**IEC 62366-2015 Conformance Report**

**Product Name:** ***{产品名称 }***

**Model:** ***{产品型号}***

**Document No.:** ***{文件编号}***

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# 1. Product description

# 1.1 Product name and model

Product Name: ***{产品名称 }***

Model: ***{产品型号}***

# 1.2 The difference between models

|  |  |  |  |
| --- | --- | --- | --- |
| **Item** | ***{产品型号1}*** | ***{产品型号2}*** | ***{产品型号3}*** |
| \*\*\* | \*\*\* | \*\*\* | \*\*\* |
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# 2 Verification index

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| --- | --- | --- | --- |
| **Clause** | **Requirement + Test** | **Result - Remark** | **P/F/****NA** |
| 4 | **Principles** | *--* | -- |
| 4.1 | **General requirements** | *--* | -- |
| 4.1.1 | **USABILITY ENGINEERING PROCESS** | *--* | -- |
|  | The MANUFACTURER shall establish, document, implement and maintain a USABILITY ENGINEERING PROCESS, as defined in Clause 5, to provide SAFETY for the PATIENT, USER and others. The PROCESS shall address USER interactions with the MEDICAL DEVICE according to the ACCOMPANYING DOCUMENTATION, including, but not limited to:  – \* transport;  – \* storage;  – installation;  – operation;  – maintenance and repair; and  – disposal.  USABILITY ENGINEERING activities for a MEDICAL DEVICE shall be planned, carried out, and documented by personnel competent on the basis of appropriate education, training, skills or experience.  Where a documented product realization PROCESS exists, such as that described in Clause 7 of ISO 13485:2003 [11], it shall incorporate the appropriate parts of or reference the USABILITY ENGINEERING PROCESS.  NOTE 1 Subclause 6.2 of ISO 13485:2003 contains additional information relating to personnel competence.  A depiction of the interrelationship between the RISK MANAGEMENT PROCESS of ISO 14971:2007 and the USABILITY ENGINEERING PROCESS described in this standard is shown in Figure A.4.  The activities described in Clause 5, as shown Figure A.4, are described in a logical order,  but they may be carried out in a flexible order as appropriate.  Consider compliance with this subclause to exist when the requirements of this International Standard have been fulfilled. | The manufacturer has established, documented, implemented and maintained a usability engineering process to provide safety for the patient, user and others related to usability.  Please refer to:  *Usability Engineering Process Program* | **P** |
| 4.1.2 | **RISK CONTROL as it relates to USER INTERFACE design** | *--* | *--* |
|  | To reduce use-related RISK, the MANUFACTURER shall use one or more of the following options, in the priority listed (as required by ISO 14971:2007, 6.2):  a) inherent SAFETY by design;  b)protective measures in the MEDICAL DEVICE itself or in the manufacturing PROCESS;  c) information for SAFETY.  NOTE Information for SAFETY can also be required by product standards and other sources.  Compliance is checked by inspection of the USABILITY ENGINEERING FILE. | RISK CONTROL relates to USER INTERFACE design in risk management report | **P** |
| 4.1.3 | **Information for SAFETY** | *--* | *--* |
|  | When, in accordance with the priorities of 4.1.2, information for SAFETY is used as a RISK CONTROL measure, the MANUFACTURER shall subject this information to the USABILITY ENGINEERING PROCESS to determine that the information  – is perceivable by,  – is understandable to, and  – supports CORRECT USE of the MEDICAL DEVICE by  USERS of the intended USER PROFILES in the context of the intended USE ENVIRONMENT.  NOTE 1 The relationship between USER perception, cognition and action is shown in Figure A.1.  NOTE 2 Examples of information for SAFETY are found in IEC 62366-2.  Conscious disregard of such information for SAFETY by the USER is considered to be an intentional act or intentional omission of an act that is counter to or violates NORMAL USE and is also beyond any further reasonable means of USER INTERFACE-related RISK CONTROL by the MANUFACTURER (i.e. ABNORMAL USE).  Compliance is checked by inspection of the information for SAFETY and the USABILITY ENGINEERING FILE. | The usability engineering process for device ***{产品名称}*** has been subject the information, when the information for safety is used as s risk control measure, the information included, but not limited to warnings or limitation of use in the User manual, labels, and the markings in the label or package, etc.  Please refer to:  *User manual*  *Label and Language Requirement*  *Labeling and Language Management Procedure*  *Usability Engineering Process Program*  *Risk management report)* | **P** |
