall be evaluated in the final system. |
| C.2.29.1 | Can the user interface design features contribute to use errors? | No |
| C.2.29.2 | Is the medical device used in an environment where distractions can cause errors? | No |
| C.2.29.3 | Does the medical device have connecting parts or accessories? | No |
| C.2.29.4 | Does the medical device have a control interface? | No |
| C.2.29.5 | Does the medical device display information? | No |

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| C.2.29.6 | Is the medical device controlled by a menu? | No |
| C.2.29.7 | Will the medical device be used by persons with special needs? | No, it shall be evaluated in the final system. |
| C.2.29.8 | Can the user interface be used to initiate user actions? | No |
| C.2.30 | Does the medical device use an alarm system? | No |
| C.2.31 | In what way(s) might the medical device be deliberately misused? | No |
| C.2.32 | Does the medical device hold data critical to patient care? | No |
| C.2.33 | Is the medical device intended to be mobile or portable? | No build in type. Be evaluated in the final system assembly |
| C.2.34 | Does the use of the medical device depend on essential performance? | No, it shall be evaluated in the final system. |
| Additional Questions for Basic Safety and Essential Performance according to IEC 60601-1<br>(The answers of these questions are inherently linked to the result of the risk assessment process. For details refer to the relevant sub-clauses and annex A of IEC 60601-1) | | |
| 4.3 | What functions of the medical device are classified as essential performance? | No essential performance. Compliance shall be investigated in the final system assembly. |
| 4.4 | What is the expected service life of the medical device? | 100,000 hours, The service life is based on previous records and feedback of marketing in previous models. |
| 4.5 | What particular risks associated with the medical device and addressed by IEC/EN 60601-1 are controlled by means other than these required by the standard? | No particular risk specific required by the standard. No alternative means is needed. |
| 4.6 | What parts (accessories) of the medical device can come into contact with the patient but fall outside of the definition of applied parts (sub-clause 3.8)? | DC to DC converter. The overall compliance of applied part shall be evaluated in the final system assembly. |
| 4.7 | What are the single fault-conditions other that these identified in sub-clause 13.2 that are feasible for the medical device? | The DC to DC converter be installed by the manufacturer of end equipment, the single fault-conditions are in accordance with IEC60601-1 clause 13.2 requirements no other special requirements. |
| 4.8 | What components of the medical device are used outside their certified (specified) ratings? | All component used in accordance with its specified rating and standard. The transformer insulation system was according to IEC60601-1:2005, Table 22. |
| 4.9 | What components with high-integrity characteristics (sub-clause 3.17) are used in the medical device? | No high-integrity component. |
| 5.1 | What combinations of simultaneous faults in the medical device are feasible? | The all tests described in RM report are TYPE TESTS (TYPE TESTS was according to IEC60601-1:2005, clause 5.1). |

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| | | For the selection of the tests to be performed, is according to risk management process of ISO14971:2007. |
| 5.4 a) | What are the least favourable working conditions for the medical device? | Power Supply of medical equipment, The tests were under the least favourable working conditions as specified in the Instructions for Use that are identified during the risk analysis. See RM report chapter 4.2 (b) for the least favourable working conditions. |
| 5.7 | What is the longest period (if longer than specified in IEC/EN 60601-1) for which the medical device could be exposed to high humidity? | The ME equipment can be exposed to high humidity for extended periods, the period is extended appropriately. See chapter 4.2(b) for humidity condition details. |
| 5.9.2.3 | What electrical controls of the medical device are provided with handles, knobs, levers, etc.? | No such parts, Compliance shall be investigated in the final system assembly. |
| 7.1.1 | Does the usability engineering process (IEC/EN 60601-1-6) for the medical device address the risks from poor usability of identification, marking and documents? | No such marking and documents, Compliance shall be investigated in the final system assembly. |
| 7.2.2 | Identification | The foreseeable misuse of marking of label was considered. See chapter 4.3 for details. |
| 7.2.5 | ME EQUIPMENT intended to receive power from other equipment | The EUT is not intended to receive power form other equipment. To be evaluated in the final system assembly. |
| 7.2.13 | Physiological effects (safety signs and warning) | The EUT is not producing physiological effects. To be evaluated in the final system assembly. |
| 7.2.17 | Protective packaging | The risks of premature unpacking, transport or storage were considered, see chapter 4.3 for details.<br><br>Product packaging is a carton which made from material corrugated paper, cartons surface showed for shipping outside and storage conditions as below<br>  |
| 7.3.3 | Batteries | No battery. |
| 7.3.7 | Supply terminals | Terminal for supply conductor marked adjacent to the terminal. |
| 7.4.2 | Control devices | No control device. To be evaluated in the final system assembly. |
| 7.5 | Safety signs | No safety sign is used. DC to DC converter building in medical power supply of EM equipment, To be evaluated in the final |

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| | | system assembly. |
| 7.9.1 | What information for the medical device shall be provided as hard copy or as marking when the accompanying documents are provided in electronic format? | Installation instruction and specification are provided. The name, model name, trademark and address of the manufacturer are provided on the Installation instruction as hardcopy. |
| 7.9.2.4 | Electrical power source | The EUT is DC to DC converter. There is no any additional source. |
| 7.9.2.5 | ME EQUIPMENT description | For packing, we will provide the product specification per one carton, and the product specification (in English) included<br>- the description of related function of the ME equipment,<br>- a brief description of the ME equipment<br>- significant physical and performance characteristics of the ME equipment |
| 7.9.2.15 | Environmental protection | DC to DC converter, applied to be evaluated in the final system assembly. |
| 7.9.3.1 | Technical description-General | For packing, we will provide the product specification per one carton. There is showed as below in product specification.<br>WARNING: Do not modify this equipment without authorization of the manufacturer. |
| 7.9.3.2 | Replacement of fuses, power supply cords, other parts | No related parts. |
| 8.1 b) | What parts of the medical device are in separate enclosures connected by power carrying conductor(s)? | Compliance shall be investigated in the final system assembly. |
| | What components of the medical device can move unexpectedly during its expected service life? | The component's movement are considered as single fault condition. |
| 8.2.2 | Connection to an external d.c. power sources | The EUT is DC to DC converter. However, there is no connection to an external DC power source. |
| 8.3 d) | What parts of the medical device, identified as coming in contact with the patient while not being applied parts themselves, are subject to the requirements for BF- or CF-type applied parts? | Power Supply of ME equipment, The overall compliance of applied part shall be evaluated in the final system assembly. |
| 8.4.2 c) | What are the accessible parts of the medical device (not being patient connections) where a current exceeding the allowable touch current could flow, either directly or via the body of the operator, to the patient, but the probability for it to happen is negligible? | The EUT is a DC to DC converter the location and accessibility of conductive parts shall be evaluated for the end system assembly.<br>The output terminal<br>The touch current is not exceeded the limit of 100 uA. The above limit does not apply to connection to a patient. If the final system |

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| | | probability of a connection to a patient, it is necessary to evaluated for the final system assembly.<br>1. Tested on leakage current was measured as well after each single fault conditions. The measured values do not exceed the values of limit.<br>Above three items are all passed the requirement of IEC60601-1: 2005 |
| 8.5.2.2 | What B-type applied parts of the medical device are not protectively earthed and, at the same time, not separated by one MOPP from protectively earthed accessible metal parts, that can make contact with source of voltage or leakage current above the permitted limits? | DC to DC converter, applied to be evaluated in the final system assembly. |
| 8.5.2.3 | What conductive parts on connectors on the patient leads for the medical device, at the end of the lead remote from the patient, are not separated from the all patient connections by one MOPP rated for the maximum mains voltage, and can come in contact with mains sockets, flat surface or other objects? | DC to DC converter, applied to be evaluated in the final system assembly. |
| 8.6.3 | What moving parts of the medical device are protectively earthed and remain reliably so during the expected service live of the medical device? | No moving parts, to be evaluated for the final system assembly. |
| 8.8.4.1 | What type(s) of insulation for the medical device require specific test protocols, other than these required by the IEC/EN 60601-1, for verifying their resistance to heat during the expected service life of the medical device? | Building-in type power supply, it shall be evaluated in the final system. |
| 8.10.1 | What components of the medical device are securely mounted for the expected service lifetime of the medical device? | The unwanted movement of which could result in unacceptable risk. The equipment designed provided two fixings to prevent such movement. |
| 8.10.2 | What conductors in the medical device are secured by double means? | The accidental detachment of which could result in unacceptable risk. The equipment designed provided two fixings to prevent accidental detachment. |
| 8.10.5 | What internal cables, wiring and cords are protected against damage to their insulation by contact with moving parts, friction at sharp corners and edges, or during assembly and opening and closing of access covers? | All internal wiring is fixed adequately (double fix) and could avoid resulting in a hazardous situation. |
| 8.11.5 | What over-current releases, able to interrupt maximum fault currents, are provided on the supply leads of the medical device? | The EUT is DC to DC converter without fuse. To be evaluated in the final system assembly. |
| 9.2.1 | What moving parts of the medical equipment need to be exposed for the medical equipment to perform its intended function? | No moving part. To be evaluated in the final system assembly. |

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| 9.2.2.4.3 | What moveable guards can be opened without the use of a tool? | No Movable guards. To be evaluated in the final system assembly. |
| 9.2.2.4.4 | What protective measures against moving parts of the medical device or move of the medical device itself are implemented? | The EUT is DC to DC converter without moving part. To be evaluated in the final system assembly. |
| 9.2.2.5 c) | What control devices of the medical device require continuous activation by the operator in order to enable its operation? | No such parts. To be evaluated in the final system assembly. |
| 9.2.2.6 | What parts of the medical device are used to position the patient or parts of the medical device itself? | No such parts. To be evaluated in the final system assembly. |
| 9.2.3.2 | What parts of the medical device require stopping means to prevent them from overtravel? | No moving part. To be evaluated in the final system assembly. |
| 9.2.4 | What emergency stopping device(s) are used with the medical device? | No such parts. To be evaluated in the final system assembly. |
| 9.2.5 | What means for releasing of the patient quickly and safely in the event of breakdown of the medical device or failure of the power supply are provided? | No such parts. To be evaluated in the final system assembly. |
| 9.3 | What rough surfaces, sharp corners and edges of the medical device are assessable during normal use? | Building in type DC to DC converter of ME equipment. To be evaluated in the final system assembly. |
| 9.4.2.4.3 | What specific test protocols, other than these suggested by the IEC/EN 60601-1, are defined for verifying the ability of the medical device to move over a threshold? | The EUT is evaluated as the DC to DC converter. To be evaluated in the final system assembly. |
| 9.5.1 | What protection against expelled parts is provided? | No expelled parts. To be evaluated in the final system assembly. |
| 9.6.1 | What levels of noise and vibration generated by the medical device require measurement against excessive levels? | DC to DC converter, to be evaluated for the final system assembly |
| 9.6.2.2 | What parts of the medical device are source of infrasound and ultrasound? | DC to DC converter, to be evaluated for the final system assembly |
| 9.7.2 | What parts of the medical device are pneumatic or hydraulic? | No such parts. To be evaluated in the final system assembly. |
| 9.7.4 | What parts of the medical device that are subject to pressure are not equipped with pressure relief devices? | No such parts. To be evaluated in the final system assembly. |
| 9.7.6 | What pressure control devices associated with pressure relief devices are provided for the medical device? | No such parts. To be evaluated in the final system assembly. |
| 9.7.7 | What pressure relief devices are provided for the medical device? | No such parts. To be evaluated in the final system assembly. |
| 9.8.1 | What parts of the medical device are designed to support loads or to provide actuating forces? | No such parts. To be evaluated in the final system assembly. |

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| 9.8.2 | What methods, other than these required by the IEC/EN 60601-1, are used to demonstrate the structural integrity of the support systems of the medical device during its expected service life? | No such parts. To be evaluated in the final system assembly. |
| 9.8.3.1 | What parts of the medical device are used for support or immobilization of the patient? | No such parts. To be evaluated in the final system assembly. |
| 9.8.3.2 | What distribution manner for the safe working load, representing the mass of the patient, operator and accessories, is used to analyze the loading forces and torques on the support assembly of the medical device? | No such parts. To be evaluated in the final system assembly. |
| 9.8.4.1 | What mechanical protective devices of primary support means are provided for the medical device? | No such parts. To be evaluated in the final system assembly. |
| 9.8.4.3 | What mechanical protective devices of primary support means of the medical device are intended to function only once (single activation)? | No such parts. To be evaluated in the final system assembly. |
| 9.8.5 | What primary support means of the medical device do not require mechanical protective device? | No such parts. To be evaluated in the final system assembly. |
| 10.1.2 | What parts of the medical device produce diagnostic or therapeutic X-radiation? | DC to DC converter. To be evaluated in the final system assembly. |
| 10.2 | What parts of the medical device produce alpha, bet, gamma, neutron or other particle radiation? | No such parts. To be evaluated in the final system assembly. |
| 10.3 | What parts of the medical device produce microwave radiation? | No such parts. To be evaluated in the final system assembly. |
| 10.5 | What parts of the medical device produce visible electromagnetic radiation? | DC to DC converter. To be evaluated in the final system assembly. |
| 11.1.1 (table 23) | What parts of the medical device can cover more than 10% of the surface area of the operator or patient's body, or 10% of the surface area of the patient's head, that are likely to be touched and for how long? | The EUT is evaluated as the DC to DC converter. To be evaluated in the final system assembly. |
| 11.1.1 (table 24) | What applied parts of the medical device can cover more than 10% of the surface area of the operator or patient's body, or 10% of the surface area of the patient's head, that are likely to be touched and for how long? | No applied parts. To be evaluated in the final system assembly. |
| 11.1.2.1 | What parts of the medical device are intended to supply heat or cool the patient? | No such parts. To be evaluated in the final system assembly. |
| 11.1.2.2 | What parts of the medical device are not intended to supply heat or cool the patient can exceed 41°C or cool below room ambient temperature in normal use or foreseeable misuse? | No such parts. To be evaluated in the final system assembly. |
| 11.1.3 | What impact a test corner will have on the heating of the medical device and nearby surfaces considering the conditions for use of the | Build in type. Be evaluated in the final system assembly |

