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| **Annex C Investigation Findings ("what were the findings?")** | | | | |  |  |  | |  | |
| **Device (bold)**: For the purpose of this Annex C, a **device** means a medical device including accessories and components. | | | | | | | |  | |  | |
| **Level 1** | | | **Level 2** | | | **Level3** | | | | |
| Term | Definition | Code | Term | Definition | Code | Term | Definition | | Code | |
| **Biological Problem Identified** | **Problems relating to, caused by or affecting biological processes or living organisms.** | C01 | Biocompatibility Problem Identified | The **device** causes cellular or tissue responses that elicit an undesirable local or systemic effect in the recipient or beneficiary of that therapy.  (See ISO 10993) | C0101 |  |  | |  | |
| Biological Contamination | The undesirable presence of living organisms such as bacteria, fungi, or viruses or their products (enzymes or toxins). | C0102 | Endotoxin Contamination | The undesirable presence of toxins associated with certain bacteria (e.g. gram negative bacteria). | | C010201 | |
| Microbial Contamination | The undesirable presence of microorganisms or microbes such as bacteria and fungi (yeasts and molds). | | C010202 | |
| Material or Material Leachate Pyrogenic Problem | The undesirable presence of pyrogens or fever-producing organisms caused by materials that permeate through the **device**. | C0103 |  |  | |  | |
| Cytotoxicity Problem Identified | The **device** was found to have an undesirable level of toxicity to living cells. | C0104 |  |  | |  | |
| Genotoxicity Problem Identified | The **device**'s ability to cause damage to genetic material (e.g. leading to malignant tumors). (See ISO 10993) | C0105 | Carcinogenic Problem | The **device**'s ability to trigger development of cancer. | | C010501 | |
| Mutagenic Problem | The **device**'s ability to change genetic information (usually DNA) of an organism and thus increasing the frequency of mutations. | | C010502 | |
| Hematological Problem Identified | The **device** affects or impacts the blood or its components. (See ISO 10993 all parts) | C0106 | Agglutination Problem | The **device** affects the ability of the blood to clot which may be induced by chemical, mechanical, or thermal properties of the **device**. | | C010601 | |
| Complement Activation Problem | The **device** affects the body's ability to activate the complement system of the immune system, thereby interfering with the ability to clear pathogens. This may be caused by an interaction of the **device** with chemicals or materials. | | C010602 | |
| Platelet Activation Problem | The **device** affects the body's ability to activate platelet formation. | | C010603 | |
| Problem due to Thrombosis Activation | The **device** causes the formation of blood clots in or along blood vessels resulting in disturbed or disrupted blood flow. | | C010604 | |
| Unintended Presence of Allergens | Unintended or unexpected presence of allergens in the **device**. If the presence of the allergen is expected but not adequately labelled, then use "Labelling Problem". | C0107 |  |  | |  | |
| Reproductive Toxicity Problem Identified | The **device** affects reproductive function, embryo development (teratogenicity), and prenatal and early postnatal development. (ISO 10993 part 3) | C010 |  |  | |  | |
| **Electrical Problem Identified** | Events associated with an electrically powered **device** where an electrical malfunction results in a device problem (e.g. electrical circuitry, contact or component failed) even if the problem is intermittent. | C02 | Electrical/Electronic Component Problem Identified | The performance of an electrical or electronic component was found to be inadequate. | C0201 |  |  | |  | |
| Hardware Timing Problem Identified | Problems that results from improper sequential activation of components. | C0202 |  |  | |  | |
| Impedance Problem Identified | Problems due to insufficient or excessive resistance to current flow either by the **device** or circuit. | C0203 |  |  | |  | |
| Insulation Problem Identified | Problems due to inadequate or incorrect electrical insulation material. | C0204 |  |  | |  | |
| Open Circuit | Problem due to an electrical circuit that does not conduct current because a switch is open, a wire is broken, etc. | C0205 |  |  | |  | |
| Current Leakage Problem | Problems related to leakage currents which may cause electric shock. These currents usually flow through the protective ground conductor. In its absence, these currents could flow from the **device** to the ground via the human body. | C0206 |  |  | |  | |
| Power Source Problem Identified | Problems related to the source that provides electrical power to the **device**. | C0207 | Energy Storage System Problem | Problems related to the energy storage system (e.g. the rechargeable battery, charging system, or capacitor) and includes problems such as premature power source depletion and battery explosions. | | C020701 | |