| 4.2 | **USABILITY ENGINEERING FILE** | *--* | *--* |
|  | The results of the USABILITY ENGINEERING PROCESS shall be stored in the USABILITY ENGINEERING FILE. The RECORDS and other documents that form the USABILITY ENGINEERING FILE may form part of other documents and files.  EXAMPLE 1 MANUFACTURER’S product design file.  EXAMPLE 2 RISK MANAGEMENT FILE.  Compliance is checked by inspection of the USABILITY ENGINEERING FILE. | The results of the usability engineering process for device ***{产品名称}*** has be recorded in the usability engineering file. The records and other documents that form the usability engineering file can form part of other documents and files.  The list of usability engineering file can be refer to Appendix A in this document  The other documents relevant to usability engineering file can be refer to Appendix B in this document) | **P** |
| 4.3 | **Tailoring of the USABILITY ENGINEERING effort** | *--* | *--* |
|  | The level of effort and the choice of methods and tools used to perform the USABILITY  ENGINEERING PROCESS may vary based on:  a) the size and COMPLEXITY of the USER INTERFACE;  b) the SEVERITY of the HARM associated with the use of the MEDICAL DEVICE;  c) the extent or complexity of the USE SPECIFICATION;  d) the presence of USER INTERFACE OF UNKNOWN PROVENANCE; and  e) the extent of the modification to an existing MEDICAL DEVICE USER INTERFACE that had been subjected to the USABILITY ENGINEERING PROCESS.  Compliance is checked by inspection of the USABILITY ENGINEERING FILE. | The form and the extent of usability engineering process for device ***{产品名称}*** has based on the nature of the product, its intended user and its intended use.  usability engineering process for device ***{产品名称}*** has been required to be scaled-up or scaled-down based on the significance of the modification as determined by the results of the risk analysis.  Please refer to:  *Usability Engineering Process Program* | **P** |
| 5 | **\* USABILITY ENGINEERING PROCESS** | *--* | *--* |
| 5.1 | **\* Prepare USE SPECIFICATION** | *--* | *--* |
|  | The MANUFACTURER shall prepare a USE SPECIFICATION.  The USE SPECIFICATION shall include:  – \* intended medical indication;  NOTE 1 This can include conditions(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented.  – intended PATIENT population;  NOTE 2 This can include age group, weight range, health, or condition.  – intended part of the body or type of tissue applied to or interacted with;  – \* intended USER PROFILE;  – \* USE ENVIRONMENT; and  – \* operating principle.  NOTE 3 The summary of the MEDICAL DEVICE USE SPECIFICATION is referred to by some authorities having jurisdiction as the ‘statement of intended use’.  Compliance is checked by inspection of the USABILITY ENGINEERING FILE. | The manufacturer had specified the application of the device( ***{产品名称 }***) in the usability engineering file and also disclosed a summary of the device  ***{产品名称}***  USE SPECIFICATION in the accompanying document,  This specification included intended medical indication, intended patient population, intended user profile, intended conditions of use and operating principle, etc.  Please refer to:  *User manual*  *Label and Language Requirement*  *Labeling and Language Management Procedure*  *Use specification)* | **P** |
| 5.2 | **\* Identify USER INTERFACE characteristics related to SAFETY and potential USE**  **ERRORS** | *--* | *--* |