| | | |
|---|---|---|
| | medical device? | |
| | What is the probability of occurrence of contact and the duration of contact for part of the medical device that are likely to be touched and for the applied parts? | DC to DC converter, no applied part. To be evaluated for the final system assembly. |
| 11.2.2.1 | What compartments of medical device containing oxygen rich environment may leak or have other related failures? | No such parts. To be evaluated in the final system assembly. |
| 11.3 | What parts of the medical device form part of the fire enclosure? | The EUT is evaluated as the DC to DC converter. To be evaluated in the final system assembly. |
| 11.5 | What parts of the medical device can come into contact with flammable agents? | No such parts. To be evaluated in the final system assembly. |
| 11.6.2 | Overflow in ME EQUIPMENT | No such parts. To be evaluated in the final system assembly. |
| 11.6.3 | What type of liquid, what volume, what duration and what location shall be used for spillage test? | No such parts. To be evaluated in the final system assembly. |
| 11.6.5 | Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS | No such parts. To be evaluated in the final system assembly. |
| 11.6.6 | What are the effects and affects of multiple cleanings/disinfections during the expected service life of the medical device/system, their parts and accessories? | The EUT is evaluated as the DC to DC converter. To be evaluated in the final system assembly. |
| 11.6.7 | What parts of the medical device are subject to sterilization in normal use and foreseeable misuse and by what type? | No such parts. To be evaluated in the final system assembly. |
| 11.6.8 | What substances the medical device may come into contact with? | No such parts. To be evaluated in the final system assembly. |
| 12.1 | What is the required accuracy of controls and instruments of the medical device? | No such parts. To be evaluated in the final system assembly. |
| 12.3 | What alarms systems (IEC/EN 60601-1-8) are employed in the medical device? | No such parts. To be evaluated in the final system assembly. |
| 12.4.1 | What outputs of the medical device can be intentionally set at levels exceeding the safety limits? | No such parts. To be evaluated in the final system assembly. |
| 12.4.2 | What indication of parameters of the medical device are associated with hazardous output? | No such parts. To be evaluated in the final system assembly. |
| 12.4.3 | What multi-purpose outputs (e.g. low-intensity and high-intensity) for different treatments are provided for the medical device? | No such parts. To be evaluated in the final system assembly. |
| 12.4.4 | What outputs of the medical device can deliver energy or sub-stances to the patient? | No such parts. To be evaluated in the final system assembly. |
| 12.4.5.2 | What part(s) of the medical device can emit intentional X-radiation for diagnostic purposes (IEC/EN 60601-1-3)? | No such parts. To be evaluated in the final system assembly. |

| | | |
|---|---|---|
| 12.4.5.3 | What part(s) of the medical device can emit radiation for radiotherapy? | No such parts. To be evaluated in the final system assembly. |
| 12.4.5.4 | What part(s) of the medical device can emit diagnostic or therapeutic radiation for purposes other than radiotherapy and X-ray diagnostic? | No such parts. To be evaluated in the final system assembly. |
| 12.4.6 | What part(s) of the medical device can generate diagnostic or therapeutic acoustic pressure? | No such parts. To be evaluated in the final system assembly. |
| 13.2.6 | What parts of the medical device contain liquid(s) that may escape in an event of a failure (single fault condition)? | No such parts. To be evaluated in the final system assembly. |
| 14.1 | Programmable electrical medical systems - General | No such parts. To be evaluated in the final system assembly. |
| 14.2 | Programmable electrical medical systems - Documentation | No such parts. To be evaluated in the final system assembly. |
| 16.6.1 | Identification of known and foreseeable hazards | No such parts. To be evaluated in the final system assembly. |
| 14.6.2 | Risk control | No such parts. To be evaluated in the final system assembly. |
| 14.7 | Requirement specification | No such parts. To be evaluated in the final system assembly. |
| 14.8 | Architecture | No such parts. To be evaluated in the final system assembly. |
| 14.9 | Design and Implementation | No such parts. To be evaluated in the final system assembly. |
| 14.10 | Verification | No such parts. To be evaluated in the final system assembly. |
| 14.11 | Programmable electrical medical systems – PEMS validation | No such parts. To be evaluated in the final system assembly. |
| 14.13 | Connection of PEMS by NETWORK/DATA COUPLING to other equipment | No such parts. To be evaluated in the final system assembly. |
| 15.1 | What controls, instruments, indicating lamps, etc. are associated with specific function(s) of the medical device? | No such parts. To be evaluated in the final system assembly. |
| 15.3.2<br>15.3.3<br>15.3.4.2<br>15.3.5 | What parts of the medical device are intended to be protected by the enclosure against damage leading to unacceptable risk? | The EUT is evaluated as the DC to DC converter. To be evaluated in the final system assembly. |
| 15.4.1 | What electrical, hydraulic, pneumatic or gas connection terminals and connectors removable without the use of a tool are provided for the medical device? | No such parts. To be evaluated in the final system assembly. |
| 15.4.2.1 a) | What automatic resetting thermal cut-outs or over-current releases are provided for the medical device? | There were not used automatic resetting thermal cut-outs or over-current releases. To be evaluated in the final system assembly. |
| 15.4.2.1 | What thermal cut-out with a safety function are | No thermal cut-out used. To be evaluated in |

| | | |
|---|---|---|
| b) | provided for the medical device? | the final system assembly. |
| 15.4.2.1 c) | What thermostats are provided for the medical device? | Not used the thermostat. To be evaluated in the final system assembly. |
| 15.4.2.1 d) | What thermal cut-outs or over-current releases, the operation of which would lead to loss of function, are provided for the medical device? | No thermal cut-out used. To be evaluated in the final system assembly. |
| 15.4.2.1 h) | What tubular heating elements are provided for the medical device? | No tubular heating elements used. To be evaluated in the final system assembly. |
| 15.4.3.1 | What housing is provided for batteries of the medical device that can vent gases during charging or discharging? | No such parts. To be evaluated in the final system assembly. |
| 15.4.3.2 | Connection | No Battery used. To be evaluated in the final system assembly. |
| 15.4.3.3 | Protection against overcharging | No Battery used. To be evaluated in the final system assembly. |
| 15.4.3.4 | Lithium batteries | No Battery used. To be evaluated in the final system assembly. |
| 15.4.3.5 | What protective devices are provided for the batteries for the medical device? | No Battery used. To be evaluated in the final system assembly. |
| 15.4.4 | Indicators | No indicator used. Compliance shall be investigated in the final system assembly. |
| 15.4.5 | What pre-set controls are provided for the medical device? | No such parts. To be evaluated in the final system assembly. |
| 15.4.7.3 b) | What areas are foot controls for the medical device intended to be operated in? | No such parts. To be evaluated in the final system assembly. |
| 16.1 | What configurations settings exist and what reconfiguration activities are permitted for the medical system? | The EUT is evaluated as the DC to DC converter. To be evaluated in the final system assembly. |
| 16.9.1 | Connection terminals and connectors | DC to DC converter. To be evaluated in the final system assembly. |
| 17 | Electromagnetic compatibility of ME equipment and ME systems | The equipment has been tested and comply with the standard IEC60601-1-2: 2007, which is required by the Council Directive of 93/42/EEC. |

## (b) Intended use & most unfavorable maximum working load condition

DC to DC converter, it could be use for medical equipment with or without patient environment.

Input/ Output rating:

| type A | type B | Input Range | Output Voltage | Full Load |
|---|---|---|---|---|
| THM 3-0510A | THM 3-0510 | 4.5 ~ 9 VDC | 3.3 VDC | 1000mA |
| THM 3-0511A | THM 3-0511 | 4.5 ~ 9 VDC | 5 VDC | 600mA |
| THM 3-0512A | THM 3-0512 | 4.5 ~ 9 VDC | 12 VDC | 250mA |
| THM 3-0513A | THM 3-0513 | 4.5 ~ 9 VDC | 15 VDC | 200mA |
| THM 3-0515A | THM 3-0515 | 4.5 ~ 9 VDC | 24 VDC | 125mA |
| THM 3-0521A | THM 3-0521 | 4.5 ~ 9 VDC | ± 5 VDC | ±300mA |
| THM 3-0522A | THM 3-0522 | 4.5 ~ 9 VDC | ± 12 VDC | ± 125mA |
| THM 3-0523A | THM 3-0523 | 4.5 ~ 9 VDC | ± 15 VDC | ± 100mA |
| THM 3-1210A | THM 3-1210 | 9 ~ 18 VDC | 3.3 VDC | 1000mA |
| THM 3-1211A | THM 3-1211 | 9 ~ 18 VDC | 5 VDC | 600mA |
| THM 3-1212A | THM 3-1212 | 9 ~ 18 VDC | 12 VDC | 250mA |
| THM 3-1213A | THM 3-1213 | 9 ~ 18 VDC | 15 VDC | 200mA |
| THM 3-1215A | THM 3-1215 | 9 ~ 18 VDC | 24 VDC | 125mA |
| THM 3-1221A | THM 3-1221 | 9 ~ 18 VDC | ± 5 VDC | ±300mA |
| THM 3-1222A | THM 3-1222 | 9 ~ 18 VDC | ± 12 VDC | ± 125mA |
| THM 3-1223A | THM 3-1223 | 9 ~ 18 VDC | ± 15 VDC | ± 100mA |
| THM 3-2410A | THM 3-2410 | 18 ~ 36 VDC | 3.3 VDC | 1000mA |
| THM 3-2411A | THM 3-2411 | 18 ~ 36 VDC | 5 VDC | 600mA |
| THM 3-2412A | THM 3-2412 | 18 ~ 36 VDC | 12 VDC | 250mA |
| THM 3-2413A | THM 3-2413 | 18 ~ 36 VDC | 15 VDC | 200mA |
| THM 3-2415A | THM 3-2415 | 18 ~ 36 VDC | 24 VDC | 125mA |
| THM 3-2421A | THM 3-2421 | 18 ~ 36 VDC | ± 5 VDC | ±300mA |
| THM 3-2422A | THM 3-2422 | 18 ~ 36 VDC | ± 12 VDC | ± 125mA |
| THM 3-2423A | THM 3-2423 | 18 ~ 36 VDC | ± 15 VDC | ± 100mA |
| THM 3-4810A | THM 3-4810 | 36 ~ 75 VDC | 3.3 VDC | 1000mA |
| THM 3-4811A | THM 3-4811 | 36 ~ 75 VDC | 5 VDC | 600mA |
| THM 3-4812A | THM 3-4812 | 36 - 75 VDC | 12 VDC | 250mA |
| THM 3-4813A | THM 3-4813 | 36 ~ 75 VDC | 15 VDC | 200mA |
| THM 3-4815A | THM 3-4815 | 36 ~ 75 VDC | 24 VDC | 125mA |
| THM 3-4821A | THM 3-4821 | 36 ~ 75 VDC | ± 5 VDC | ±300mA |
| THM 3-4822A | THM 3-4822 | 36 ~ 75 VDC | ± 12 VDC | ± 125mA |

| | | | | |
|---|---|---|---|---|
| THM 3-4823A | THM 3-4823 | 36 ~ 75 VDC | ± 15 VDC | ± 100mA |
| THM 3-2410WIA | THM 3-2410WI | 9 ~ 36 VDC | 3.3 VDC | 1000mA |
| THM 3-2411WIA | THM 3-2411WI | 9 ~ 36 VDC | 5 VDC | 600mA |
| THM 3-2412WIA | THM 3-2412WI | 9 ~ 36 VDC | 12 VDC | 250mA |
| THM 3-2413WIA | THM 3-2413WI | 9 ~ 36 VDC | 15 VDC | 200mA |
| THM 3-2415WIA | THM 3-2415WI | 9 ~ 36 VDC | 24 VDC | 125mA |
| THM 3-2421WIA | THM 3-2421WI | 9 ~ 36 VDC | ± 5 VDC | ±300mA |
| THM 3-2422WIA | THM 3-2422WI | 9 ~ 36 VDC | ± 12 VDC | ± 125mA |
| THM 3-2423WIA | THM 3-2423WI | 9 ~ 36 VDC | ± 15 VDC | ± 100mA |
| THM 3-4810WIA | THM 3-4810WI | 18 ~ 75 VDC | 3.3 VDC | 1000mA |
| THM 3-4811WIA | THM 3-4811WI | 18 ~ 75 VDC | 5 VDC | 600mA |
| THM 3-4812WIA | THM 3-4812WI | 18 ~ 75 VDC | 12 VDC | 250mA |
| THM 3-4813WIA | THM 3-4813WI | 18 ~ 75 VDC | 15 VDC | 200mA |
| THM 3-4815WIA | THM 3-4815WI | 18 ~ 75 VDC | 24 VDC | 125mA |
| THM 3-4821WIA | THM 3-4821WI | 18 ~ 75 VDC | ± 5 VDC | ±300mA |
| THM 3-4822WIA | THM 3-4822WI | 18 ~ 75 VDC | ± 12 VDC | ± 125mA |
| THM 3-4823WIA | THM 3-4823WI | 18 ~ 75 VDC | ± 15 VDC | ± 100mA |
| THM 6-0510A | THM 6-0510 | 4.5 ~ 9 VDC | 3.3 VDC | 1800mA |
| THM 6-0511A | THM 6-0511 | 4.5 ~ 9 VDC | 5 VDC | 1200mA |
| THM 6-0512A | THM 6-0512 | 4.5 ~ 9 VDC | 12 VDC | 500mA |
| THM 6-0513A | THM 6-0513 | 4.5 ~ 9 VDC | 15 VDC | 400mA |
| THM 6-0515A | THM 6-0515 | 4.5 ~ 9 VDC | 24 VDC | 250mA |
| THM 6-0521A | THM 6-0521 | 4.5 ~ 9 VDC | ± 5 VDC | ± 600mA |
| THM 6-0522A | THM 6-0522 | 4.5 ~ 9 VDC | ± 12 VDC | ± 250mA |
| THM 6-0523A | THM 6-0523 | 4.5 ~ 9 VDC | ± 15 VDC | ± 200mA |
| THM 6-1210A | THM 6-1210 | 9 ~ 18 VDC | 3.3 VDC | 1800mA |
| THM 6-1211A | THM 6-1211 | 9 ~ 18 VDC | 5 VDC | 1200mA |
| THM 6-1212A | THM 6-1212 | 9 ~ 18 VDC | 12 VDC | 500mA |
| THM 6-1213A | THM 6-1213 | 9 ~ 18 VDC | 15 VDC | 400mA |
| THM 6-1215A | THM 6-1215 | 9 ~ 18 VDC | 24 VDC | 250mA |
| THM 6-1221A | THM 6-1221 | 9 ~ 18 VDC | ± 5 VDC | ± 600mA |
| THM 6-1222A | THM 6-1222 | 9 ~ 18 VDC | ± 12 VDC | ± 250mA |
| THM 6-1223A | THM 6-1223 | 9 ~ 18 VDC | ± 15 VDC | ± 200mA |
| THM 6-2410A | THM 6-2410 | 18 ~ 36 VDC | 3.3 VDC | 1800mA |
| THM 6-2411A | THM 6-2411 | 18 ~ 36 VDC | 5 VDC | 1200mA |
| THM 6-2412A | THM 6-2412 | 18 ~ 36 VDC | 12 VDC | 500mA |
| THM 6-2413A | THM 6-2413 | 18 ~ 36 VDC | 15 VDC | 400mA |
| THM 6-2415A | THM 6-2415 | 18 ~ 36 VDC | 24 VDC | 250mA |