| Loss of Power | A **device** that experienced problems due to a loss in the power supply. | | C020702 | |
| Power Fluctuation | The **device** failed due to fluctuations within the power supply (e.g. transient power, power spike, power dip, or power sequencing). | | C020703 | |
| Short Circuit | Problems due to an unintentionally low-resistance connection between two points in an electric circuit, resulting in either excessive current flow that often causes damage or in a new shorter circuit that draws current away from the original pathways and components. | C0208 |  |  | |  | |
| Signal Loss | Problems due to the loss or weakening of an electrical signal or signals. | C0209 |  |  | |  | |
| **Electromagnetic Compatibility Problem Identified** | **Device**-to-**device** or **device**-environment problem resulting from electromagnetic disturbances. | C03 | Conducted Interference | Problems related to electromagnetic interference (EMI) by physical contact with conductors (e.g. wires, resistors, terminals) as opposed to radiated EMI which is caused by induction (without physical contact of the conductors). | C0301 |  |  | |  | |
| Electrostatic Discharge | Problems due to sudden and momentary bursts of electrical current flowing between two objects at different electrical potentials. | C0302 |  |  | |  | |
| Inadequate Immunity | Problems related to immunity or capabilities to resist electromagnetic interference (EMI). | C0303 |  |  | |  | |
| Unintended Emission | Problems due to unintended emission of electromagnetic energy by the **device**. | C0304 |  |  | |  | |
| Radiofrequency Interference (RFI) | Problems due to radiofrequency interference. RFI is a disturbance that affects an electrical circuit due to either electromagnetic conduction or electromagnetic radiation emitted from an external source. | C0305 |  |  | |  | |
| Interoperability Problem Identified | Problems with the mechanical, electrical, or communication interface between two or more separate **devices**. | C04 | Communications Problem Identified | **Devices** that do not send or receive adequate signals (this speaks to the interoperability between **devices**). | C0401 | Wired Communication Problem | Communications problems between **devices** within a wired system. | | C040101 | |
| Wireless Communication Problem | Communications problems between **devices** within a wireless system. | | C040102 | |
| Network Communication Problem | Communications problems between **devices** within a network system. | | C040103 | |
| Incompatible Component/ Accessory | A **device** that malfunctions due to a component(s)/accessory that does not operate correctly and according to the **device**'s specifications. | C0402 |  |  | |  | |
| Device Not Compatible With Another Device | A **device** that malfunctions due to being used in combination with, or in the presence of, another **device**. | C0403 |  |  | |  | |
| Unintended Compatibility | The **device** was confirmed to be compatible with another **device** with which the **device** is intended to be incompatible. | C0404 |  |  | |  | |
| **Labeling and Instructions for Use/Maintenance** | Insufficient, inadequate,  or  incorrect information   provided on a **device**'s label or documentation      regarding   e.g.   its intended use,  directions for use,  and characteristics of the **device**,   including its maintenance. | C05 | Inadequate   Labelling   and/or   Instructions for Use | Inadequate information   on the labels or in the instructions for use    e.g. steps that are difficult to follow or that are missing. | C0501 |  |  | |  | |
| Incorrect    Labeling   and/or  Instructions for Use | Missing, incorrect, or inappropriate information  on the labels   e.g. mislabeled contents or **device** labeling characteristics or package contents. | C0502 |  |  | |  | |
| Inadequate or Incorrect   Instructions for Maintenance | Inadequate or incorrect information   in the instructions for maintenance. | C0503 |  |  | |  | |
| **Material   and/or   Chemical    Problem     Identified** | Problems with the **device** materials   or how its materials react to other elements      either  within the **device**   or  within the environment. | C06 | Degradation Problem Identified | Problems that occur when the **device** becomes worn, weakened, corroded, or broken down due to processes such as aging, permeation, and corrosion. | C0601 |  |  | |  | |
| Inappropriate Material | Problems that occur due to the presence of a material that should not be present or part of the **device**. | C0602 | Improper Composition/ Concentration | Problems associated with the improper combination of materials or elements present in the **device** (e.g. improper composition of the materials of a capacitor). | | C060201 | |
| Improper Physical Structure | Problems related to the incorrect or inadequate arrangement of the parts, components, elements, or materials. | | C060202 | |
| Molecular Structure Problem | Problems related to the presence of an inappropriate molecular geometry somewhere in the **device** (i.e. the spatial arrangement of atoms in a molecule and the chemical bonds that hold the atoms together). | | C060203 | |