|  | The MANUFACTURER shall identify USER INTERFACE characteristics that could be related to SAFETY as part of a RISK ANALYSIS performed according to ISO 14971:2007, 4.2. This identification may also be performed using the tools and techniques from the USABILITY ENGINEERING PROCESS. This identification shall include consideration of the PRIMARY OPERATING FUNCTIONS that are provided in applicable particular MEDICAL DEVICE SAFETY standards.  NOTE 1 ISO 14971:2007, C.2.29 to C.2.34 provides a list of questions that can be used to identify USER INTERFACE characteristics that could impact SAFETY. The list of questions is not exhaustive.  Based on the identified USER INTERFACE characteristics and USE SPECIFICATION, the MANUFACTURER shall identify the USE ERRORS that could occur and are related to the USER INTERFACE. This identification may be accomplished by conducting a TASK analysis.[27][28][29]  NOTE 2 TASK analysis is described in IEC 62366-2.  The results of this identification of characteristics related to SAFETY shall be stored in the USABILITY ENGINEERING FILE.  Compliance is checked by inspection of the USABILITY ENGINEERING FILE. | The manufacturer had identified USER INTERFACE characteristics that could be related to SAFETY and record them in the usability engineering file  Please refer to:  *User manual*  *Identify User Interface characteristics related to Safety and potential Use errors)* | **P** |
| 5.3 | **\* Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS** | *--* | *--* |
|  | The MANUFACTURER shall identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS,which could affect PATIENTS, USERS or others, related to use of the MEDICAL DEVICE. This identification shall be conducted as part of a RISK ANALYSIS performed according to ISO 14971:2007, 4.3 and the first paragraph of ISO 14971:2007, 4.4.  NOTE 1 Annex B contains examples of possible HAZARDS and HAZARDOUS SITUATIONS related to USABILITY.  During the identification of HAZARDS and HAZARDOUS SITUATIONS, the following shall be considered:  – USE SPECIFICATION, including USER PROFILE(S) (see 5.1);  – information on HAZARDS and HAZARDOUS SITUATIONS known for existing USER INTERFACES of MEDICAL DEVICES of a similar type, if available; and  – identified USE ERRORS (see 5.2).  The results of this identification of HAZARDS and HAZARDOUS SITUATIONS shall be stored in the USABILITY ENGINEERING FILE.  NOTE 2 During the identification of HAZARDS or HAZARDOUS SITUATIONS, ABNORMAL USE conditions can be identified.  Compliance is checked by inspection of the USABILITY ENGINEERING FILE. | The manufacturer had identified known or foreseeable HAZARDS and HAZARDOUS SITUATIONS, which could affect PATIENTS, USERS or others, related to use of the MEDICAL DEVICE. according to EN ISO 14971, 4.2.  Please refer to :  *Risk management report—*  *Identify known or foreseeable Hazard and Hazardous Situations)* | **P** |
| 5.4 | **\* Identify and describe HAZARD-RELATED USE SCENARIOS** |  |  |
|  | The MANUFACTURER shall identify and describe the reasonably foreseeable HAZARD-RELATED USE SCENARIOS associated with the identified HAZARDS and HAZARDOUS SITUATIONS. The description of each identified HAZARD-RELATED USE SCENARIO shall include all TASKS and their sequences as well as the SEVERITY of the associated HARM.  NOTE Annex B contains examples of specifying sequences of USER actions that could result in HAZARDS being exposed to USERS.  Compliance is checked by inspection of the USABILITY ENGINEERING FILE. | The manufacturer had identified and describe the reasonably foreseeable HAZARD-RELATED USE SCENARIOS associated with the identified HAZARDS and HAZARDOUS SITUATIONS.  Please refer to :  *Identify and select Hazard-related use scenarios* | **P** |
| **5.5** | **\* Select the HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION** |  |  |
|  | The MANUFACTURER shall select the HAZARD-RELATED USE SCENARIOS to be included in the SUMMATIVE EVALUATION.  The MANUFACTURER shall select either:  – all HAZARD-RELATED USE SCENARIOS; or  – the subset of the HAZARD-RELATED USE SCENARIOS based on the SEVERITY of the potential HARM that could be caused by USE ERROR (e.g. for which medical intervention would be needed).  The choice of the scheme used to select the HAZARD-RELATED USE SCENARIOS may additionally depend on other circumstances specific to the MEDICAL DEVICE and the MANUFACTURER.  NOTE Examples of selection schemes are given in Annex A, 5.5, and IEC 62366-2.  A summary of any selection scheme, the rationale for its use and the results of applying it shall be stored in the USABILITY ENGINEERING FILE.  Compliance is checked by inspection of the USABILITY ENGINEERING FILE. | The manufacturer had selected the HAZARD-RELATED USE SCENARIOS to be included in the SUMMATIVE EVALUATION  Please refer to :  *Identify and select Hazard-related use scenarios* | **P** |