| | | | | |
|---|---|---|---|---|
| THM 6-2421A | THM 6-2421 | 18 ~ 36 VDC | ± 5 VDC | ± 600mA |
| THM 6-2422A | THM 6-2422 | 18 ~ 36 VDC | ± 12 VDC | ± 250mA |
| THM 6-2423A | THM 6-2423 | 18 ~ 36 VDC | ± 15 VDC | ± 200mA |
| THM 6-4810A | THM 6-4810 | 36 ~ 75 VDC | 3.3 VDC | 1800mA |
| THM 6-4811A | THM 6-4811 | 36 ~ 75 VDC | 5 VDC | 1200mA |
| THM 6-4812A | THM 6-4812 | 36 - 75 VDC | 12 VDC | 500mA |
| THM 6-4813A | THM 6-4813 | 36 ~ 75 VDC | 15 VDC | 400mA |
| THM 6-4815A | THM 6-4815 | 36 ~ 75 VDC | 24 VDC | 250mA |
| THM 6-4821A | THM 6-4821 | 36 ~ 75 VDC | ± 5 VDC | ± 600mA |
| THM 6-4822A | THM 6-4822 | 36 ~ 75 VDC | ± 12 VDC | ± 250mA |
| THM 6-4823A | THM 6-4823 | 36 ~ 75 VDC | ± 15 VDC | ± 200mA |
| THM 6-4810A | THM 6-4810 | 9 ~ 36 VDC | 3.3 VDC | 1800mA |
| THM 6-4811A | THM 6-4811 | 9 ~ 36 VDC | 5 VDC | 1200mA |
| THM 6-4812A | THM 6-4812 | 9 ~ 36 VDC | 12 VDC | 500mA |
| THM 6-4813A | THM 6-4813 | 9 ~ 36 VDC | 15 VDC | 400mA |
| THM 6-4815A | THM 6-4815 | 9 ~ 36 VDC | 24 VDC | 250mA |
| THM 6-4821A | THM 6-4821 | 9 ~ 36 VDC | ± 5 VDC | ± 600mA |
| THM 6-4822A | THM 6-4822 | 9 ~ 36 VDC | ± 12 VDC | ± 250mA |
| THM 6-4823A | THM 6-4823 | 9 ~ 36 VDC | ± 15 VDC | ± 200mA |
| THM 6-4810WIA | THM 6-4810WI | 18 ~ 75 VDC | 3.3 VDC | 1800mA |
| THM 6-4811WIA | THM 6-4811WI | 18 ~ 75 VDC | 5 VDC | 1200mA |
| THM 6-4812WIA | THM 6-4812WI | 18 ~ 75 VDC | 12 VDC | 500mA |
| THM 6-4813WIA | THM 6-4813WI | 18 ~ 75 VDC | 15 VDC | 400mA |
| THM 6-4815WIA | THM 6-4815WI | 18 ~ 75 VDC | 24 VDC | 250mA |
| THM 6-4821WIA | THM 6-4821WI | 18 ~ 75 VDC | ± 5 VDC | ± 600mA |
| THM 6-4822WIA | THM 6-4822WI | 18 ~ 75 VDC | ± 12 VDC | ± 250mA |
| THM 6-4823WIA | THM 6-4823WI | 18 ~ 75 VDC | ± 15 VDC | ± 200mA |
| THM 10-0510A | THM 10-0510 | 4.5 ~ 9 VDC | 3.3 VDC | 2500mA |
| THM 10-0511A | THM 10-0511 | 4.5 ~ 9 VDC | 5 VDC | 2000mA |
| THM 10-0512A | THM 10-0512 | 4.5 ~ 9 VDC | 12 VDC | 830mA |
| THM 10-0513A | THM 10-0513 | 4.5 ~ 9 VDC | 15 VDC | 670mA |
| THM 10-0515A | THM 10-0515 | 4.5 ~ 9 VDC | 24 VDC | 416mA |
| THM 10-0521A | THM 10-0521 | 4.5 ~ 9 VDC | ± 5 VDC | ± 1000mA |
| THM 10-0522A | THM 10-0522 | 4.5 ~ 9 VDC | ± 12 VDC | ± 416mA |
| THM 10-0523A | THM 10-0523 | 4.5 ~ 9 VDC | ± 15 VDC | ± 333mA |
| THM 10-1210A | THM 10-1210 | 9 ~ 18 VDC | 3.3 VDC | 2500mA |
| THM 10-1211A | THM 10-1211 | 9 ~ 18 VDC | 5 VDC | 2000mA |
| THM 10-1212A | THM 10-1212 | 9 ~ 18 VDC | 12 VDC | 830mA |

| | | | | |
|---|---|---|---|---|
| THM 10-1213A | THM 10-1213 | 9 ~ 18 VDC | 15 VDC | 670mA |
| THM 10-1215A | THM 10-1215 | 9 ~ 18 VDC | 24 VDC | 416mA |
| THM 10-1221A | THM 10-1221 | 9 ~ 18 VDC | ± 5 VDC | ± 1000mA |
| THM 10-1222A | THM 10-1222 | 9 ~ 18 VDC | ± 12 VDC | ± 416mA |
| THM 10-1223A | THM 10-1223 | 9 ~ 18 VDC | ± 15 VDC | ± 333mA |
| THM 10-2410A | THM 10-2410 | 18 ~ 36 VDC | 3.3 VDC | 2500mA |
| THM 10-2411A | THM 10-2411 | 18 ~ 36 VDC | 5 VDC | 2000mA |
| THM 10-2412A | THM 10-2412 | 18 ~ 36 VDC | 12 VDC | 830mA |
| THM 10-2413A | THM 10-2413 | 18 ~ 36 VDC | 15 VDC | 670mA |
| THM 10-2415A | THM 10-2415 | 18 ~ 36 VDC | 24 VDC | 416mA |
| THM 10-2421A | THM 10-2421 | 18 ~ 36 VDC | ± 5 VDC | ± 1000mA |
| THM 10-2422A | THM 10-2422 | 18 ~ 36 VDC | ± 12 VDC | ± 416mA |
| THM 10-2423A | THM 10-2423 | 18 ~ 36 VDC | ± 15 VDC | ± 333mA |
| THM 10-4810A | THM 10-4810 | 36 ~ 75 VDC | 3.3 VDC | 2500mA |
| THM 10-4811A | THM 10-4811 | 36 ~ 75 VDC | 5 VDC | 2000mA |
| THM 10-4812A | THM 10-4812 | 36 - 75 VDC | 12 VDC | 830mA |
| THM 10-4813A | THM 10-4813 | 36 ~ 75 VDC | 15 VDC | 670mA |
| THM 10-4815A | THM 10-4815 | 36 ~ 75 VDC | 24 VDC | 416mA |
| THM 10-4821A | THM 10-4821 | 36 ~ 75 VDC | ± 5 VDC | ± 1000mA |
| THM 10-4822A | THM 10-4822 | 36 ~ 75 VDC | ± 12 VDC | ± 416mA |
| THM 10-4823A | THM 10-4823 | 36 ~ 75 VDC | ± 15 VDC | ± 333mA |
| THM 10-2410WIA | THM 10-2410WI | 9 ~ 36 VDC | 3.3 VDC | 2500mA |
| THM 10-2411WIA | THM 10-2411WI | 9 ~ 36 VDC | 5 VDC | 2000mA |
| THM 10-2412WIA | THM 10-2412WI | 9 ~ 36 VDC | 12 VDC | 830mA |
| THM 10-2413WIA | THM 10-2413WI | 9 ~ 36 VDC | 15 VDC | 670mA |
| THM 10-2415WIA | THM 10-2415WI | 9 ~ 36 VDC | 24 VDC | 416mA |
| THM 10-2421WIA | THM 10-2421WI | 9 ~ 36 VDC | ± 5 VDC | ± 1000mA |
| THM 10-2422WIA | THM 10-2422WI | 9 ~ 36 VDC | ± 12 VDC | ± 416mA |
| THM 10-2423WIA | THM 10-2423WI | 9 ~ 36 VDC | ± 15 VDC | ± 333mA |
| THM 10-4810WIA | THM 10-4810WI | 18 ~ 75 VDC | 3.3 VDC | 2500mA |
| THM 10-4811WIA | THM 10-4811WI | 18 ~ 75 VDC | 5 VDC | 2000mA |
| THM 10-4812WIA | THM 10-4812WI | 18 ~ 75 VDC | 12 VDC | 830mA |
| THM 10-4813WIA | THM 10-4813WI | 18 ~ 75 VDC | 15 VDC | 670mA |
| THM 10-4815WIA | THM 10-4815WI | 18 ~ 75 VDC | 24 VDC | 416mA |
| THM 10-4821WIA | THM 10-4821WI | 18 ~ 75 VDC | ± 5 VDC | ± 1000mA |
| THM 10-4822WIA | THM 10-4822WI | 18 ~ 75 VDC | ± 12 VDC | ± 416mA |
| THM 10-4823WIA | THM 10-4823WI | 18 ~ 75 VDC | ± 15 VDC | ± 333mA |

High Humidity exposed suggest: 48 hours, 15% to 95% non-condensing,

Operating temperature is maximal +50 ºC for 10W

Operating temperature is maximal +70 ºC for 6W

Operating temperature is maximal +80 ºC for 3W

DC to DC converter, No applied parts, the overall compliance of applied part shall be evaluated in the final system assembly

The equipments are Class II, build-in type, DC/DC power supply.

Pollution degree of equipment: Pollution Degree 2

Operation altitude of equipment: 0-5000 m

Provided two MOPP between input and output circuit, base on 250Vac

| | |
|---|---|
| Transportation temperature, humidity, pressure | -20 to +80°C / 10% ~ 90 %, 540 ~ 1060 hPa |
| Storage temperature, humidity, pressure | -20 to +80°C / 10% ~ 90 %, 540 ~ 1060 hPa |
| Operation temperature, humidity, pressure | 0°C ~ 40°C / 20% ~ 80 %, 540 ~ 1060 hPa |

**The reasonably foreseeable misuse listed as below table.**

Following list are on known and foreseeable hazards associated with the medical device in both normal and fault conditions.

| Item | Foreseeable misuse and hazards identification |
|---|---|
| A1 | Output overload. |
| A2 | Output short. |
| A3 | Building-in type power supply, it shall be evaluated in the final system. |
| A4 | Premature unpacking, transport or storage |