| Inadequate Physicochemical Properties | Problems that occur   due to the   physicochemical   properties. | C0603 |  |  | |  | |
| Incompatible Material | Problems that occur   due to the incompatibility of materials that co-exist   simultaneously   as part of the **device**. | C0604 |  |  | |  | |
| Reactivity Problem Identified | Problems that occur due to the reactivity of materials   (e.g. over-react or under-react). | C0605 |  |  | |  | |
| Tolerance Stack-Up | Problems that result from  a combination of   specification variances   of the components. | C0606 |  |  | |  | |
| **Mechanical   Problem    Identified** | Problems that result from   internal  or external forces   including  fluids,  other objects, or environmental or  physiologic influences. | C07 | Device Migration | A **device** that has moved from its original location due to external forces (e.g. stent or lead movement). | C0701 |  |  | |  | |
| Friction Problem Identified | Problems caused by its surface coming in contact with another surface or fluid. | C0702 |  |  | |  | |
| Leakage/Seal | Problems caused by inadequate/broken seal within the **device**. | C0703 |  |  | |  | |
| Lubrication Problem Identified | Problems that occurred because of the presence of either too much or too little lubricant where required (e.g. connectors, leading to failure mechanisms such as corrosion). | C0704 |  |  | |  | |
| Stiffness Problem Identified | Problems that occurred when its material is either too flexible/pliable or inflexible/rigid when in contact by an applied force. | C0705 |  |  | |  | |
| Stress Problem Identified | Problems caused by either excessive or inadequate physical force exerted on it by another object resulting in problems e.g. wear, bending, deformation, fracture, fatigue. | C0706 | Deformation Problem | Problems caused by changes in the shape or size of the **device** due to an applied force. This can be a result of tensile forces, compressive forces, shear, bending, tensile (pulling), or torsion. | | C070601 | |
| Fatigue Problem | Problems due to the weakening or breakdown of its material when subjected to stress or a series of repeated stresses. | | C070602 | |
| Fracture Problem | Problems caused by the separation of a component, object, or material into two or more pieces including shear. | | C070603 | |
| Mechanical Shock Problem | Problems caused by the sudden violent blow or collision to the whole **device** (e.g. by dropping). | | C070604 | |
| Vibration Problem | Problems caused by the constant rhythmic motion of the **device**, or something in the environment to which the **device** is exposed. | | C070605 | |
| Wear Problem | Problems due to the premature or expected erosion of its material by use, deterioration, or change. | | C070606 | |
| Incorrect Dimension | Problems caused by incorrect physical dimensions of the **device** or one of its parts | C0707 |  |  | |  | |
| Optical Problem Identified | Problems related to the optical properties of a **device**. | C08 | Optical Transmission Problem Identified | Problems with the **device**'s ability to pass light energy. | C0801 |  |  | |  | |
| Light Source Problem Identified | Problems with the optical properties of a **device** such as diopter, glare, and irradiance or glistening. | C0802 |  |  | |  | |
| Clinical Imaging Problem Identified | Problems that occur with **devices** used for radiographic or imaging procedures e.g. CT scanners, magnetic resonance imaging. | C09 | Gradient Induced Field Problem | Problems that result from the gradient-induced fields generated during radiologic procedures e.g. magnetic resonance imaging. | C0901 |  |  | |  | |
| Image Artifact | The unacceptable distortion of an image due to signal loss that may occur during a radiologic procedure such as magnetic resonance imaging. | C0902 |  |  | |  | |
| Magnetically-Induced Movement | Problems due to unintended or excessive movement created by the application of magnetic fields. | C0903 |  |  | |  | |
| Radiofrequency Induced Overheating | Problems due to unintended radiofrequency-induced temperature increase that can occur in the vicinity of the **device**. | C0904 |  |  | |  | |
| Software  Problem  Identified | Problems related to the **device** software. | C10 | Configuration Issue | Problems due to change control or incorrect version, including regional requirements. | C1001 |  |  | |  | |
| Design Error | The **device** had faulty (incomplete or incorrect) software design. | C1002 | Data Compression Error | Data was lost or corrupted during the operation of reducing storage space or communication bandwidth. | | C100201 | |
| Incorrect Algorithm | The **device** software was found to implement an incorrect sequence of steps for a specific computation. | | C100202 | |
| Incorrect Data Definition | The **device** software was found to contain errors in specifying or manipulating data items. | | C100203 | |