| **5.6** | **\* Establish USER INTERFACE SPECIFICATION** |  |  |
|  | The MANUFACTURER shall establish and maintain a USER INTERFACE SPECIFICATION.  The USER INTERFACE SPECIFICATION shall consider:  – the USE SPECIFICATION (see 5.1);  – the known or foreseeable USE ERRORS associated with the MEDICAL DEVICE (see 5.2); and  – the HAZARD-RELATED USE SCENARIOS (see 5.4).  The USER INTERFACE SPECIFICATION shall include:  – testable technical requirements relevant to the USER INTERFACE, including the requirements for those parts of the USER INTERFACE associated with the selected RISK CONTROL measures;  NOTE Technical requirements for the USER INTERFACE can include display colour, character size, or placement of the controls.  – an indication as to whether ACCOMPANYING DOCUMENTATION is required; and  – an indication as to whether MEDICAL DEVICE-specific training is required.  The USER INTERFACE SPECIFICATION shall be stored in the USABILITY ENGINEERING FILE. The USER INTERFACE SPECIFICATION may be integrated into other specifications.  Compliance is checked by inspection of the USABILITY ENGINEERING FILE. | The manufacturer had established and maintained a USER INTERFACE SPECIFICATION.  Please refer to :  *User Interface Specification* | **P** |
| **5.7** | **\* Establish USER INTERFACE EVALUATION plan** |  |  |
| **5.7.1** | **General** |  |  |
|  | The MANUFACTURER shall establish and maintain a USER INTERFACE EVALUATION plan for the USER INTERFACE SPECIFICATION.  The USER INTERFACE EVALUATION plan shall   1. document the objective and identify the method of any planned FORMATIVE EVALUATIONS and SUMMATIVE EVALUATIONS;   NOTE 1 Examples of FORMATIVE EVALUATION and SUMMATIVE EVALUATION methods are given in IEC 62366-2  b) if USABILITY TESTS are employed,  – document the involvement of the representative intended USERS and USER PROFILE to which they belong.  EXAMPLE 1 In a FORMATIVE EVALUATION, clinical personnel from the MANUFACTURER are used for a nurse\_USER GROUP.  EXAMPLE 2 In a SUMMATIVE EVALUATION, a panel of practicing intensive care nurses are used for a critical care nursing USER PROFILE.  Multiple USER PROFILES may be combined into a USER GROUP for the purposes of a  USABILITY TEST;  – document the test environment and other conditions of use, based on the USE SPECIFICATION;  NOTE 2 These are the specific conditions of use which could affect the USER’S TASKS performance.  EXAMPLE 3 Conditions of use could include location-specific conditions such as lighting, noise and activity levels.  EXAMPLE 4 Conditions of use could include personnel-specific conditions such as use of the MEDICAL DEVICE while wearing personal protective equipment (e.g. surgical gloves and safety goggles).  EXAMPLE 5 Conditions of use could include social conditions such as stress levels and working in teams.  – specify whether ACCOMPANYING DOCUMENTATION is provided during the test;  – specify whether MEDICAL DEVICE-specific training is provided prior to the test and the minimum elapsed time between the training and the beginning of the test.  USER INTERFACE EVALUATION methods may be quantitative or qualitative. USER INTERFACE  EVALUATION may be performed in a variety of locations, such as, in a laboratory setting, in a simulated USE ENVIRONMENT or in the actual USE ENVIRONMENT.  NOTE 3 See 4.3 for scaling of the USABILITY ENGINEERING effort.  The USER INTERFACE EVALUATION plan may be integrated into other plans.  The USER INTERFACE EVALUATION plan shall be stored in the USABILITY ENGINEERING FILE.  Compliance is checked by inspection of the USABILITY ENGINEERING FILE. | The manufacturer had established and maintained a USER INTERFACE EVALUATION plan for the USER INTERFACE SPECIFICATION  Please refer to :  *User Interface evaluation plan* | **P** |
| **5.7.2** | **\* FORMATIVE EVALUATION planning** |  |  |