## 4.3 Identification of hazards

Following list are identification of hazard for medical device,
(Note: the evaluation of possible hazards by R/D engineer base on engineering judgment and ISO 14971, Annex E.2, table E1)

| Item | hazards identification | Hazards Type |
|---|---|---|
| B1 | Line voltage from mains to cause hazard. | Building-in type power supply, it shall be evaluated in the final system. |
| B2 | Touch current (Earth leakage current) of accessible parts to cause hazard. | Building-in type power supply, it shall be evaluated in the final system. |
| B3 | Touch current (Output leakage current) of accessible parts to cause hazard. | Building-in type power supply, it shall be evaluated in the final system. |
| B4 | Stored energy to cause hazard. | Electromagnetic energy - Electric Shock |
| B5 | High temperature to cause hazard. | Thermal energy – High temperature |
| B6 | Input current of Label less than measured value of equipment may cause fire hazard. | Labelling - Inadequate description of performance characteristics |
| B7 | X capacitor connected between Line and Neutral may cause electric shock. | Electromagnetic energy - Electric Shock |
| B8 | Fuse may not operate to cause fire hazard. | Electromagnetic energy - Electric Shock |
| B9 | Unsuitable rating of critical component (transformer, main transistor, Bridge Rectifier, wiring….) to cause fire hazard. | Electromagnetic energy - Electric Shock<br>Thermal energy – High temperature |
| B10 | Critical component fault (transformer, main transistor, Photo coupler, Bridge Rectifier, PWM IC…..etc) to cause fire hazard | Electromagnetic energy - Electric Shock<br>Thermal energy – High temperature |

| | | |
|---|---|---|
| B11 | High electrical voltage to cause insulating materials dielectric breakdown | Electromagnetic energy - Electric Shock |
| B12 | Critical component or wires displaced to cause hazard | Mechanical energy - Vibration |
| B13 | Electromagnetic phenomenon (electric fields and magnetic fields) of equipment into the environment | Radiation energy - EMC |
| B14 | Overheat to cause thermoplastic materials shrinkage or distortion | Building-in type power supply, it shall be evaluated in the final system. |
| B15 | Rating misused for Component | Electromagnetic energy - Electric Shock<br>Thermal energy – High temperature |
| B16 | Equipment expose at high humidity preconditioning treatment to cause electric shock. | Electromagnetic energy - Electric Shock |
| B17 | Markings of Label were not clearly readable to cause hazard. | Labelling - Inadequate description of performance characteristics |
| B18 | Instructions or technical description document not provided to cause hazard. | Labelling - Inadequate description of performance characteristics |
| B19. | Information of instructions not enough to cause hazard. | Labelling - Inadequate description of performance characteristics |
| B20 | The Instruction not included the disposal of waste products, residues, etc to cause hazard. | Labelling - Inadequate description of performance characteristics |
| B21 | User modified the ME equipment to cause hazard. | Labelling - Inadequate disclosure of limitations |
| B22 | The resistance to heat of insulation material (Plastic connector or bobbin etc) are not retained to cause hazard | Thermal energy – High temperature |
| B23 | Components of equipment, the unwanted movement or vibration to cause hazard. | Mechanical energy - Vibration |
| B24 | The accidental detachment of wirings to cause hazard. | Mechanical energy - Vibration |
| B25 | Wiring contact with a moving part or from friction at sharp corners and edges to cause hazard | Mechanical energy – sharp, edges |
| B26 | For equipment, no external fuses provided to cause hazard. | Electromagnetic energy - Electric Shock |
| B27 | Rough surfaces, sharp corners and edges of ME equipment to cause hazard. | Building-in type power supply, it shall be evaluated in the final system. |
| B28 | The equipment placed in a corner in normal used to cause fire hazard. | Thermal energy – High temperature |
| B29 | Constructional of Fire Enclosure not meet IEC | Building-in type power supply, it shall be |

| | | |
|---|---|---|
| | 60601-1/A1: 2012 to cause hazard. | evaluated in the final system. |
| | | |

## 4.4 Estimation of the risks for each hazardous situation

The decision of each hazardous risk were referred to recommendation of ISO14971, requirement of IEC 60601-1 and IEC 60601-1-2.

| Item | Initial Risk Estimation | | | | |
|---|---|---|---|---|---|
| | Risk | Probability | Severity of the harm | Risk level (refer to chapter 3.3 Risk Index Matrix for details) | Date of Assessment |
| A1 | Output overload. | 4 | 4 | 16 | 2016-07-20 |
| A2 | Output short. | 4 | 3 | 12 | 2016-07-20 |
| A3 | Voltage mismatch. | -- | -- | -- | Building-in type power supply, it shall be evaluated in the final system. |
| A4 | Premature unpacking, transport or storage | 3 | 3 | 9 | 2016-07-20 |
| B1 | Line voltage from mains | -- | -- | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B2 | Touch current (Earth leakage current) of accessible parts to cause hazard. | -- | -- | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B3 | Touch current (Output leakage current) of accessible parts to cause hazard. | -- | -- | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B4 | Stored energy | -- | -- | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B5 | High temperature | 5 | 2 | 10 | 2016-07-20 |
| B6 | Input current of Label less than measured value of equipment may cause fire hazard. | 4 | 4 | 16 | 2016-07-20 |
| B7 | X capacitor connected between Line and Neutral may cause electric shock. | -- | -- | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B8 | Fuse may not operate to cause fire hazard. | -- | -- | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B9 | Unsuitable rating of critical component (transformer, main transistor, Bridge Rectifier, wiring….) to cause fire hazard. | 5 | 4 | 20 | 2016-07-20 |

| Item | Initial Risk Estimation | | | | |
|---|---|---|---|---|---|
| | Risk | Probability | Severity of the harm | Risk level (refer to chapter 3.3 Risk Index Matrix for details) | Date of Assessment |
| B10 | Critical component fault (transformer, main transistor, Photo coupler, Bridge Rectifier, PWM IC…..etc) to cause fire hazard | 5 | 4 | 20 | 2016-07-20 |
| B11 | High electrical voltage to cause insulating materials dielectric breakdown | 5 | 4 | 20 | 2016-07-20 |
| B12 | Critical component or wires displaced to cause hazard | 4 | 4 | 16 | 2016-07-20 |
| B13 | Electromagnetic phenomenon of equipment into the environment | 1 | 3 | 3 | 2016-07-20 |
| B14 | Overheat to cause thermoplastic materials shrinkage or distortion | 2 | 2 | 4 | 2016-07-20 |
| B15 | Rating misused for Component with high-integrity characteristics | 1 | 1 | 1 | 2016-07-20 |
| B16 | Equipment expose at high humidity preconditioning treatment to cause electric shock. | 4 | 4 | 16 | 2016-07-20 |
| B17 | Markings of Label were not clearly readable to cause hazard. | 4 | 3 | 12 | 2016-07-20 |
| B18 | Instructions or technical description document not provided to cause hazard. | 4 | 3 | 12 | 2016-07-20 |
| B19 | Information of instructions not enough to cause hazard. | 3 | 3 | 9 | 2016-07-20 |
| B20 | The Instruction not included the disposal of waste products, residues, etc to cause hazard. | 3 | 4 | 12 | 2016-07-20 |
| B21 | User modified the ME equipment to cause hazard. | 3 | 3 | 9 | 2016-07-20 |
| B22 | The resistance to heat of insulation material (bobbin etc) are not retained to cause hazard | 4 | 4 | 16 | 2016-07-20 |
| B23 | Components of equipment, the unwanted movement or vibration to cause hazard. | 4 | 4 | 16 | 2016-07-20 |

| Item | Initial Risk Estimation | | | | |
|---|---|---|---|---|---|
| | Risk | Probability | Severity of the harm | Risk level (refer to chapter 3.3 Risk Index Matrix for details) | Date of Assessment |
| B24 | The accidental detachment of wirings to cause hazard. | 3 | 3 | 9 | 2016-07-20 |
| B25 | wiring contact with a moving part or from friction at sharp corners and edges to cause hazard | 4 | 3 | 12 | 2016-07-20 |
| B26 | For equipment, no external fuses provided to cause hazard. | 4 | 3 | 12 | 2016-07-20 |
| B27 | Rough surfaces, sharp corners and edges of ME equipment to cause hazard. | -- | -- | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B28 | The equipment placed in a corner in normal used to cause fire hazard. | -- | -- | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B29 | Constructional of Fire Enclosure not meet IEC 60601-1/A1: 2012 to cause hazard. | -- | -- | -- | Building-in type power supply, it shall be evaluated in the final system. |
| Note: | | | | | |

## 5. Risk evaluation

For each identified hazardous situation, the manufacturer decided, using the criteria defined in the risk management plan, if risk reduction is required.

If risk reduction is not required, the requirements given in 6.2 to 6.6 do not apply for this hazardous situation.

The results of this risk evaluation were recorded as below.

| **Item** | Risk | Risk level<br>Risk=Severity x probability<br>Result: Risk=1~4, acceptable; 5~25, unacceptable | Date of Assessment |
|---|---|---|---|
| A1 | Output overload. | 16 (unacceptable) | 2016-07-20 |
| A2 | Output short. | 12 (unacceptable) | 2016-07-20 |
| A3 | Voltage mismatch. | -- | Building-in type power supply, it shall be evaluated in the final system. |
| A4 | Premature unpacking, transport or storage | 9 (unacceptable) | 2016-07-20 |
| B1 | Line voltage from mains | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B2 | Touch current (Enclosure leakage current) of accessible parts to cause hazard. | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B3 | Touch current (Output leakage current) of accessible parts to cause hazard. | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B4 | Stored energy | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B5 | High temperature | 10 (unacceptable, to be reduced) | 2016-07-20 |
| B6 | Input current of Label less than measured value of equipment may cause fire hazard. | 16 (unacceptable, to be reduced) | 2016-07-20 |
| B7 | X capacitor connected between Line and Neutral may cause electric shock. | -- | Building-in type power supply, it shall be evaluated in the |

| Item | Risk | Risk level<br>Risk=Severity x probability<br>Result: Risk=1~4, acceptable; 5~25, unacceptable | Date of Assessment |
|---|---|---|---|
| | | | final system. |
| B8 | Fuse may not operate to cause fire hazard. | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B9 | Unsuitable rating of critical component (transformer, main transistor, Bridge Rectifier, wiring….) to cause fire hazard. | 20 (unacceptable, to be reduced) | 2016-07-20 |
| B10 | Critical component fault (transformer, main transistor, Photo coupler, Bridge Rectifier, PWM IC…..etc) to cause fire hazard | 20 (unacceptable, to be reduced) | 2016-07-20 |
| B11 | High electrical voltage to cause insulating materials dielectric breakdown | 20 (unacceptable, to be reduced) | 2016-07-20 |
| B12 | Critical component or wires displaced to cause hazard | 16 (unacceptable, to be reduced) | 2016-07-20 |
| B13 | Electromagnetic phenomenon of equipment into the environment | 3 (acceptable) | 2016-07-20 |
| B14 | Overheat to cause thermoplastic materials shrinkage or distortion | 4 (acceptable) | 2016-07-20 |
| B15 | Openings of enclosure to cause fire hazard | 1 (acceptable) | 2016-07-20 |
| B16 | Equipment expose at high humidity preconditioning treatment to cause electric shock. | 16 (unacceptable, to be reduced) | 2016-07-20 |
| B17 | Markings of Label were not clearly readable to cause hazard. | 12 (unacceptable, to be reduced) | 2016-07-20 |
| B18 | Instructions or technical description document not provided to cause hazard. | 12 (unacceptable, to be reduced) | 2016-07-20 |
| B19 | Information of instructions not enough to cause hazard. | 9 (unacceptable, to be reduced) | 2016-07-20 |
| B20 | The Instruction not included the disposal of waste products, residues, etc to cause hazard. | 12 (unacceptable, to be reduced) | 2016-07-20 |

| Item | Risk | Risk level<br>Risk=Severity x probability<br>Result: Risk=1~4, acceptable; 5~25, unacceptable | Date of Assessment |
|---|---|---|---|
| B21 | User modified the ME equipment to cause hazard. | 9 (unacceptable, to be reduced) | 2016-07-20 |
| B22 | The resistance to heat of insulation material (bobbin etc) are not retained to cause hazard | 16 (unacceptable, to be reduced) | 2016-07-20 |
| B23 | Components of equipment, the unwanted movement or vibration to cause hazard. | 16 (unacceptable, to be reduced) | 2016-07-20 |
| B24 | The accidental detachment of wirings to cause hazard. | 9 (unacceptable, to be reduced) | 2016-07-20 |
| B25 | wiring contact with a moving part or from friction at sharp corners and edges to cause hazard | 12 (unacceptable, to be reduced) | 2016-07-20 |
| B26 | For equipment, no external fuses provided to cause hazard. | 12 (unacceptable, to be reduced) | 2016-07-20 |
| B27 | Rough surfaces, sharp corners and edges of ME equipment to cause hazard. | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B28 | The equipment placed in a corner in normal used to cause fire hazard. | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B29 | Constructional of Fire Enclosure not meet IEC 60601-1/A1: 2012 to cause hazard. | -- | Building-in type power supply, it shall be evaluated in the final system. |
| | | | |

