**EU-MDR - ISO 14971-2019 Considerations**

| **EU-MDR Clause** | **ISO 14971:2019 Clause** | **Notes and Comments** |
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| Risk means the combination of the probability of occurrence of harm and the severity of that harm [Art 2(23)] | **Covered**See 3.18 |  |
| In the labelling, instructions for use, making available, putting into service, and advertising of devices, it shall be prohibited to use text, names, trademarks, pictures, and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose [Art. 7(1)(c)] | **Not Covered**ISO 14971:2019 does not have this requirement. |  |
| Manufacturers shall establish, document, implement, and maintain a system for risk management as described in Section 3 of Annex I. [Art. 10(2)] | **Partially Covered**ISO 14971:2019 provides a system for risk management. However, there are requirements in the MDR the international standard doesn’t cover. |  |
| The quality management system shall address risk management as set out in in Section 3 of Annex I; [Art. 10(9)(e)] | **Partially Covered**Article I says, “This document does not require that the manufacturer have a quality management system in place. However, risk management can be an integral part of a quality management system”.ISO 14971:2019 doesn’t fully align with Annex I(3). |  |
| The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use. [Art. 20(4)] | Partially CoveredISO 14971:2019 includes information for safety as a risk reduction measure, but doesn’t include a mark indicating a special risk. |  |
| [Devices] shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. [Ann. I(1)] | **Partially Covered**ISO 14971:2019 says that devices should be safe but does not include effectiveness.The standard defines harm as “injury or damage to the health of people, or damage to property or the environment”.Section 7.4 includes a benefit-risk analysis but applies when the risk is unacceptable and risk reduction is not practicable.The standard defines state of the art as “developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience”. The EU-MDR doesn’t have a definition. | Similar language in the MDD led to a content deviation requiring risk-benefit analysis for all hazards regardless of acceptability. |
| The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio. [Ann. I(2)] | **Partially Covered**Note 1 to section 4.2 says, “The manufacturer’s policy for establishing criteria for risk acceptability can define the approaches to risk control, for example reducing risk as low as reasonably practicable, reducing risk as low as reasonably achievable, or reducing risk as far as possible without adversely affecting the benefit-risk ratio”. | Neither the EU-MDR nor ISO 14971:2019 define the benefit-risk ratio. Neither document explains how to determine it.ISO 14971:2019 Annex A mentions the balance between benefit and risk. Presumably the benefit-risk ratio is a measure of the balance. |
| Manufacturers shall establish, implement, document, and maintain a risk management system. [Ann. I(3)] | **Partially Covered**ISO 14971:2019 provides a risk management system, but it doesn’t satisfy all the EU-MDR requirements. |  |
| Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. [Ann. I(3)] | **Covered**The risk management plan in 4.4 is a life-cycle plan. Section 10 updates the risk management file using information from the production and post-production activities. |  |
| In carrying out risk management manufacturers shall establish and document a risk management plan for each device. [Ann. I(3)(a)] | **Covered**ISO 14971:2019, 4.4 includes a risk management plan. |  |
| In carrying out risk management manufacturers shall identify and analyze the known and foreseeable hazards associated with each device. [Ann. I(3)(b)] | **Covered**ISO 14971:2019, 5.4 includes identification and documentation of known and foreseeable hazards associated with the medical device |  |
| In carrying out risk management manufacturers shall estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse. [Ann. I(3)(c)] | **Covered**ISO 14971:2019, 5.2 includes:For the particular medical device being considered, the manufacturer shall document the intended use.The manufacturer shall also document reasonably foreseeable misuse. |  |
| In carrying out risk management manufacturers shall eliminate or control the risks referred to in Ann. I(3)(c) in accordance with the requirements of Ann. I(4). [Ann. I(3)(d)] | **Partially Covered**In ISO 14971:2019 5.2 leads to the risk reduction measures in 7.1. However, those risk reduction measures are not the same wording as the risk reduction measures in the EU-MDR. |  |
| In carrying out risk management, manufacturers shall evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability. [Ann. I(3)(e)] | **Partially Covered**ISO 14971:2019, 10 collects information from production and post-production activities and uses it to update the risk management file.The section does not include the risk-benefit ratio. |  |
| In carrying out risk management manufacturers shall, based on the evaluation of the impact of the information referred to in Ann. I(3)(e), if necessary, amend control measures in line with the requirements of Ann. I(4). [Ann. I(3)(f)] | **Covered**ISO 14971:2019, 10.3 evaluates the impact of the information and analysis on previously implemented risk control measures. |  |
| Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. [Ann. I(4)] | **Covered**ISO 14971:2019, 3.28 defines state of the art as “developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience”. The EU-MDR doesn’t have a definition. |  |
| To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. [Ann. I(4)] | **Covered**ISO 14971:2019, 7.3 evaluates residual risk for acceptability.ISO 14971:2019, 8 evaluates overall residual risk for acceptability |  |
| In selecting the most appropriate solutions, manufacturers shall, in the following order of priority: (a) eliminate or reduce risks as far as possible through safe design and manufacture. [Ann. I(4)(a)] | **Partially Covered**ISO 14971:2019, 7.1The manufacturer shall use one or more of the following risk control options in the priority order listed: a) inherently safe design and manufacture | The wording is not identical, but the result will be the same in both cases. |
| In selecting the most appropriate solutions, manufacturers shall, in the following order of priority: (b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated. [Ann. I(4)(b)] | **Partially Covered**ISO 14971:2019, 7.1The manufacturer shall use one or more of the following risk control options in the priority order listed: b) protective measures in the medical device itself or in the manufacturing process | The wording is not identical, but the result will be the same in both cases. |
| In selecting the most appropriate solutions, manufacturers shall, in the following order of priority: (c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users. [Ann. I(4)(c)] | **Partially Covered**ISO 14971:2019, 7.1The manufacturer shall use one or more of the following risk control options in the priority order listed: c) information for safety and, where appropriate, training | The wording is not identical, but the result will be the same in both cases. |
| Manufacturers shall inform users of any residual risks. [Ann. I(4)] | Partially CoveredISO 14971:2019, 8 says, “If the overall residual risk is judged acceptable, the manufacturer shall decide which residual risks to disclose and what information is necessary to include in the accompanying documentation in order to disclose those residual risks”. | The EU-MDR requires disclosure of all residual risk, while ISO 14971:2019 allows to manufacturer to determine which residual risks to disclose. |
| In eliminating or reducing risks related to use error, the manufacturer shall reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety) [Ann. I(5)(a)] | **Not Covered**ISO 14971:2019 does not have a requirement for ergonomic features. | Table C.1 – Examples of Hazards does not include this as a hazard. |
| In eliminating or reducing risks related to use error, the manufacturer shall give consideration to the technical knowledge, experience, education, training, and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled, or other users) [Ann. I(5)(b)] | **Not Covered**ISO 14971:2019 has a definition of use error, but does not have requirements. | Table C.1 – Examples of Hazards does not include this as a hazard.IEC 62366-1:2015 on human factors includes use errors in an ISO 14971:2007 context. |
| All known and foreseeable risks, and any undesirable side-effects, shall be minimized and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use. [Ann. I(8)] | **Partially Covered**ISO 14971:2019, 7.4 includes a benefit-risk analysis but applies when the risk is unacceptable and risk reduction is not practicable. | Similar language in the MDD led to a content deviation requiring risk-benefit analysis for all hazards regardless of acceptability. |
| Devices shall be designed, manufactured, and packaged in such a way as to minimize the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure. [Ann. I(10.2)] | **Not Covered**ISO 14971:2019 does not have requirements for contaminants or residues. | Table C.1 – Examples of Hazards includes Immunological agents –Irritants – cleaning residues |
| Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products, and processing residues, that may be released from the device. [Ann. I(10.4.1)] | **Not Covered**ISO 14971:2019 does not have requirements for substances or particles. | Table C.1 – Examples of Hazards includes Immunological agents – Allergenic – antiseptic substancesTable C.1 – Examples of Hazards includes Chemical agents – Particles (including micro- and nanoparticles) |
| If the intended use of [devices with certain levels of some chemicals] includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use. [Ann. I(10.4.5)] | **Not Covered**ISO 14971:2019 does not have requirements for these chemicals in general nor for the population segments that include pregnant women, breastfeeding women, or children. | Table C.1 – Examples of Hazards does not include these chemicals or these population segments |
| Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used. [Ann. I(10.5)] | **Not Covered**ISO 14971:2019 does not have requirements for the unintentional ingress of substances. | Table C.1 – Examples of Hazards does not include unintentional ingress of substances |
| Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials. [Ann. I(10.6)] | **Not Covered**ISO 14971:2019 does not have requirements for the unintentional ingress of particles. | Table C.1 – Examples of Hazards includes Chemical agents – Particles (including micro- and nanoparticles) |
| Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. [Ann. I(11.1)] | **Not Covered**ISO 14971:2019 does not have requirements for infections of users, patients, or other persons. | Table C.1 – Examples of Hazards does not include infection |
| The design shall reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries. [Ann. I(11.1)(a)] | **Not Covered**ISO 14971:2019 does not have requirements for unintended cuts and pricks. | Table C.1 – Examples of Hazards does not include unintended cuts and pricks |
| Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilization indicated by the manufacturer. [Ann. I(11.7)] | **Not Covered**ISO 14971:2019 does not have requirements for microbial contamination. | Table C.1 – Examples of Hazards includes multiple biological agents |
| Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimize all possible risks, such as misconnection. [Ann. I(14.1)] | **Not Covered**ISO 14971:2019 does not have requirements for the misconnection of fluid, gas transfer, electrical coupling, or mechanical coupling. | Table C.1 – Examples of Hazards does not include these misconnections |
| Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional, and where appropriate ergonomic features. [Ann. I(14.2)(a)] | **Not Covered**ISO 14971:2019 does not have requirements for physical features. | Table C.1 – Examples of Hazards includes a variety of physical features |
| Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences. [Ann. I(14.2)(b)] | **Not Covered**ISO 14971:2019 does not have requirements for external influences or environmental conditions | Table C.1 – Examples of Hazards includes a variety of external influences and environmental conditions |
| Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use. [Ann. I(14.2)(c)] | **Not Covered**ISO 14971:2019 does not have requirements for contact with materials, liquids, and substances | Table C.1 – Examples of Hazards includes a variety of contact with materials, liquids, and substances |
| Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts. [Ann. I(14.2)(d)] | **Not Covered**ISO 14971:2019 does not have requirements for negative interaction between software and the IT environment within which it operates and interacts | Table C.1 – Examples of Hazards does not include these negative interactions |
| Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible the risks of accidental ingress of substances into the device. [Ann. I(14.2)(e)] | **Not Covered**ISO 14971:2019 does not have requirements for accidental ingress of substances into the device | Table C.1 – Examples of Hazards does not include accidental ingress of substances into the device |
| Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given. [Ann. I(14.2)(f)] | **Not Covered**ISO 14971:2019 does not have requirements for reciprocal interference with other devices | Table C.1 – Examples of Hazards does not include reciprocal interference with other devices |
| Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism. [Ann. I(14.2)(g)] | **Not Covered**ISO 14971:2019 does not have requirements for situations where maintenance or calibration are not possible | Table C.1 – Examples of Hazards does not include situations where maintenance or calibration are not possible |
| Devices shall be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion. [Ann. I(14.3)] | **Not Covered**ISO 14971:2019 does not have requirements for fire or explosion during normal useISO 14971:2019 does not have requirements for fire or explosion in a single fault condition | Table C.1 – Examples of Hazards does not include fire or explosion during normal useTable C.1 – Examples of Hazards does not include fire or explosion in a single fault condition |
| The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. [Ann. I(16.1)(b)] | **Not Covered**ISO 14971:2019 does not have requirements for the operating instructions for devices emitting hazardous or potentially hazardous radiationISO 14971:2019 does not have requirements for the installation of devices emitting hazardous or potentially hazardous radiation | Table C.1 – Examples of Hazards does not include requirements for the operating instructions for devices emitting hazardous or potentially hazardous radiationTable C.1 – Examples of Hazards does not include requirements for the installation of devices emitting hazardous or potentially hazardous radiation |
| Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or non- ionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions. [Ann. I(16.2)(a)] | **Not Covered**ISO 14971:2019 does not have requirements for user emission control for devices designed to emit hazardous, or potentially hazardous, levels of ionizing and/or non- ionizing radiation | Table C.1 – Examples of Hazards does not include requirements for user emission control for devices designed to emit hazardous, or potentially hazardous, levels of ionizing and/or non- ionizing radiation |
| Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability, and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance. [Ann. I(17.1] | **Not Covered**ISO 14971:2019 does not have requirements for single fault conditions for devices that incorporate electronic programmable systems | Table C.1 – Examples of Hazards does not include requirements for single fault conditions for devices that incorporate electronic programmable systems |
| For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification, and validation. [Ann. I(17.2] | **Not Covered**ISO 14971:2019 does not have requirements for software development | IEC 62304:2006/AMD 1:2015 is a process standard for medical device software development in an ISO 14971:2007 context. |
| For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks. [Ann. I(18.1] | **Not Covered**ISO 14971:2019 does not have requirements for non-implantable active devices in a single fault condition | Table C.1 – Examples of Hazards does not include non-implantable active devices in a single fault condition |
| Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment. [Ann. I(18.5)] | **Not Covered**ISO 14971:2019 does not have requirements for electromagnetic interference | Table C.1 – Examples of Hazards does not include electromagnetic interference |
| Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer. [Ann. I(18.7)] | **Not Covered**ISO 14971:2019 does not have requirements for accidental electric shocks | Table C.1 – Examples of Hazards does include electrical energy as a hazard |
| Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents, and overheating of the devices. [Ann. I(19.1)(a)] | **Not Covered**ISO 14971:2019 does not have requirements for energy sources | Table C.1 – Examples of Hazards lists a variety of energy hazards |
| Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment. [Ann. I(19.1)(b)] | **Not Covered**ISO 14971:2019 does not have requirements for active implantable devices | Table C.1 – Examples of Hazards does include active implantable devices |
| Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible risks which may arise where maintenance and calibration are impossible, including excessive increase of leakage currents [Ann. I(19.1)(c)(1st indent)] | **Not Covered**ISO 14971:2019 does not have requirements for active implantable devices | Table C.1 – Examples of Hazards does include active implantable devices |
| Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible risks which may arise where maintenance and calibration are impossible, including ageing of the materials used [Ann. I(19.1)(c)(2nd indent)] | **Not Covered**ISO 14971:2019 does not have requirements for active implantable devices | Table C.1 – Examples of Hazards does include active implantable devices |
| Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible risks which may arise where maintenance and calibration are impossible, including excess heat generated by the device. [Ann. I(19.1)(c)(3rd indent)] | **Not Covered**ISO 14971:2019 does not have requirements for active implantable devices | Table C.1 – Examples of Hazards does include active implantable devices |
| Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible risks which may arise where maintenance and calibration are impossible, including decreased accuracy of any measuring or control mechanism. [Ann. I(19.1)(c)(4th indent)] | **Not Covered**ISO 14971:2019 does not have requirements for active implantable devices | Table C.1 – Examples of Hazards does include active implantable devices |
| Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts. [Ann. I(20.1)] | **Not Covered**ISO 14971:2019 does not have requirements for mechanical risk | Table C.1 – Examples of Hazards lists a variety of mechanical energy hazards |
| Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance. [Ann. I(20.2)] | **Not Covered**ISO 14971:2019 does not have requirements for vibrations | Table C.1 – Examples of Hazards includes vibrating parts |
| Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance. [Ann. I(20.3)] | **Not Covered**ISO 14971:2019 does not have requirements for noise | Table C.1 – Examples of Hazards includes Acoustic energy – sound pressure |
| Terminals and connectors to the electricity, gas, or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimize all possible risks. [Ann. I(20.4)] | **Not Covered**ISO 14971:2019 does not have requirements for terminals and connectors | Table C.1 – Examples of Hazards does not include terminals and connectors |
| Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. [Ann. I(20.5)] | **Not Covered**ISO 14971:2019 does not have requirements for fitting parts | Table C.1 – Examples of Hazards does not include fitting parts |
| Information on the parts themselves and/or their housings shall be given on moving parts where the direction of movement needs to be known in order to avoid a risk. [Ann. I(20.5)] | **Not Covered**ISO 14971:2019 does not have requirements for fitting parts | Table C.1 – Examples of Hazards does not include fitting parts |
| Protection against the risks posed to the patient or user by devices supplying energy or substances: Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user. [Ann. I(21.1)] | **Not Covered**ISO 14971:2019 does not have requirements for devices supplying energy or substances | Table C.1 – Examples of Hazards includes areas that may apply such as Delivery – too fast and Delivery – too slow |