|  | The USER INTERFACE evaluation plan for FORMATIVE EVALUATION shall address:  a) the evaluation methods being used;  NOTE 1 Objectives for a FORMATIVE EVALUATION can include exploring the extent to which the elements of the USER INTERFACE are recognizable, understandable and operable by the USER.  b) which part of the USER INTERFACE is being evaluated; and  c) when in the USABILITY ENGINEERING PROCESS to perform each of the USER INTERFACEEVALUATIONS.  NOTE 2 The MANUFACTURER can find it helpful to apply focus and effort to the FORMATIVE EVALUATION early on, because the information derived from this is a valuable input to the design PROCESS.  Compliance is checked by inspection of the USABILITY ENGINEERING FILE**.** | The manufacturer had established USER INTERFACE evaluation plan for FORMATIVE EVALUATION  Please refer to :  *User Interface evaluation plan* | **P** |
| **5.7.3** | **\* SUMMATIVE EVALUATION planning** |  |  |
|  | For each selected HAZARD-RELATED USE SCENARIO (see 5.5), the USER INTERFACE EVALUATION plan for SUMMATIVE EVALUATION shall specify:   1. the evaluation method being used and a rationale that the method produces OBJECTIVE EVIDENCE;   NOTE 1 The SUMMATIVE EVALUATION of the information for SAFETY can require different methods than for other parts of the USER INTERFACE.  b) which part of the USER INTERFACE is being evaluated;  c) where applicable, the criteria for determining whether the information for SAFETY is  perceivable, understandable and supports CORRECT USE of the MEDICAL DEVICE (4.1.3);  NOTE 2 The SUMMATIVE EVALUATION of the information for SAFETY is typically completed prior to initiating the SUMMATIVE EVALUATION of the remainder of the USER INTERFACE. It is usually a separate USABILITY TEST with different USERS.  d) \* the availability of the ACCOMPANYING DOCUMENTATION and provision of training during the SUMMATIVE EVALUATION; and  NOTE 3 A SUMMATIVE EVALUATION can include training as part of the protocol, as appropriate, to simulate realistic use. An appropriate wait time might be needed between the training and the rest of the SUMMATIVE EVALUATION to allow for representative learning decay.  e) \* for a USABILITY TEST,  – the test environment and conditions of use and a rationale for how they are adequately  representative of the actual conditions of use; and  – the method of collecting data during the USABILITY TEST for the subsequent analysis of observed USE ERRORS.  The SUMMATIVE EVALUATION may be performed in a single evaluation or multiple evaluations.  NOTE 4 The planning for SUMMATIVE EVALUATION will likely not be finalized until after the FORMATIVE EVALUATIONhas been completed.  NOTE 5 Guidance on the evaluation of the adequacy of RISK CONTROL measures can be found in ISO 14971:2007, Clause D.4.  Compliance is checked by inspection of the USABILITY ENGINEERING FILE. | The manufacturer had established USER INTERFACE evaluation plan for SUMMATIVE EVALUATION  Please refer to :  *User Interface evaluation plan* | **P** |
| **5.8** | **\* Perform USER INTERFACE design, implementation and FORMATIVE EVALUATION** |  |  |
|  | The MANUFACTURER shall design and implement the USER INTERFACE, including the ACCOMPANYING DOCUMENTATION if needed, and training capability, if needed, as described in the USER INTERFACE SPECIFICATION.  The MANUFACTURER shall utilize, as appropriate, USABILITY ENGINEERING methods and techniques, including FORMATIVE EVALUATION to accomplish this design and implementation. The results of the utilized FORMATIVE EVALUATION shall be stored in the USABILITY ENGINEERING FILE. Where new USE ERRORS, HAZARDS, HAZARDOUS SITUATIONS or HAZARD-RELATED USE SCENARIOS are discovered during this step, the MANUFACTURER shall repeat the steps of  Clause 5 as appropriate.  NOTE 1 ISO 14971:2007, Subclause 6.6 requires that design changes resulting from the USABILITY ENGINEERING PROCESS be reviewed to determine if other HAZARDS or HAZARDOUS SITUATIONS have been generated.  