## 6. Risk control

### 6.1 Risk reduction

Risk control activities was according to **6.2** to **6.7**

### 6.2 Risk control option analysis

One of following risk control options apply:
a) inherent safety by design;
b) protective measures in the medical device itself or in the manufacturing process;
c) information for safety

| Item | Risk | Risk control option analysis | Note |
|---|---|---|---|
| A1 | Output overload. | a) inherent safety by design | Designed regulating network of OVP, OCP into circuit |
| A2 | Output short. | a) inherent safety by design | Designed regulating network of OVP, OCP into circuit |
| A3 | Voltage mismatch. | -- | Building-in type power supply, it shall be evaluated in the final system. |
| A4 | Premature unpacking, transport or storage | a) inherent safety by design | The outside of packaging marked environmental conditions for transport and storage according to IEC60601-1:2005, ISO 780 and ISO15223.  |
| B1 | Line voltage from mains | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B2 | Touch current (Enclosure leakage current) of accessible parts to cause hazard. | a) inherent safety by design | DC/DC converter no Y cap. and Bridge Cap. used. |
| B3 | Touch current (Output leakage current) of accessible parts to cause hazard | a) inherent safety by design | DC/DC converter no Y cap. and Bridge Cap. used. |
| B4 | Stored energy | a) inherent safety by design | DC/DC converter no Y cap. and Bridge Cap. used. |
| B5 | High temperature | a) inherent safety by design | Designed Transformer to meet Class A or B (95 or 120 deg. C) limited of IEC60601-1:2005.<br>Building-in type power supply, it shall be evaluated in the final system. |
| B6 | Input current of Label less than measured value of equipment may cause fire | a) inherent safety by design | Provided rating information on label drawing of unit or installation instruction to comply with IEC60601-1:2005, clause 4.11, power input test requirement. |

| | | | |
|---|---|---|---|
| | hazard. | | |
| B7 | X capacitor connected between Line and Neutral may cause electric shock. | a) inherent safety by design | DC/DC converter no X cap. used. |
| B8 | Fuse may not operate to cause fire hazard. | a) inherent safety by design | DC/DC converter, no fuse used. it shall be evaluated in the final system. |
| B9 | Unsuitable rating of critical component (transformer, main transistor, Bridge Rectifier, wiring….) to cause fire hazard. | a) inherent safety by design | According to our design procedure to use within their specified ratings. |
| B10 | Critical component fault (transformer, main transistor, Photo coupler, Bridge Rectifier, PWM IC…..etc) to cause fire hazard | a) inherent safety by design | According to our design procedure, all components and wiring are used within their specified ratings.<br>And comply with IEC60601-1:2005, clause 13, single fault conditions test requirement. |
| B11 | High electrical voltage to cause insulating materials dielectric breakdown | a) inherent safety by design | Insulation materials were used withstand voltage minimum 4000Vac. And application was complying with IEC 60601-1:2005 requirements. |
| B12 | Critical component or wires displaced to cause hazard | a) inherent safety by design | The equipment designed provided two fixings (Mechanically securing, glue, soldering, physical fit…..) to prevent such movement. |
| B13 | Electromagnetic phenomenon of equipment into the environment | a) inherent safety by design | Designed EMI copper shielding for Transformer. |
| B14 | Overheat to cause thermoplastic materials shrinkage or distortion | a) inherent safety be design | Used suitable plastic case for heating test result. |
| B15 | Rating misused for Component with high-integrity characteristics | a) inherent safety by design | According to our procedure, all components and wiring are used within their specified ratings |
| B16 | Equipment expose at high humidity preconditioning treatment to cause electric shock. | a) inherent safety by design | Forbid absorbent material used in equipment to comply with IEC60601-1:2005, clause 5.7 requirement. |
| B17 | Markings of Label were not clearly readable to cause hazard. | a) inherent safety by design | Used Waterproof Labels material ( UL certificated) |
| B18 | Instructions or technical description document not provided to cause hazard. | a) inherent safety by design | For packing, we will provide the instruction manual per one carton. There is showed as below in instruction manual. |
| B19. | Information of instructions not enough to cause | a) inherent safety by design | The product specification shall be according to IEC60601-1:2005, clause 7.9.2.5 provided following information: |

| | | | |
|---|---|---|---|
| | hazard. | | a. brief description of the ME equipment<br>b. how the ME equipment functions<br>c. the significant physical and performance characteristics of the ME equipment<br>d. conditions of safe operation, transport and storage |
| B20 | The Instruction not included the disposal of waste products, residues, etc to cause hazard. | a) inherent safety by design | The instructions shall be according to IEC60601-1:2005, clause 7.9.2.15 and 7.9.3.1 provided following information:<br>- It was showed in the instruction manual, as " Do not dispose this product in the household waste, please, follow the respective national law for proper disposal."<br>- The sign  showed on the instruction. |
| B21 | User modified the ME equipment to cause hazard. | a) inherent safety by design | The product specification shall be according to IEC60601-1:2005, clause 7.9.3.1 provided following information:<br>**WARING**: Do not modify this equipment without authorization of the manufacturer. |
| B22 | The resistance to heat of insulation material (plastic enclosure or bobbin etc) are not retained to cause hazard | a) inherent safety by design | Used high thermal rating of plastic material with UL94 approved to meet with to IEC60601-1:2005, Ball pressure test requirement. |
| B23 | Components of equipment, the unwanted movement or vibration to cause hazard. | a) inherent safety by design | The movable components (with 10N) will provide two fixings (Mechanically securing, glue, soldering, physical fit…..) to prevent such movement |
| B24 | The accidental detachment of wirings to cause hazard. | a) inherent safety by design | The internal wire provided with two fixings (Mechanically securing, glue, soldering, physical fit…..) to prevent such accidental detachment |
| B25 | wiring contact with a moving part or from friction at sharp corners and edges to cause hazard | a) inherent safety by design | Designed wire-ways of internal wire shall be smooth and free form sharp edges. Wires shall be protected so that they do not come into contact with burrs, cooling fins, moving parts. |
| B26 | No fuses provided on each supply lead to cause hazard. | c) information for safety | Provide external fuse adequate information to the final system. |
| B27 | Rough surfaces, sharp corners and edges of ME equipment to cause hazard. | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B28 | The equipment placed in a corner in normal used to cause fire hazard. | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B29 | Constructional of Fire Enclosure not meet IEC 60601-1/A1: 2012 to | -- | Building-in type power supply, it shall be evaluated in the final system. |

| | | | |
|---|---|---|---|
| | cause hazard. | | |

## 6.3 Implementation of risk control measure(s)

All risk control measures were verified and effective. See below for details.

| Item | Risk | verified | Note |
|---|---|---|---|
| A1 | Output overload. | Designed regulating network of OVP, OCP into circuit | Comply with IEC 60601-1/A1: 2012, clause 13, single fault conditions test requirement. |
| A2 | Output short. | Designed regulating network of OVP, OCP into circuit | Comply with IEC 60601-1/A1: 2012, clause 13, single fault conditions test requirement. |
| A3 | Voltage mismatch. | -- | Building-in type power supply, it shall be evaluated in the final system. |
| A4 | Premature unpacking, transport or storage | The outside of packaging marked environmental conditions for transport and storage | Comply with IEC60601-1:2005, ISO 780 and ISO15223 requirement. |
| B1 | Line voltage from mains | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B2 | Touch current (Enclosure leakage current) of accessible parts to cause hazard. | DC/DC converter no Y cap. and Bridge Cap. used. | Not comply with IEC 60601-1/A1: 2012, clause 8.7, leakage current test requirement. |
| B3 | Touch current (Output leakage current) of accessible parts to cause hazard | DC/DC converter no Y cap. and Bridge Cap. used. | Not comply with IEC 60601-1/A1: 2012, clause 8.7, leakage current test requirement. |
| B4 | Stored energy | DC/DC converter no Y cap. and Bridge Cap. used. | Not comply with IEC 60601-1/A1: 2012, clause 8.4.3 requirement. |
| B5 | High temperature | Designed Transformer to meet Class A or B (95 or 120 deg. C). | Comply with IEC 60601-1/A1: 2012, Table 22, Table 23 requirement. |
| B6 | Input current of Label less than measured value of equipment may cause fire hazard. | Provided rating information on label drawing of unit | Comply with IEC 60601-1/A1: 2012, clause 4.11, power input test requirement. |
| B7 | X capacitor connected between Line and Neutral may cause electric shock. | DC/DC converter no X cap. used. | Not comply with IEC 60601-1/A1: 2012, clause 8.4.3, voltage limitation test requirement. |
| B8 | Fuse may not operate to cause fire hazard. | DC/DC converter, no fuse used. | Not comply with IEC 60601-1/A1: 2012, clause 13, single fault conditions test requirement. |
| B9 | Unsuitable rating of critical component (transformer, main transistor, Bridge | According to our design procedure to use within their specified ratings. | Comply with IEC 60601-1/A1: 2012, clause 4.8 requirement. |

| Item | Risk | verified | Note |
|---|---|---|---|
| | Rectifier, wiring….) to cause fire hazard. | | |
| B10 | Critical component fault (transformer, main transistor, Photo coupler, Bridge Rectifier, PWM IC…..etc) to cause fire hazard | According to our design procedure, all components and wiring are used within their specified ratings. | Comply with IEC 60601-1/A1: 2012, clause 13, single fault conditions test requirement. |
| B11 | High electrical voltage to cause insulating materials dielectric breakdown | Insulation materials were used withstand voltage complies with standard requirement. | Complying with IEC 60601-1/A1: 2012 clause 8.8 requirements. |
| B12 | Critical component or wires displaced to cause hazard | The equipment designed provided two fixings (Mechanically securing, glue, soldering, physical fit…..) to prevent such movement. | Complying with IEC 60601-1/A1: 2012 clause 9.3 requirements. |
| B13 | Electromagnetic phenomenon of equipment into the environment | Designed steady and solid enclosure to covered unit. | Complying with IEC60601-1-2 requirements. |
| B14 | Overheat to cause thermoplastic materials shrinkage or distortion | Used suitable plastic case | Complying with IEC 60601-1/A1: 2012 clause 11 requirements. |
| B15 | Rating misused for Component with high-integrity characteristics | According to our procedure, all components and wiring are used within their specified ratings | Comply with IEC 60601-1/A1: 2012, clause 4.8 requirement. |
| B16 | Equipment expose at high humidity preconditioning treatment to cause electric shock. | Forbid absorbent material used in equipment | Complying with IEC 60601-1/A1: 2012 clause 5.7 requirements. |
| B17 | Markings of Label were not clearly readable to cause hazard. | Used Waterproof Labels material ( UL certificated) | Comply with IEC 60601-1/A1: 2012, clause 7.1.2 & 7.1.3, durability of marking test requirement. |
| B18 | Instructions or technical description document not provided to cause hazard. | For packing, we will provide the instruction manual per one carton. There is showed as below in instruction manual. | Comply with IEC 60601-1/A1: 2012, clause 7 requirement. |
| B19 · | Information of instructions not | The instructions provided | Comply with IEC 60601-1/A1: 2012, clause 7 requirement. |

| Item | Risk | verified | Note |
|---|---|---|---|
| | enough to cause hazard. | | |
| B20 | The Instruction not included the disposal of waste products, residues, etc to cause hazard. | The instructions provided | Comply with IEC 60601-1/A1: 2012, clause 7 requirement. |
| B21 | User modified the ME equipment to cause hazard. | The instructions provided with waring information | Comply with IEC 60601-1/A1: 2012, clause 7.9.3.1 requirement. |
| B22 | The resistance to heat of insulation material (plastic connector or bobbin etc) are not retained to cause hazard | Provided with high temp. rating plastic material | Comply with IEC 60601-1/A1: 2012, clause 8.8.4.1 Ball pressure test requirement. |
| B23 | Components of equipment, the unwanted movement or vibration to cause hazard. | The movable components (with 10N) will provide two fixings (Mechanically securing, glue, soldering, physical fit…..) to prevent such movement | Comply with IEC 60601-1/A1: 2012, clause 8.9.4 clearance/creepage measurement requirement. |
| B24 | The accidental detachment of wirings to cause hazard. | The internal wire provided with two fixings (Mechanically securing, glue, soldering, physical fit…..) to prevent such accidental detachment | Comply with IEC 60601-1/A1: 2012, clause 8.10.1 requirement. |
| B25 | wiring contact with a moving part or from friction at sharp corners and edges to cause hazard | Designed wire-ways of internal wire shall be smooth and free form sharp edges. Wires shall be protected so that they do not come into contact with burrs, cooling fins, moving parts | Comply with IEC 60601-1/A1: 2012, clause 8.10.1 requirement. |
| B26 | For equipment, no external fuses provided to cause hazard. | Provide external fuse adequate information to the final system. | Comply with IEC 60601-1/A1: 2012, clause 8.10.1 requirement. |
| B27 | Rough surfaces, sharp corners and edges of ME equipment to cause hazard. | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B28 | The equipment placed in a corner in normal used to cause fire hazard. | -- | Building-in type power supply, it shall be evaluated in the final system. |
| B29 | Constructional of Fire Enclosure not meet | -- | Building-in type power supply, it shall be evaluated in the final system. |

| Item | Risk | verified | Note |
|---|---|---|---|
| | IEC 60601-1/A1: 2012 to cause hazard. | | |

## 6.4 Residual risk evaluation

According to procedure, all residual risks are judged acceptable. No further risk control measures shall be applied after the risk control measures are applied, See below table for details.

| | | **Initial Risk Estimation (Before Risk Control0** | | | | **Risk Estimation (After Risk Control )** | | |
|---|---|---|---|---|---|---|---|---|
| item | Risk | Probability | Severity of the harm | Risk level (refer to chapter 3.3 Risk Index Matrix for details) | Risk control measure | Probability | Severity of the harm | Risk level (refer to chapter 3.3 Risk Index Matrix for details) |
| A1 | Output overload. | 4 | 4 | 16 (unacceptable) | After risk control measure[1)] | 2 | 2 | 4 (acceptable) |
| A2 | Output short. | 4 | 3 | 12 (unacceptable) | After risk control measure[1] | 2 | 2 | 4 (acceptable) |
| A3 | Voltage mismatch. | -- | -- | -- | -- | -- | -- | -- |
| A4 | Premature unpacking, transport or storage | 3 | 3 | 9 (unacceptable) | After risk control measure[1] | 1 | 2 | 2 (acceptable) |
| B1 | Line voltage from mains | -- | -- | -- | -- | -- | -- | -- |
| B2 | Touch current (Enclosure leakage current) of accessible parts to cause hazard. | -- | -- | -- | -- | -- | -- | -- |
| B3 | Touch current (Output leakage current) of accessible parts to cause hazard | -- | -- | -- | -- | -- | -- | -- |
| B4 | Stored energy | -- | -- | -- | -- | -- | -- | -- |
| B5 | High temperature | 5 | 2 | 10 (unacceptable) | After risk control measure[1] | 1 | 2 | 2 (acceptable) |
| B6 | Input current of Label less than measured value of equipment may cause fire hazard. | 4 | 4 | 16 (unacceptable) | After risk control measure[1] | 1 | 2 | 2 (acceptable) |
| B7 | X capacitor connected between | -- | -- | -- | -- | -- | -- | -- |

