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| **EMC Test Plan** |  |

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| --- | --- |
| Applicant’s name |  |
| Applicant’s address |  |
| Trade Mark |  |
| Test item description |  |
| Model/Type reference |  |
| Test standards |  |

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# Administrative Data

|  |  |
| --- | --- |
| **General information (for report)** | |
| Ordernumber (your number) |  |
| Applicant  (incl. address and contact person:) |  |
| Manufacturer (when different to applicant) |  |
| Name and address of factory(ies)  includes more than one factory location :  A declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory. |  |

# Description of the Equipment Under Test

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| --- | --- |
| **Equipment characteristics** | |
| Test item description: |  |
| Model/Type reference |  |
| electrical Ratings: |  |
| Classification of installation and use: |  |
| ME equipment or ME system will be tested as: | Table-top equipment:  floor-standing equipment:  Combination of table-top and floor-standing equipment: |
| Descripton of any Patient-Coupled cable terminations to be used: |  |
| General product information: |  |
| Equipment Description: |  |
| Software and Firmware Version: |  |
| Version of EUT: | Prototype:  Production Version: |
| Unit(s) Tested  (include serial numbers): |  |
| Number of sample to be tested:  (The number of samples for each EMC test) |  |
| Intended use: |  |
| Intended healthcare environment: | Test levels for “Professional healthcare facility environment”  Test levels for “Home healthcare enviroment”  SPECIAL ENVIRONMENTS:  If special environments is used: detailed Immunity test levels for each test: |
| Emission: |  |
| Standard | CISPR 11  CISPR 14-1  CISPR 32  ISO 7137 |
| Classification | Class A  Class B  Group 1  Group 2 |
| Any deviations from the Basic EMC standards or from this collateral standard: |  |

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| **Marking Plate** |
| |  | | --- | |  | |

# Operation Mode and Configuration of EUT

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| **EUT Operation Mode(s)** | |
| For Immunity: |  |
| For Emission: |  |

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| **EUT Configuration** | |
| For Immunity: |  |
| For Emission: |  |
| Supplementary information (include any special me equipment or me system hardware or software needed to perform the tests). | |

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| **Potential equalization conductor used** |
| Yes  No |
| Note: If yes, include information on connection to the terminal for connection of a potential equalization conductor used during testing. |

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| **Testing of permanently installed large ME equipment or large ME system:** This exempt from the testing requirements of IEC 61000-4-3 is only used for permanently installed large ME Equipment and large ME Systems that are constructed in such a way that simulated operation of subsystems is not feasible. According to IEC 60601-1-2:2014 chapter 8.6 | | | |
| Yes  No  If Yes, include the following information | |
| Frequencies tested |  |
| Power levels of RF test sources |  |
| Modulation of RF test sources |  |
| Test distance used |  |
| Other relevant information related to test |  |

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| **Power interface:  Immunity** | | | | | | |
| *Mode No.:* | *Voltage (V):* | *Current  (A):* | *Power  (W):* | *Frequency  (DC/AC - Hz):* | *Phases (No.)* | *Comments* |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **Emission** | | | | | | |
| *Mode No.:* | *Voltage (V):* | *Current  (A):* | *Power  (W):* | *Frequency  (DC/AC - Hz):* | *Phases (No.)* | *Comments* |
|  |  |  |  |  |  |  |
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| --- | --- | --- | --- | --- | --- | --- | --- |
| **SIP/SOP and Input/output Ports:** | | | | | | | |
| *Port* No. | *Name:* | *Type\** | | *Cable shielded  (Y/N)* | *Cable length used / maximum* | | *Comments:* |
|  |  |  | |  |  | |  |
|  |  |  | |  |  | |  |
|  |  |  | |  |  | |  |
|  |  |  | |  |  | |  |
| \*Note | | | |  | | |  | | |
| AC = AC power port | | | | DC = DC power port | | | Batt = Battery | | |
| N/E = Non-Electrical | | | | SIP/SOP = Signal Input/Output | | | PC = Patient-Coupled Cable | | |
| TP = Telecommunication Port | | | | IC = Interconnection Cable | | |  | | |

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| **EUT and Supporting Equipment used during test:** | | | | | | | | |
| *Use\*:* | *Product Type:* | *Manufacturer:* | | *Model:* | *Serial no. or ID:* | | | *Comments:* |
| none |  |  | |  |  | | |  |
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|  |  |  | |  |  | |  | |
| \*Note | | | |  | | |  | | | |
| EUT = Equipment Under Test | | | | AE = Accessories / Associated Equipment | | | SIM = Simulator (Not Subjected to Test ) | | | |

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| **EUT Internal Operating Frequencies** | |
| *Frequency (MHz)* | *Description* |
|  |  |

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| **Dwell time during testing** | |
| *Test* | *Dwell time (sec.)* |
| Radiated, radio-frquency, electromagnetic field  IEC 61000-4-3:2006 + A1:2007 + A2:2010 |  |
| Immunity to conducted disturbances, induced by radio-frequency fields IEC 61000-4-6:2013 |  |

# Performance Criteria and Methods of Observation

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| --- | --- |
| **Basic Safety, Essential Performance and Immunity Pass/Fail Criteria as determined by the manufacturer** | |
| Description of Basic Safety and Essential Performance: |  |
| Description how the Basic Safety and Essential Performance were monitored during each test: |  |
| Immunity Pass/Fail Criteria: |  |

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| --- | --- | --- |
| **Describe any deviations from the Immunity Pass/Fail Criteria:** | | |
| **Test Description** | **Pass/Fail Criteria description** | **Part 2 reference** |
| Electrostatic Discharges |  |  |
| Radiated RF EM Fields |  |  |
| Proximity Wireless fields |  |  |
| Electrical Fast Transients and bursts |  |  |
| Surges |  |  |
| Conducted Disturbances, induced by RF fields |  |  |
| Voltage Dips and Interruptions |  |  |
| Rated Power-frequency Magnetic Field |  |  |
| Note: Specific, detailed **immunity** pass/fail criteria, shall be based on applicable part two standards or risk management, for **immunity** with regard to em disturbances. These pass/fail criteria shall be included in the risk management file | | |

# Electrostatic Discharge - Test points

# Reference documentation

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| --- | --- | --- |
| **Document** | **Document ID** | **Reference - content** |
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# Revision History

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| --- | --- | --- | --- | --- |
| **Revision History** | | | | |
| *Edition* | | *Date* | *Issued by* | *Modifications* |
|  | |  |  |  |
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|  | |  |  | |
| Aktuelle Version: | | | 1 | Ab dieser Zeile muss alles ausgeblendet formatiert sein! |

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| *Dokumentnummer der Vorlage:* | BV000001-EMV1-001-038 |