If training on the specific MEDICAL DEVICE is required for the safe use of the MEDICAL DEVICE by the intended USER, the MANUFACTURER shall design and implement a training capability for the EXPECTED SERVICE LIFE of the MEDICAL DEVICE by doing at least one of the following:  – provide the materials necessary for training;  – ensure that the materials necessary for training are available;  – make the training available; or  – make training available to the RESPONSIBLE ORGANIZATION that enables it to train its USERS.  NOTE 2 The training capability is intended to enable the RESPONSIBLE ORGANIZATION to provide training to their USERS for the EXPECTED SERVICE LIFE of the MEDICAL DEVICE.  Compliance is checked by inspection of the USABILITY ENGINEERING FILE, including for evidence of the FORMATIVE EVALUATION, if performed, and the existence of the training strategy, if required. | The manufacturer had implemented FORMATIVE EVALUATION  Please refer to :  *Formative Evaluation report* | **P** |
| **5.9** | **\* Perform SUMMATIVE EVALUATION of the USABILITY of the USER INTERFACE** |  |  |
|  | Upon completion of the design and implementation of the USER INTERFACE, the MANUFACTURER shall perform a SUMMATIVE EVALUATION of each HAZARD-RELATED USE SCENARIO selected in 5.5 on the final or production equivalent USER INTERFACE according to the USER INTERFACE EVALUATION plan. For SUMMATIVE EVALUATION, the MANUFACTURER may use data obtained from  the SUMMATIVE EVALUATIONS of products with an equivalent USER INTERFACE together with a technical rationale for how this data is applicable. The results shall be stored in the USABILITY ENGINEERING FILE.  The data from the SUMMATIVE EVALUATION shall be analysed to identify the potential consequences of all USE ERRORS that occurred. If the consequences can be linked to a HAZARDOUS SITUATION, the root cause of each USE ERROR shall be determined. The root causes should be determined based on observations of USER performance and subjective comments from the USER related to that performance.  If new USE ERRORS, HAZARDS, HAZARDOUS SITUATIONS or HAZARD-RELATED USE SCENARIOS are discovered during this data analysis:  – if yes, then the MANUFACTURER shall repeat the activities of Clause 5 as appropriate;  – if not, the MANUFACTURER shall determine whether further improvement of the USER INTERFACE design as it relates to SAFETY is necessary and practicable.  1) if yes, then the MANUFACTURER shall re-enter the USABILITY ENGINEERING PROCESS at 5.6;  2) if not, then the MANUFACTURER shall:  NOTE 1 There can be RISK CONTROLS that are not USER INTERFACE-related that are practicable solutions to reduce USER INTERFACE-related RISK.   1. document why improvement is not practicable;   NOTE 2 Guidance for how to determine that further RISK reduction in the USER INTERFACE is not practicable is found in ISO 14971:2007, 6.2.  ii) identify the data from the USABILITY ENGINEERING PROCESS needed to determine the RESIDUAL RISK related to use; and  iii) evaluate the RESIDUAL RISK according to ISO 14971:2007, 6.4.  NOTE 3 ISO 14971:2007, Subclause 6.6 requires that design changes resulting from the USABILITY ENGINEERING PROCESS be reviewed to determine non-USER INTERFACE related HAZARDS or HAZARDOUS SITUATIONS have been generated.  NOTE 4 ISO 14971:2007, Clause 7 requires that all RESIDUAL RISK be considered when evaluating the overall RESIDUAL RISK of the MEDICAL DEVICE, including the RESIDUAL RISK associated with USABILITY of the MEDICAL DEVICE.  If the USABILITY ENGINEERING PROCESS detailed in this International Standard has been complied with, then the USABILITY of a MEDICAL DEVICE as it relates to SAFETY is presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary.  NOTE 5 Such OBJECTIVE EVIDENCE can subsequently originate from POST-PRODUCTION surveillance.  Compliance is checked by inspection of the USABILITY ENGINEERING FILE and by application of the requirements of ISO 14971:2007, 6.4. | The manufacturer had implementated SUMMATIVE EVALUATION  Please refer to :  *Summative Evaluation report* | **P** |
| **5.10** | **USER INTERFACE OF UNKNOWN PROVENANCE** |  |  |
|  | Instead of all the requirements of 5.1 through 5.9, UOUP may be evaluated according to  Annex C.  Compliance is checked by application of Annex C. | / | NA |

# 3． Conclusion

All applicable test were performed and test result comply with the requirement of IEC 62366-1:2015.