| | | Initial Risk Estimation (Before Risk Control0 | | | | Risk Estimation (After Risk Control ) | | |
|---|---|---|---|---|---|---|---|---|
| item | Risk | Probability | Severity of the harm | Risk level (refer to chapter 3.3 Risk Index Matrix for details) | Risk control measure | Probability | Severity of the harm | Risk level (refer to chapter 3.3 Risk Index Matrix for details) |
| | Line and Neutral may cause electric shock. | | | | | | | |
| B8 | Fuse may not operate to cause fire hazard. | -- | -- | -- | -- | -- | -- | -- |
| B9 | Unsuitable rating of critical component (transformer, main transistor, Bridge Rectifier, wiring….) to cause fire hazard. | 5 | 4 | 20 (unacceptable) | After risk control measure[1] | 2 | 2 | 4 (acceptable) |
| B10 | Critical component fault (transformer, main transistor, Photo coupler, Bridge Rectifier, PWM IC…..etc) to cause fire hazard | 5 | 4 | 20 (unacceptable) | After risk control measure[1] | 2 | 2 | 4 (acceptable) |
| B11 | High electrical voltage to cause insulating materials dielectric breakdown | 5 | 4 | 20 (unacceptable) | After risk control measure[1] | 2 | 2 | 4 (acceptable) |
| B12 | Critical component or wires displaced to cause hazard | 4 | 4 | 16 (unacceptable) | After risk control measure[1] | 2 | 1 | 2 (acceptable) |
| B13 | Electromagnetic phenomenon of equipment into the environment | 2 | 4 | 8 (unacceptable) | After risk control measure[1] | 1 | 3 | 3 (acceptable) |
| B14 | Overheat to cause thermoplastic materials shrinkage or distortion | 5 | 4 | 20 (unacceptable) | After risk control measure[1] | 2 | 2 | 4 (acceptable) |
| B15 | Rating misused for Component with high-integrity characteristics | 4 | 4 | 16 (unacceptable) | After risk control measure[1] | 2 | 1 | 2 (acceptable) |

| | | Initial Risk Estimation (Before Risk Control0 | | | | Risk Estimation (After Risk Control ) | | |
|---|---|---|---|---|---|---|---|---|
| item | Risk | Probability | Severity of the harm | Risk level (refer to chapter 3.3 Risk Index Matrix for details) | Risk control measure | Probability | Severity of the harm | Risk level (refer to chapter 3.3 Risk Index Matrix for details) |
| B16 | Equipment expose at high humidity preconditioning treatment to cause electric shock. | 4 | 4 | 16 (unacceptable) | After risk control measure[1] | 2 | 2 | 4 (acceptable) |
| B17 | Markings of Label were not clearly readable to cause hazard. | 4 | 3 | 12 (unacceptable) | After risk control measure[1] | 2 | 1 | 2 (acceptable) |
| B18 | Instructions or technical description document not provided to cause hazard. | 4 | 3 | 12 (unacceptable) | After risk control measure[1] | 1 | 1 | 1 (acceptable) |
| B19. | Information of instructions not enough to cause hazard. | 3 | 3 | 9 (unacceptable) | After risk control measure[1] | 1 | 1 | 1 (acceptable) |
| B20 | The Instruction not included the disposal of waste products, residues, etc to cause hazard. | 3 | 4 | 12 (unacceptable) | After risk control measure[1] | 1 | 2 | 2 (acceptable) |
| B21 | User modified the ME equipment to cause hazard. | 3 | 3 | 9 (unacceptable) | After risk control measure[1] | 1 | 1 | 1 (acceptable) |
| B22 | The resistance to heat of insulation material (bobbin etc) are not retained to cause hazard | 4 | 4 | 16 (unacceptable) | After risk control measure[1] | -- | -- | -- |
| B23 | Components of equipment, the unwanted movement or vibration to cause hazard. | 4 | 4 | 16 (unacceptable) | After risk control measure[1] | 1 | 4 | 4 (acceptable) |
| B24 | The accidental | 3 | 3 | 9 | After risk | 3 | 1 | 3 |

| | | Initial Risk Estimation (Before Risk Control0 | | | | Risk Estimation (After Risk Control ) | | |
|---|---|---|---|---|---|---|---|---|
| item | Risk | Probability | Severity of the harm | Risk level (refer to chapter 3.3 Risk Index Matrix for details) | Risk control measure | Probability | Severity of the harm | Risk level (refer to chapter 3.3 Risk Index Matrix for details) |
| | detachment of wirings to cause hazard. | | | (unacceptable) | control measure[1] | | | (acceptable) |
| B25 | wiring contact with a moving part or from friction at sharp corners and edges to cause hazard | 4 | 2 | 12 (unacceptable) | After risk control measure[1] | 2 | 1 | 2 (acceptable) |
| B26 | For equipment, no external fuses provided to cause hazard. | 4 | 2 | 12 (unacceptable) | After risk control measure[1] | 1 | 1 | 1 (acceptable) |
| B27 | Rough surfaces, sharp corners and edges of ME equipment to cause hazard. | -- | -- | -- | -- | -- | -- | -- |
| B28 | The equipment placed in a corner in normal used to cause fire hazard. | -- | -- | -- | -- | -- | -- | -- |
| B29 | Constructional of Fire Enclosure not meet IEC 60601-1/A1: 2012 to cause hazard. | -- | -- | -- | -- | -- | -- | -- |

Note:

1) See chapter 6.2 for manner of risk control details and chapter 6.3 for evidence details.

### 6.5 Risk/benefit analysis
According to procedure, No need to risk/benefit analysis because all residual risk is judged acceptable after risk control (using the criteria defined in the risk management plan).

### 6.6 Risks arising from risk control measures
No new hazards or hazardous situations arising from risk control measures because all risk control measures are inherent design in equipment before process of risk management and result of these control measures are acceptable.

And all previously identified hazardous situations were not affected by the introduction of the risk control measures.

### 6.7 Completeness of risk control
All identified hazardous situations have been considered. The results of activity are recorded by Quality Assurance department.

## 7. Evaluation of overall residual risk acceptability
After all risk control measures have been implemented and verified, the overall residual risk posed by the power supply is acceptable using the criteria defined in the risk management plan.

## 8. Risk management report
The report was intended to ensure that the risk management plan was properly implemented. The overall residual risk is acceptable and there are appropriate methods in place to collect and analyze production and post-production information.

# Attachment: Risk Management Plan

# Risk Management Plan

## DC-DC Converter

Model: THM x-yzAz1z1z1z1z1z1z1, where x = 3, 6 or 10 representing output power, y = 05, 12, 24 or 48, z = 10, 11, 12, 13, 15, 21, 22 or 23, z1 can be any alphanumeric or blank for marketing purpose and no impact to safety.

THM x-yzz1z1z1z1z1z1z1, where x = 3, 6 or 10 representing output power, y = 05, 12, 24 or 48, z = 10, 11, 12, 13, 15, 21, 22 or 23, z1 can be any alphanumeric or blank for marketing purpose and no impact to safety.

THM x-yzWIAz1z1z1z1z1z1z1, where x = 3, 6 or 10 representing output power, y = 24 or 48, z = 10, 11, 12, 13, 15, 21, 22 or 23, z1 can be any alphanumeric or blank for marketing purpose and no impact to safety.

THM X-YZWIZ1Z1Z1Z1Z1Z1Z1, WHERE X = 3, 6 OR 10 REPRESENTING OUTPUT POWER, Y = 24 OR 48, Z = 10, 11, 12, 13, 15, 21, 22 OR 23, Z1 CAN BE ANY ALPHANUMERIC OR BLANK FOR MARKETING PURPOSE AND NO IMPACT TO SAFETY.

# 1 Introduction

This risk management plan was established in accordance with ISO 14971 and considers the recommendations of all informative attachments of this standard. This risk management plan is in accordance with all requirements listed in appendix F. Its task is to describe the risk management process for the following product group:

## DC-DC Converter

**Model: THM x-yzAz1z1z1z1z1z1z1 , where x = 3, 6 or 10 representing output power, y = 05, 12, 24 or 48, z = 10, 11, 12, 13, 15, 21, 22 or 23, z1 can be any alphanumeric or blank for marketing purpose and no impact to safety.**

**Model THM x-yzz1z1z1z1z1z1z1, where x = 3, 6 or 10 representing output power, y = 05, 12, 24 or 48, z = 10, 11, 12, 13, 15, 21, 22 or 23, z1 can be any alphanumeric or blank for marketing purpose and no impact to safety.**

**Model THM x-yzWIAz1z1z1z1z1z1z1, where x = 3, 6 or 10 representing output power, y = 24 or 48, z = 10, 11, 12, 13, 15, 21, 22 or 23, z1 can be any alphanumeric or blank for marketing purpose and no impact to safety.**

**Model THM x-yzWIz1z1z1z1z1z1z1, where x = 3, 6 or 10 representing output power, y = 24 or 48, z = 10, 11, 12, 13, 15, 21, 22 or 23, z1 can be any alphanumeric or blank for marketing purpose and no impact to safety.**

to identify potential risks, evaluate them and to control them effectively. This risk management plan describes the risk management process of the medical device manufacturer

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for the above mentioned medical device. It covers all phases of the life cycle, starting with the concept (design and development control), production, storage / despatch up to decommissioning or waste disposal in accordance with ISO 14971

In this risk management plan the following areas are covered:

- Description of the medical device and designation of the performance properties (ISO 14971)
- Designation of personnel, responsibilities and competence within the risk management process (ISO 14971)
- Evaluation of the risk management process through the management (ISO 14971)
- Criteria for the acceptability of risks (ISO 14971)
- Flow chart of the risk management process (ISO 14971)

# 2 Description of the Medical Device and Designation of Performance Properties

## 2.1. Specific Properties and Intended Use

DC to DC converter, it could be use for medical equipment with or without patient environment.

Input/ Output rating:

| type A | type B | Input Range | Output Voltage | Full Load |
|---|---|---|---|---|
| THM 3-0510A | THM 3-0510 | 4.5 ~ 9 VDC | 3.3 VDC | 1000mA |
| THM 3-0511A | THM 3-0511 | 4.5 ~ 9 VDC | 5 VDC | 600mA |
| THM 3-0512A | THM 3-0512 | 4.5 ~ 9 VDC | 12 VDC | 250mA |
| THM 3-0513A | THM 3-0513 | 4.5 ~ 9 VDC | 15 VDC | 200mA |
| THM 3-0515A | THM 3-0515 | 4.5 ~ 9 VDC | 24 VDC | 125mA |
| THM 3-0521A | THM 3-0521 | 4.5 ~ 9 VDC | ± 5 VDC | ±300mA |
| THM 3-0522A | THM 3-0522 | 4.5 ~ 9 VDC | ± 12 VDC | ± 125mA |
| THM 3-0523A | THM 3-0523 | 4.5 ~ 9 VDC | ± 15 VDC | ± 100mA |
| THM 3-1210A | THM 3-1210 | 9 ~ 18 VDC | 3.3 VDC | 1000mA |
| THM 3-1211A | THM 3-1211 | 9 ~ 18 VDC | 5 VDC | 600mA |
| THM 3-1212A | THM 3-1212 | 9 ~ 18 VDC | 12 VDC | 250mA |
| THM 3-1213A | THM 3-1213 | 9 ~ 18 VDC | 15 VDC | 200mA |
| THM 3-1215A | THM 3-1215 | 9 ~ 18 VDC | 24 VDC | 125mA |
| THM 3-1221A | THM 3-1221 | 9 ~ 18 VDC | ± 5 VDC | ±300mA |
| THM 3-1222A | THM 3-1222 | 9 ~ 18 VDC | ± 12 VDC | ± 125mA |
| THM 3-1223A | THM 3-1223 | 9 ~ 18 VDC | ± 15 VDC | ± 100mA |
| THM 3-2410A | THM 3-2410 | 18 ~ 36 VDC | 3.3 VDC | 1000mA |
| THM 3-2411A | THM 3-2411 | 18 ~ 36 VDC | 5 VDC | 600mA |
| THM 3-2412A | THM 3-2412 | 18 ~ 36 VDC | 12 VDC | 250mA |
| THM 3-2413A | THM 3-2413 | 18 ~ 36 VDC | 15 VDC | 200mA |
| THM 3-2415A | THM 3-2415 | 18 ~ 36 VDC | 24 VDC | 125mA |
| THM 3-2421A | THM 3-2421 | 18 ~ 36 VDC | ± 5 VDC | ±300mA |
| THM 3-2422A | THM 3-2422 | 18 ~ 36 VDC | ± 12 VDC | ± 125mA |
| THM 3-2423A | THM 3-2423 | 18 ~ 36 VDC | ± 15 VDC | ± 100mA |
| THM 3-4810A | THM 3-4810 | 36 ~ 75 VDC | 3.3 VDC | 1000mA |
| THM 3-4811A | THM 3-4811 | 36 ~ 75 VDC | 5 VDC | 600mA |
| THM 3-4812A | THM 3-4812 | 36 - 75 VDC | 12 VDC | 250mA |
| THM 3-4813A | THM 3-4813 | 36 ~ 75 VDC | 15 VDC | 200mA |
| THM 3-4815A | THM 3-4815 | 36 ~ 75 VDC | 24 VDC | 125mA |
| THM 3-4821A | THM 3-4821 | 36 ~ 75 VDC | ± 5 VDC | ±300mA |
| THM 3-4822A | THM 3-4822 | 36 ~ 75 VDC | ± 12 VDC | ± 125mA |
| THM 3-4823A | THM 3-4823 | 36 ~ 75 VDC | ± 15 VDC | ± 100mA |