| Protection against the risks posed to the patient or user by devices supplying energy or substances: Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source. [Ann. I(21.2)] | **Not Covered**ISO 14971:2019 does not have requirements for devices supplying energy or substances | Table C.1 – Examples of Hazards includes areas that may apply such as Delivery – too fast and Delivery – too slow |
| Protection against the risks posed to the patient or user by devices supplying energy or substances: The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient. [Ann. I(21.3)] | **Not Covered**ISO 14971:2019 does not have requirements for devices supplying energy or substances | Table C.1 – Examples of Hazards includes Information, but does not specifically include this type of hazard |
| Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons: Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply. [Ann. I(22.1)] | **Not Covered**ISO 14971:2019 does not have requirements for devices intended for use by lay persons | Table C.1 – Examples of Hazards does not include lay person useIEC 62366-1:2015 on human factors to help ensure correct use by lay persons |
| Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons: Devices for use by lay persons shall be designed and manufactured in such a way as to ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information [Ann. I(22.2)(1st indent)] | **Not Covered**ISO 14971:2019 does not have requirements for devices intended for use by lay persons | Table C.1 – Examples of Hazards does not include lay person useIEC 62366-1:2015 on human factors to help ensure correct use by lay persons |
| Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons: Devices for use by lay persons shall be designed and manufactured in such a way as to reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries. [Ann. I(22.2)(2nd indent)] | **Not Covered**ISO 14971:2019 does not have requirements for devices intended for use by lay persons | Table C.1 – Examples of Hazards does not include lay person useIEC 62366-1:2015 on human factors to help ensure correct use by lay persons |
| Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons: Devices for use by lay persons shall be designed and manufactured in such a way as to reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results. [Ann. I(22.2)(3rd indent)] | **Not Covered**ISO 14971:2019 does not have requirements for devices intended for use by lay persons | Table C.1 – Examples of Hazards does not include lay person useIEC 62366-1:2015 on human factors to help ensure correct use by lay persons |
| Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons: Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person can verify that, at the time of use, the device will perform as intended by the manufacturer. [Ann. I(22.3)(1st indent)] | **Not Covered**ISO 14971:2019 does not have requirements for devices intended for use by lay persons | Table C.1 – Examples of Hazards does not include lay person useIEC 62366-1:2015 on human factors to help ensure correct use by lay persons |
| Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons: Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person, if applicable, is warned if the device has failed to provide a valid result. [Ann. I(22.3)(2nd indent)] | **Not Covered**ISO 14971:2019 does not have requirements for devices intended for use by lay persons | Table C.1 – Examples of Hazards does not include lay person useIEC 62366-1:2015 on human factors to help ensure correct use by lay persons |
| Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions, or warnings in the information supplied by the manufacturer. [Ann. I(23.1)(g)] | **Partially Covered**ISO 14971:2019, 8 says, “If the overall residual risk is judged acceptable, the manufacturer shall decide which residual risks to disclose and what information is necessary to include in the accompanying documentation in order to disclose those residual risks”.The EU-MDR is more explicit about the location in the accompanying documentation. |  |
| The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant, methods for eliminating the risks encountered by persons involved in installing, calibrating, or servicing devices. [Ann. I(23.1)(k)(4th indent)] | **Not Covered**ISO 14971:2019 does not have requirements for the verification of installation | Table C.1 – Examples of Hazards does not include installation verification |
| If the device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. This information shall be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors shall be addressed in detail. [Ann. I(23.1)(p)] | **Not Covered**ISO 14971:2019 does not have requirements for the re-use of single use devices | Table C.1 – Examples of Hazards does not include the re-use of single use devices |
| Information that allows the user and/or patient to be informed of any warnings, precautions, contra- indications, measures to be taken, and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken, and limitations of use regarding the device. The information shall cover, where appropriate: warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment. [Ann. I(23.1)(s)(3rd indent)] | **Not Covered**ISO 14971:2019 does not have requirements for this specific type of information. |  |