| Interface Design Error | The **device** software was found to contain errors in the user interface (including usability problems) or the interfaces with other systems. | | C100204 | |
| Non-Functional Defect | The **device** software contained software errors that did not impact its operation. | | C100205 | |
| Software Timing Problem | Problems that results from the incorrect sequencing or activation of software modules. | | C100206 | |
| Software Maintenance Problem Identified | The **device** software was not maintained/updated properly. | C1003 |  |  | |  | |
| Software Installation Problem Identified | The **device** software was not installed as per the specifications or failed to properly install. | C1004 |  |  | |  | |
| Software Requirement Error | The software requirements for the **device** are either incomplete, inadequate, or in conflict. | C1005 |  |  | |  | |
| Software Runtime Error | The **device** software failed during operation as a result of a coding error. | C1006 |  |  | |  | |
| Software Security Vulnerability | The **device** software failed to provide adequate authorization, access control, protection and accountability features. | C1007 |  |  | |  | |
| Erroneous Data Transfer | The **device** software fails to transfer the expected data within a system or to another **device**. | C1008 |  |  | |  | |
| Data Storage or Loss of Data | Storage of data was unsuccessful in total or in part. | C1009 |  |  | |  | |
| Thermal Problem | Problems related to the temperature of the **device**.Note: For problems related to environmental temperature use ''Environment Problem Identified''. | C11 | Overheating Problem Identified | The **device** was found to become hotter than expected during operation.This applies to **devices** which are not intended to deliver heat.Use "Excessive heating identified" for **devices** which are intended to deliver heat during operation.Use "Inadequate cooling identified" if the overheating was related to a problem with a cooling system. | C1101 |  |  | |  | |
| Excessive Heating Identified | The **device** delivered more heat than intended or expected during operation. This applies to **devices** which are intended to deliver heat. Use "Overheating problem identified" for **devices** which are not intended to deliver heat during operation. | C1102 |  |  | |  | |
| Excessive Cooling Identified | The **device** cooled the patient or another **device** more than intended or expected during operation. | C1103 |  |  | |  | |
| Inadequate Cooling Identified | The **device** did not sufficiently cool the patient or another **device** during operation. | C1104 |  |  | |  | |
| Protective System Problem Identified | Problems related to the system(s) designed to prevent or warn about unsafe operation of the **device**. | C12 | Fail-safe Problem Identified | A system intended to prevent unsafe operation of the **device** did not operate correctly. | C1201 |  |  | |  | |
| Alarm System Problem Identified | A system intended to warn of a potentially unsafe condition did not operate correctly. | C1202 |  |  | |  | |
| Problem of Device to Self-Test | Malfunction of the **device**'s self-test system. | C1203 |  |  | |  | |
| Problem to Auto Stop | An auto stop function of a **device** did not operate correctly. | C1204 |  |  | |  | |
| Premature Indicator Activation | A system intended to indicate the **device** status was triggered prematurely. | C1205 |  |  | |  | |
| Reset Problem | The **device** does not reset properly. | C1206 |  |  | |  | |
| Shielding Problem | Inadequate shielding of/by the **device**. | C1207 |  |  | |  | |
| Missing or Inadequate Safety Measures | Safety measures are inadequately applied or missing. | C1208 |  |  | |  | |
| Operational Problem Identified | Problems that occur during the performance, use, or functioning of the **device**. | C13 | Device Incorrectly Reprocessed | Problems associated with the failure to properly and adequately reprocess the **device**. | C1301 | Device Incorrectly Cleaned During Reprocessing | The cleaning procedure is not followed correctly or used inappropriate cleaning materials. | | C130101 | |
| Device Incorrectly Disinfected/Sterilised During Reprocessing | The disinfection/sterilization process was incorrect and/or the wrong products for disinfection/sterilization were used. | | C130102 | |
| Device Incorrectly Assembled During Reprocessing | Incorrect assembly of the **device** following reprocessing. | | C130103 | |
| Failure to Calibrate | A **device** that cannot calibrate (establish the relationship between a measuring device and the units of measure) to ensure accurate readings. | C1302 |  |  | |  | |
| Device Difficult to Operate | Problems including set-up, operation, and disassembly of equipment. Not including reprocessing. | C1303 |  |  | |  | |
| Incorrect Interpretation of Results/Data | Problems resulting from the incorrect interpretation by the user of the results or data provided by the **device**. | C1304 |  |  | |  | |