| | | | | |
|---|---|---|---|---|
| THM 3-2410WIA | THM 3-2410WI | 9 ~ 36 VDC | 3.3 VDC | 1000mA |
| THM 3-2411WIA | THM 3-2411WI | 9 ~ 36 VDC | 5 VDC | 600mA |
| THM 3-2412WIA | THM 3-2412WI | 9 ~ 36 VDC | 12 VDC | 250mA |
| THM 3-2413WIA | THM 3-2413WI | 9 ~ 36 VDC | 15 VDC | 200mA |
| THM 3-2415WIA | THM 3-2415WI | 9 ~ 36 VDC | 24 VDC | 125mA |
| THM 3-2421WIA | THM 3-2421WI | 9 ~ 36 VDC | ± 5 VDC | ±300mA |
| THM 3-2422WIA | THM 3-2422WI | 9 ~ 36 VDC | ± 12 VDC | ± 125mA |
| THM 3-2423WIA | THM 3-2423WI | 9 ~ 36 VDC | ± 15 VDC | ± 100mA |
| THM 3-4810WIA | THM 3-4810WI | 18 ~ 75 VDC | 3.3 VDC | 1000mA |
| THM 3-4811WIA | THM 3-4811WI | 18 ~ 75 VDC | 5 VDC | 600mA |
| THM 3-4812WIA | THM 3-4812WI | 18 ~ 75 VDC | 12 VDC | 250mA |
| THM 3-4813WIA | THM 3-4813WI | 18 ~ 75 VDC | 15 VDC | 200mA |
| THM 3-4815WIA | THM 3-4815WI | 18 ~ 75 VDC | 24 VDC | 125mA |
| THM 3-4821WIA | THM 3-4821WI | 18 ~ 75 VDC | ± 5 VDC | ±300mA |
| THM 3-4822WIA | THM 3-4822WI | 18 ~ 75 VDC | ± 12 VDC | ± 125mA |
| THM 3-4823WIA | THM 3-4823WI | 18 ~ 75 VDC | ± 15 VDC | ± 100mA |
| THM 6-0510A | THM 6-0510 | 4.5 ~ 9 VDC | 3.3 VDC | 1800mA |
| THM 6-0511A | THM 6-0511 | 4.5 ~ 9 VDC | 5 VDC | 1200mA |
| THM 6-0512A | THM 6-0512 | 4.5 ~ 9 VDC | 12 VDC | 500mA |
| THM 6-0513A | THM 6-0513 | 4.5 ~ 9 VDC | 15 VDC | 400mA |
| THM 6-0515A | THM 6-0515 | 4.5 ~ 9 VDC | 24 VDC | 250mA |
| THM 6-0521A | THM 6-0521 | 4.5 ~ 9 VDC | ± 5 VDC | ± 600mA |
| THM 6-0522A | THM 6-0522 | 4.5 ~ 9 VDC | ± 12 VDC | ± 250mA |
| THM 6-0523A | THM 6-0523 | 4.5 ~ 9 VDC | ± 15 VDC | ± 200mA |
| THM 6-1210A | THM 6-1210 | 9 ~ 18 VDC | 3.3 VDC | 1800mA |
| THM 6-1211A | THM 6-1211 | 9 ~ 18 VDC | 5 VDC | 1200mA |
| THM 6-1212A | THM 6-1212 | 9 ~ 18 VDC | 12 VDC | 500mA |
| THM 6-1213A | THM 6-1213 | 9 ~ 18 VDC | 15 VDC | 400mA |
| THM 6-1215A | THM 6-1215 | 9 ~ 18 VDC | 24 VDC | 250mA |
| THM 6-1221A | THM 6-1221 | 9 ~ 18 VDC | ± 5 VDC | ± 600mA |
| THM 6-1222A | THM 6-1222 | 9 ~ 18 VDC | ± 12 VDC | ± 250mA |
| THM 6-1223A | THM 6-1223 | 9 ~ 18 VDC | ± 15 VDC | ± 200mA |
| THM 6-2410A | THM 6-2410 | 18 ~ 36 VDC | 3.3 VDC | 1800mA |
| THM 6-2411A | THM 6-2411 | 18 ~ 36 VDC | 5 VDC | 1200mA |
| THM 6-2412A | THM 6-2412 | 18 ~ 36 VDC | 12 VDC | 500mA |
| THM 6-2413A | THM 6-2413 | 18 ~ 36 VDC | 15 VDC | 400mA |
| THM 6-2415A | THM 6-2415 | 18 ~ 36 VDC | 24 VDC | 250mA |
| THM 6-2421A | THM 6-2421 | 18 ~ 36 VDC | ± 5 VDC | ± 600mA |
| THM 6-2422A | THM 6-2422 | 18 ~ 36 VDC | ± 12 VDC | ± 250mA |
| THM 6-2423A | THM 6-2423 | 18 ~ 36 VDC | ± 15 VDC | ± 200mA |
| THM 6-4810A | THM 6-4810 | 36 ~ 75 VDC | 3.3 VDC | 1800mA |
| THM 6-4811A | THM 6-4811 | 36 ~ 75 VDC | 5 VDC | 1200mA |

| | | | | |
|---|---|---|---|---|
| THM 6-4812A | THM 6-4812 | 36 - 75 VDC | 12 VDC | 500mA |
| THM 6-4813A | THM 6-4813 | 36 ~ 75 VDC | 15 VDC | 400mA |
| THM 6-4815A | THM 6-4815 | 36 ~ 75 VDC | 24 VDC | 250mA |
| THM 6-4821A | THM 6-4821 | 36 ~ 75 VDC | ± 5 VDC | ± 600mA |
| THM 6-4822A | THM 6-4822 | 36 ~ 75 VDC | ± 12 VDC | ± 250mA |
| THM 6-4823A | THM 6-4823 | 36 ~ 75 VDC | ± 15 VDC | ± 200mA |
| THM 6-4810A | THM 6-4810 | 9 ~ 36 VDC | 3.3 VDC | 1800mA |
| THM 6-4811A | THM 6-4811 | 9 ~ 36 VDC | 5 VDC | 1200mA |
| THM 6-4812A | THM 6-4812 | 9 ~ 36 VDC | 12 VDC | 500mA |
| THM 6-4813A | THM 6-4813 | 9 ~ 36 VDC | 15 VDC | 400mA |
| THM 6-4815A | THM 6-4815 | 9 ~ 36 VDC | 24 VDC | 250mA |
| THM 6-4821A | THM 6-4821 | 9 ~ 36 VDC | ± 5 VDC | ± 600mA |
| THM 6-4822A | THM 6-4822 | 9 ~ 36 VDC | ± 12 VDC | ± 250mA |
| THM 6-4823A | THM 6-4823 | 9 ~ 36 VDC | ± 15 VDC | ± 200mA |
| THM 6-4810WIA | THM 6-4810WI | 18 ~ 75 VDC | 3.3 VDC | 1800mA |
| THM 6-4811WIA | THM 6-4811WI | 18 ~ 75 VDC | 5 VDC | 1200mA |
| THM 6-4812WIA | THM 6-4812WI | 18 ~ 75 VDC | 12 VDC | 500mA |
| THM 6-4813WIA | THM 6-4813WI | 18 ~ 75 VDC | 15 VDC | 400mA |
| THM 6-4815WIA | THM 6-4815WI | 18 ~ 75 VDC | 24 VDC | 250mA |
| THM 6-4821WIA | THM 6-4821WI | 18 ~ 75 VDC | ± 5 VDC | ± 600mA |
| THM 6-4822WIA | THM 6-4822WI | 18 ~ 75 VDC | ± 12 VDC | ± 250mA |
| THM 6-4823WIA | THM 6-4823WI | 18 ~ 75 VDC | ± 15 VDC | ± 200mA |
| THM 10-0510A | THM 10-0510 | 4.5 ~ 9 VDC | 3.3 VDC | 2500mA |
| THM 10-0511A | THM 10-0511 | 4.5 ~ 9 VDC | 5 VDC | 2000mA |
| THM 10-0512A | THM 10-0512 | 4.5 ~ 9 VDC | 12 VDC | 830mA |
| THM 10-0513A | THM 10-0513 | 4.5 ~ 9 VDC | 15 VDC | 670mA |
| THM 10-0515A | THM 10-0515 | 4.5 ~ 9 VDC | 24 VDC | 416mA |
| THM 10-0521A | THM 10-0521 | 4.5 ~ 9 VDC | ± 5 VDC | ± 1000mA |
| THM 10-0522A | THM 10-0522 | 4.5 ~ 9 VDC | ± 12 VDC | ± 416mA |
| THM 10-0523A | THM 10-0523 | 4.5 ~ 9 VDC | ± 15 VDC | ± 333mA |
| THM 10-1210A | THM 10-1210 | 9 ~ 18 VDC | 3.3 VDC | 2500mA |
| THM 10-1211A | THM 10-1211 | 9 ~ 18 VDC | 5 VDC | 2000mA |
| THM 10-1212A | THM 10-1212 | 9 ~ 18 VDC | 12 VDC | 830mA |
| THM 10-1213A | THM 10-1213 | 9 ~ 18 VDC | 15 VDC | 670mA |
| THM 10-1215A | THM 10-1215 | 9 ~ 18 VDC | 24 VDC | 416mA |
| THM 10-1221A | THM 10-1221 | 9 ~ 18 VDC | ± 5 VDC | ± 1000mA |
| THM 10-1222A | THM 10-1222 | 9 ~ 18 VDC | ± 12 VDC | ± 416mA |
| THM 10-1223A | THM 10-1223 | 9 ~ 18 VDC | ± 15 VDC | ± 333mA |
| THM 10-2410A | THM 10-2410 | 18 ~ 36 VDC | 3.3 VDC | 2500mA |
| THM 10-2411A | THM 10-2411 | 18 ~ 36 VDC | 5 VDC | 2000mA |
| THM 10-2412A | THM 10-2412 | 18 ~ 36 VDC | 12 VDC | 830mA |
| THM 10-2413A | THM 10-2413 | 18 ~ 36 VDC | 15 VDC | 670mA |

| | | | | |
|---|---|---|---|---|
| THM 10-2415A | THM 10-2415 | 18 ~ 36 VDC | 24 VDC | 416mA |
| THM 10-2421A | THM 10-2421 | 18 ~ 36 VDC | ± 5 VDC | ± 1000mA |
| THM 10-2422A | THM 10-2422 | 18 ~ 36 VDC | ± 12 VDC | ± 416mA |
| THM 10-2423A | THM 10-2423 | 18 ~ 36 VDC | ± 15 VDC | ± 333mA |
| THM 10-4810A | THM 10-4810 | 36 ~ 75 VDC | 3.3 VDC | 2500mA |
| THM 10-4811A | THM 10-4811 | 36 ~ 75 VDC | 5 VDC | 2000mA |
| THM 10-4812A | THM 10-4812 | 36 - 75 VDC | 12 VDC | 830mA |
| THM 10-4813A | THM 10-4813 | 36 ~ 75 VDC | 15 VDC | 670mA |
| THM 10-4815A | THM 10-4815 | 36 ~ 75 VDC | 24 VDC | 416mA |
| THM 10-4821A | THM 10-4821 | 36 ~ 75 VDC | ± 5 VDC | ± 1000mA |
| THM 10-4822A | THM 10-4822 | 36 ~ 75 VDC | ± 12 VDC | ± 416mA |
| THM 10-4823A | THM 10-4823 | 36 ~ 75 VDC | ± 15 VDC | ± 333mA |
| THM 10-2410WIA | THM 10-2410WI | 9 ~ 36 VDC | 3.3 VDC | 2500mA |
| THM 10-2411WIA | THM 10-2411WI | 9 ~ 36 VDC | 5 VDC | 2000mA |
| THM 10-2412WIA | THM 10-2412WI | 9 ~ 36 VDC | 12 VDC | 830mA |
| THM 10-2413WIA | THM 10-2413WI | 9 ~ 36 VDC | 15 VDC | 670mA |
| THM 10-2415WIA | THM 10-2415WI | 9 ~ 36 VDC | 24 VDC | 416mA |
| THM 10-2421WIA | THM 10-2421WI | 9 ~ 36 VDC | ± 5 VDC | ± 1000mA |
| THM 10-2422WIA | THM 10-2422WI | 9 ~ 36 VDC | ± 12 VDC | ± 416mA |
| THM 10-2423WIA | THM 10-2423WI | 9 ~ 36 VDC | ± 15 VDC | ± 333mA |
| THM 10-4810WIA | THM 10-4810WI | 18 ~ 75 VDC | 3.3 VDC | 2500mA |
| THM 10-4811WIA | THM 10-4811WI | 18 ~ 75 VDC | 5 VDC | 2000mA |
| THM 10-4812WIA | THM 10-4812WI | 18 ~ 75 VDC | 12 VDC | 830mA |
| THM 10-4813WIA | THM 10-4813WI | 18 ~ 75 VDC | 15 VDC | 670mA |
| THM 10-4815WIA | THM 10-4815WI | 18 ~ 75 VDC | 24 VDC | 416mA |
| THM 10-4821WIA | THM 10-4821WI | 18 ~ 75 VDC | ± 5 VDC | ± 1000mA |
| THM 10-4822WIA | THM 10-4822WI | 18 ~ 75 VDC | ± 12 VDC | ± 416mA |
| THM 10-4823WIA | THM 10-4823WI | 18 ~ 75 VDC | ± 15 VDC | ± 333mA |

High Humidity exposed suggest: 48 hours, 15% to 95% non-condensing,

Operating temperature is maximal +50 ºC for 10W

Operating temperature is maximal +70 ºC for 6W

Operating temperature is maximal +80 ºC for 3W

DC to DC converter, No applied parts, the overall compliance of applied part shall be evaluated in the final system assembly

The equipments are Class II, build-in type, DC/DC power supply.

Pollution degree of equipment: Pollution Degree 2

Operation altitude of equipment: 0-5000 m

Provided two MOPP between input and output circuit, base on 250Vac

| | |
|---|---|
| Transportation temperature, humidity, pressure | -20 to +80°C / 10% ~ 90 %, 540 ~ 1060 hPa |
| Storage temperature, humidity, pressure | -20 to +80°C / 10% ~ 90 %, 540 ~ 1060 hPa |
| Operation temperature, humidity, pressure | 0°C ~ 40°C / 20% ~ 80 %, 540 ~ 1060 hPa |

## Product Lifetime:

This DC to DC converter average lifespan has been determined with approximately 100,000 hours.

## Performance properties in case of intended use:

Based on above mentioned purpose the following performance properties can be derived, which forcefully have to be achieved in intended effect and safety:

1. Electrical Safety according to IEC 60601-1:2012

## 5. Personnel and Responsibilities in the Risk Management Process

Persons performing risk management tasks shall have the knowledge and experience appropriate to the tasks assigned to them

a) R&D department: Responsible for carrying out the RM report
(The person shall be trained ISO14971 or with ISO14971 experience.)

b) Safety section: Responsible for reviewing the RM report.
(The person shall be trained ISO14971 or with ISO14971 experience.)

c) Sales department: Responsible for collects data and from customer and market

d) QA department: Responsible for document any decisions and actions taken.

e) Top management: Responsibilities as below
- Defining of criteria for the acceptability of risks
- Approval of the risk management plan and report
- Ensuring the availability of appropriate resources
- ensuring the assignment of qualified personnel for risk management
- Checking of the results of risk management activities (suitability and effectiveness)

## 6 Criteria to Analyze and Evaluate the Acceptability of Risks

***Risk Management Policy***

Criteria for risk acceptability has defined based upon applicable national or regional regulations and relevant International Standards, and taken into account available information such as the generally accepted state of the art and known stakeholder concerns.

Based on the guidelines being set up by the company management the identified risks will be evaluated in the risk management worksheet and reported in annual risk management reports as follows (according to ISO 14971:2007, Appendix F.5):

### 6.1. A: Severity of Harm (Negligible, Minor, Serious, Critical, Catastrophic)

| **Severity** (Impact of event occurrence) | | **Definition** |
|---|---|---|
| Common term | Rank (1=lowest) | |
| Catastrophic | 5 | Could result in death, or life-threatening injury |
| Critical | 4 | Could result in permanent partial disability, injuries |

| | | |
|---|---|---|
| Serious | 3 | Could result in injury requiring professional medical intervention |
| Minor | 2 | Could result in temporary injury not requiring professional medical intervention |
| Negligible | 1 | Inconvenience or temporary discomfort, these do not require any medical treatment. |

## 6.2. B: Probability of Occurrence(Improbable/Remote/Occasional/Probable/Frequent)

| **Probability** (Likelihood of event occurrence) | | **Definition** |
|---|---|---|
| Common term | Rank (1=lowest) | |
| Frequent | 5 | With a probability of occurrence more than $10^{-3}$, or occurs more than once a month |
| Probable | 4 | With a probability of occurrence less than $10^{-3}$ but greater than $10^{-4}$, or occurs more than once a season |
| Occasional | 3 | With a probability of occurrence less than $10^{-4}$ but greater than $10^{-5}$, or occurs more than once a year |
| Remote | 2 | With a probability of occurrence less than $10^{-5}$ but greater than $10^{-6}$, or occurs more than once a product life-cycle |
| Improbable | 1 | With a probability of occurrence less than $10^{-6}$, unlikely to occur, but possible. |

## 6.3. Criteria for the Acceptability of Risks

Risk Index Matrix

| **Severity rank** / **Probability rank** | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|
| **5** | Unacceptable, moderate risk | Unacceptable, moderate risk | Unacceptable, high risk | Unacceptable, extreme risk | Unacceptable, extreme risk |
| **4** | Acceptable, Insignificant risk | Unacceptable, moderate risk | Unacceptable, high risk | Unacceptable, high risk | Unacceptable, extreme risk |
| **3** | Acceptable, Insignificant risk | Acceptable, Insignificant risk | Unacceptable, moderate risk | Unacceptable, high risk | Unacceptable, high risk |
| **2** | Acceptable, Insignificant risk | Acceptable, Insignificant risk | Acceptable, Insignificant risk | Unacceptable, moderate risk | Unacceptable, moderate risk |
| **1** | Acceptable, Insignificant risk | Acceptable, Insignificant risk | Acceptable, Insignificant risk | Acceptable, Insignificant risk | Unacceptable, Insignificant risk |

| | |
|---|---|
| **Risk (index) acceptability level.....:** | Risk=Severity x probability<br>Result: Risk=1~4, acceptable; 5~25, unacceptable |

## Risk Acceptability Assessment Criteria

The following criteria will be used according to IEC 60601-1:1988, IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) and IEC 60601-1-2

Electromagnetic Energy Hazards

Humidity, cleaning, harmful ingress of liquids could affect the integrity of electrical insulation. Assessment criteria in determining if the resulting risk is acceptable include:

- no signs of wetting the hazardous parts; or
- the leakage current measurements to evaluate the accessibility to the hazardous parts, the dielectric strength test to evaluate the integrity of electrical insulation and measurement of electrical insulation coordination such as creepage distance and air clearances.

Mechanical Energy Hazards

Mechanical stress (caused by pushing, impact and rough handling) of the product could affect the integrity of electrical insulation and assessment criteria in determining if the resulting risk is acceptable include:

- no structural damages; or
- the dielectric strength test to evaluate the integrity of electrical insulation and measurement of electrical insulation coordination such as creepage distance and air clearances.

Thermal Energy Hazards

Molding stress (during fabrication of enclosure) could affect the integrity of mechanical strength and assessment criteria in determining if the resulting risk is acceptable include:

- no deformation of enclosure; or
- the dielectric strength test to evaluate the integrity of electrical insulation and measurement of electrical insulation coordination such as creepage distance and air clearances.

Fire Hazards

Assessment criteria in determining if the resulting risk is acceptable include:

- not exceeding maximum temperature; or
- no emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities (demonstrated by no ignition of the cheesecloth), or no deformation of enclosure

## 7 Controlling of the Management Process by the Management

The risk management will be achieved continuously, to analyse the experience achieved with the product in question, to evaluate the risk situation and to document this appropriately in the risk management worksheet. If necessary, or in case of special incidents, the management or its deputy will initiate an extraordinary meeting with responsible person. The management controls include the evaluation of actions taken as well as the success of these actions. It includes also the evaluation of available information about competitors' products.

**Verification Plan:**

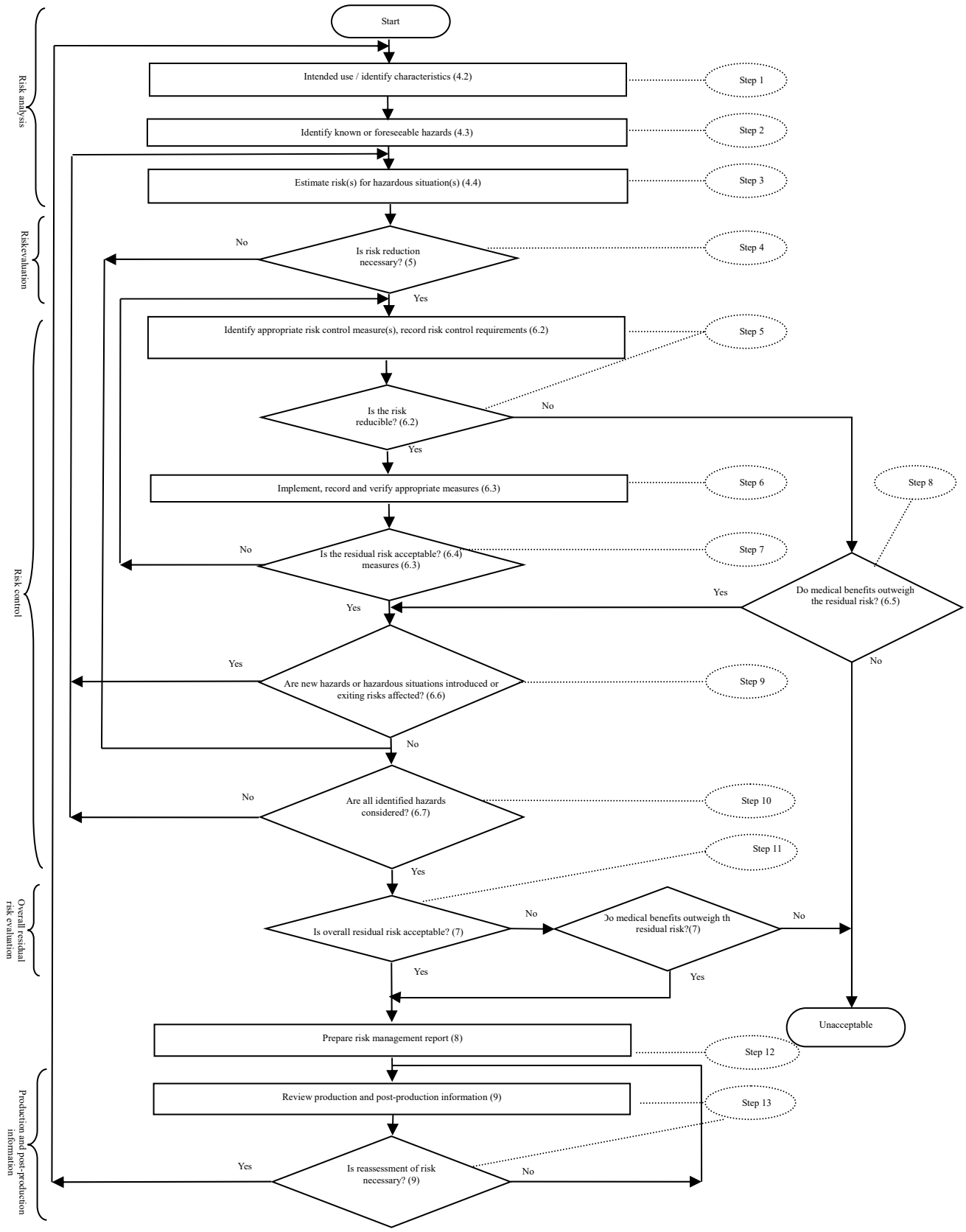
All risk control measures were verified and effective. See “Safety Test Report”, “EMC- test report” for result details.

In addition, the least favourable working conditions according to IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) are to be considered for verification.

## 8 Flow Chart of Risk Management Process

The below flow chart describes the levels of realization of the management process and designates single steps for the risk analysis, risk evaluation, action management and the risk controlling.

## Flow Chart: Flow of the Risk Management Process




After availability and release of the risk management plan the below mentioned steps will be followed:

**Step 1: Intended Use and Identification of Characteristics Related to the Safety of the Medical Device**

The intended use and each reasonably imaginable and foreseeable misuse will be described in the risk management plan together with the product performance properties, which may influence the safety of the medical device. Then, the performance properties will be taken over into the risk management worksheet and the risks will be evaluated which occur if these performance properties are not achieved. For describing the features of the medical device and its environment in which it is used, Appendix C of the current standard EN ISO 14971:2012 is applied.

**Step 2: Identification of Hazards**

All known and foreseeable failures / dysfunctions / hazards, which infringe the function and safety of the medical device, will be identified. For this the medical device will be analysed in its regular mode, failure mode, (also in case of reasonably foreseeable misuse). Moreover already earlier discovered hazards, incidents or situations will be considered.

Starting point is always the identified features mentioned in Step 1, as well as the hazards listed in the tables of ISO 14971. These tables are listed in the appendix of the risk management plan and are to be considered accordingly within the risk management worksheet.

**Step 3: Estimation of the Risk(s) for Each Hazardous Situation**

For each defined or assumed hazard of Step 2 the implied risk will be assessed. The expected physical damage or severity of harm, and probability of occurrence.

Reasonably foreseeable sequences or combinations of events that can result in a hazardous situation will be considered and the resulting hazardous situation(s) will be recorded.

**Step 4: Risk Evaluation**

After that each risk will be evaluated, whether it is acceptable or not and whether a risk reduction is required. The criteria to evaluate the acceptability are listed in the risk management plan.

**Step 5: Risk Control Option Analysis**

For risks which are within the acceptable area no actions of risk control will be taken. Risks, which are outside this area, will be treated case by case. Any risk control measures have the goal to reach at least the „ALARP acceptance level“ (As Low As Reasonably Practicable).

**Step 6: Implementation of Risk Control Measures**

The execution of the actions of Step 5, and the effectiveness of the risk control measures taken will be evaluated/verified and recorded in the risk management worksheet.

**Step 7: Residual Risk Evaluation**

The residual risks will be evaluated and documented in the risk management worksheet. In case a residual risk is not acceptable, Step 5 will be repeated.

**Step 8: Risk / Benefit Analysis**

Not acceptable risks can be accepted in exceptional cases, if a particularly high benefit is to be expected for the patient, and alternative products or treatment measures with minor risks are not available.

**Step 9: Risks Arising from Risk Control Measures**

In this step whether the actions of risk control and/or risk reduction would introduce new hazards or hazardous situations will be evaluated. In this case Step 3 has to be repeated.

**Step 10: Completeness of Risk Control**

In this step, whether all relevant risks have been considered and whether the risk evaluation process is complete will be checked. In case the risk evaluation is acknowledged as complete, the term “no further action” is stated in the risk management worksheet (Risk Management Worksheet I) or if this is not true, appropriate descriptions of proposed risk control measures have to be stated (Risk Management Worksheet II).

**Step 11: Evaluation of Overall Residual Risk Acceptability**

After the completion of all risk control measures, the whole residual risks as well as the acceptability of the residual risks will be evaluated. The evaluation of the residual risks will be performed analogically to the evaluation of the basic risks.

**Step 12: Risk Management Report**

There will be a summarizing risk management report. It will summarize the risk analysis, risk evaluation and management of preventive respectively risk control measures. This risk management report will be set up and released at least once per year by the management or its deputy.

**Step 13: Production and Post-Production Information**

Experience and information, which are collected during production and during the post production phase, are evaluated, starting with step 3.

In each case the insights obtained during the risk management process will be implemented in any applicable product-related documents (e.g. Risk Management Worksheet I and II, instructions for use, labels and packaging).