| Patient Sample Problem | Problems that occurred due to endogenous or exogenous interferent in the sample, or unexpected variation in the target analyte/marker. | C14 | New or Unknown Interferent | New or unknown endogenous or exogenous interferent (sample) identified. | C1401 |  |  | |  | |
| Known Interferent | Known interferent in the sample identified. | C1402 |  |  | |  | |
| Change in Target Marker/Variant/ Mutant | Problem due to change in target marker/variant/mutant which is not covered in the labelling. | C1403 |  |  | |  | |
| Pre-analytical Handling Problem | Incorrect pre-analytical handling of patient's sample by the user. | C1404 |  |  | |  | |
| Environment Problem Identified | Problems that occurred due to factors within the environment   e.g. dust, dirt, humidity, temperature. | C15 | Environmental Temperature Problem Identified | **Device** performance was affected by the temperature, or changes in temperature, of the environment in which it was used. | C1501 |  |  | |  | |
| Dust or Dirt Problem Identified | A **device** that experienced problems due to ingress, or coating, of dust or dirt. | C1502 |  |  | |  | |
| Contamination of Environment by Device | Operation of the **device** results in contamination of the nearby environment e.g. dust, dirt, smoke, heat or biological material. | C1503 |  |  | |  | |
| Environmental Pressure Problem Identified | **Device** performance was affected by the pressure, or changes in pressure, of the environment in which it was used. | C1504 |  |  | |  | |
| Ambient Light Problem Identified | **Device** performance was affected by ambient light.This term applies to the direct effects of ambient light on the **device**, and to the user's ability to operate the **device** (e.g. to read **device** output). | C1505 |  |  | |  | |
| Environmental Humidity Problem Identified | **Device** performance was affected by the humidity, or changes in humidity, of the environment in which it was used. | C1506 |  |  | |  | |
| Manufacturing Process Problem Identified | Problems with a **device** that can be traced to a problem in the manufacturing and/or production process. | C16 | Assembly Problem Identified | Problems that occurred because the **device** was assembled incorrectly. | C1601 |  |  | |  | |
| Sterilization Problem Identified | Problems that occurred during terminal sterilization by the manufacturer. | C1602 |  |  | |  | |
| Installation Problem Identified | A **device** that malfunctions because it was incorrectly installed, set-up, or configured (e.g. misconfiguration of an "automatic" defibrillator to "semi-automatic", thereby leading to failure). | C1603 |  |  | |  | |
| Maintenance of Manufacturing Machinery | Problems caused by failure to maintain manufacturing equipment used to producethe **device**. | C1604 |  |  | |  | |
| Packaging Problem Identified | Problems that occurred because of the **device** packaging. | C1605 | Packaging Compromised | Problems that occurred because of a compromised packaging of the **device** (e.g. broken or incomplete seal). | | C160501 | |
| Packaging Materials Problem | Problems that occurred because of the composition or type of packaging materials was inappropriate for the **device**. | | C160502 | |
| Packaging Contains Unintended Material | Problems that occurred because unintended material was packaged with the **device**. | | C160503 | |
| Packaging Contains Incorrect Device | Problems that occurred because the packaging contained an incorrect **device**. | | C160504 | |
| Maintenance Problem Identified | A **device** malfunction or problem   that occurs after production   because the **device** was not   properly maintained according to the instructions   (e.g. maintenance  may be performed by user facility,  distributor, or service provider). | C17 |  |  |  |  |  | |  | |
| Transport/Storage Problem Identified | Problems was caused by transport or storage conditions. | C18 | Transport Problem Identified | Problems traced to how the **device** was transported e.g. temperature of shipping compartment or method of transportation. | C1801 |  |  | |  | |
| Storage Problem Identified | Problems that result from storing the **device** in an uncontrolled or improper environment (e.g. moisture sensitive **devices** stored in a humid environment). | C1802 |  |  | |  | |
| **No Device Problem Found** | The **device**   either   functioned as intended   or   a problem was not found. | C19 |  |  |  |  |  | |  | |
| No Findings Available | **Use when  no investigation can be performed  and therefore no results will be obtained.** | C20 |  |  |  |  |  | |  | |
| Results Pending Completion of Investigation | Investigation is ongoing and results are not yet available.  Do not use this code if the investigation is complete. | C21 |  |  |  |  |  | |  | |
| Appropriate   Term/Code   Not Available | Problems is not adequately described by any other term.     Note: This code must not be used unless there is no other feasible code.   The preferred term should be documented when submitting an adverse event report.   This information will be used to determine if a new term should be added to the code table. | C22 |  |  |  |  |  | |  | |