**Compliance with essential requirements**

The purpose of this document is to demonstrate that the eFI2 and incorporated eFI+ meet the relevant essential requirements outlined in Part II of the UK MDR 2002, Annex I (as modiﬁed by Part II of Schedule 2A to the UK MDR 2002).UK MDR 2002 is taken from MDR 2017/745 (i.e. they are the same).

In the table below, we have identified the requirements that apply to the eFI2.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **MDR clause number** | **Annex 1 - MDR 2017/745 clause** | **Applicable? (Yes/No)** | **Method of Conformity** | **Justification for non-applicable clauses** |
| 1 | Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They 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. | Yes | Instructions on the use of the eFI2 and incorporated eFI+ algorithms will be provided on the eFI2 GitHub. The instructions will provide information for the software companies responsible for implementing the algorithms into the primary care electronic health records, and also to primary care clinicians who will be using the output of the eFI2 algorithms. | n/a |
| 2 | 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. | - | - | - |
| 3 | Manufacturers shall establish, implement, document and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall: | - | - | - |
| 3a | Establish and document a risk management plan for each device; | Yes | Refer to **Risk Management Plan** in MHRA Technical Documentation folder | - |
| 3b | Identify and analyse the known and foreseeable hazards associated with each device; | Yes | A **Hazard Log** is available in the development repository and is updated in accordance with the **Risk Management Plan** | - |
| 3c | Estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse; | Yes | Risks will be estimated and evaluated using the processes detailed within the **Hazard Log** | - |
| d | eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4; | Yes | See Section 4 |  |
| 3e | 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; and | Yes | Due to close collaboration with the relevant software companies (TPP, EMIS, Cerner UK) the development team will be kept informed of hazards and issues that arise during implementation. These can be added to the **Hazard log** and dealt with using the **Risk Management Plan**, where necessary. | 3e |
| 3f | based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4. | Yes | Issues will be added to the **Hazard log** and dealt with using the **Risk Management Plan**, where necessary. |  |
| 4 | 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. 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. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority: | - | - | - |
| 4a | eliminate or reduce risks as far as possible through safe design and manufacture; | Yes | During the design phase of the eFI2 and eFI+ algorithms, internal and external validations were performed in two large datasets. This helps ensure the tools have predictive validity. The **Hazard Log** includes residual risks associated with each hazard and methods to eliminate or reduce the risks as far as possible. | 4a |
| 4b | Where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and | Yes | Please see **Hazard Log** which includes risks that cannot be completely eliminated |  |
| 4c | provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users. | Yes | The eFI2 GitHub will provide instructions along with a **Hazard Log** and **Risk Management Plan** |  |
| 5 | In eliminating or reducing risks related to use error, the manufacturer shall: | - | - | - |
| 5a | 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), and | Yes | The health or safety of the patient or user is unlikely to be compromised because the eFI2 is a decision-support tool to assist clinicians in their clinical decision-making. | - |
| 5b | 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) | Yes | The relevant software companies (TPP, EMIS, Cerner) will be supported by the development team to implement the eFI2 an incorporated eFI+ algorithms into electronic healthcare records. | - |
| 6 | The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions | Yes | The health or safety of the patient or user is unlikely to be compromised because the eFI2 is a decision-support tool to assist clinicians in their clinical decision-making. | - |
| 7 | Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer | No | n/a | The device is software distributed digitally so the principle of this requirement is not applicable. |
| 8 | All known and foreseeable risks, and any undesirable side-effects, shall be minimised 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 | Yes | Please refer to **Hazard Log** for information on foreseeable risks and how to mitigate them. |  |
| 9 | For the devices referred to in Annex XVI, the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons. | No | n/a | The device is software and not one referred to in Annex XVI |
| 10 | Chemical, physical and biological properties | No | n/a | The device is software so the principle of this requirement is not applicable. |
| 11 | Infection and microbial contamination | No | n/a | The device is software so the principle of this requirement is not applicable. |
| 12 | Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body | No | n/a | The device is software so the principle of this requirement is not applicable. |
| 13 | Devices incorporating materials of biological origin | No | n/a | The device is software so the principle of this requirement is not applicable. |
| 14 | Construction of devices and interaction with their environment | No | n/a | The device is software so the principle of this requirement is not applicable. |
| 15 | Devices with a diagnostic or measuring function | No | n/a | The device is software so the principle of this requirement is not applicable. |
| 16 | Protection against radiation | No | n/a | The device is software so the principle of this requirement is not applicable. |
| 7 | Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves |  |  |  |
| 17.1 | 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; | Yes | The eFI2 is embedded into electronic health records by software companies (TPP, EMIS , Cerner). Information services have similarly embedded the original eFI, so the risk of a fault occurring is minimal. |  |
| 17.2 | 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; | Yes | The eFI2 is an evidence-based tool that was developed, validated and tested. The principles of development have also been taken into consideration, including the **Risk Management Plan** |  |
| 3 | Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise); | No | n/a | This device is software but is not intended to be used in combination with mobile computing platforms. |
| 4 | Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended. | Yes | The eFI2 will be embedded in electronic health records by information services. Therefore the security measures will be the same as those already used to protect electronic health records. |  |
| 18 | Active devices and devices connected to them. |  |  |  |
| 18.1 | 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. | Yes | Please refer to **Risk Management Plan** |  |
| 18.2 | Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical. | No | n/a | Although an active device, the device is software, which does not depend on an internal power supply, so the principle of this requirement is not applicable. |
| 18.3 | Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure. | No | n/a | Although an active device, the device is software, which does not depend on an internal power supply, so the principle of this requirement is not applicable. |
| 18.4 | Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health. | No | n/a | The eFI2 uses a statistical prognostic model to predict the possibility of a patient being admitted into hospital with a fall/fracture, requiring increased home care package, requiring nursing home admission or all-cause morality, using health deficits (symptoms, diagnoses, diseases, conditions) recorded in electronic healthcare records. The values presented in the eFI2 score are probabilities of these events occurring in the next 12 months. |
| 18.5 | 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. | No | n/a | Although an active device, the device is software, which is not affected by electromagnetic interference, so the principle of this requirement is not applicable. |
| 18.6 | Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended. | No | n/a | Although an active device, the device is software, which is not affected by electromagnetic interference, so the principle of this requirement is not applicable. |
| 18.7 | 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. | No | n/a | Although an active device, the device is software, which cannot administer accidental electric shocks, so the principle of this requirement is not applicable. |
| 18.8 | Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended. | Yes | The eFI2 is embedded in electronic health care records and therefore access is to authorised personnel only |  |
| 19 | Particular requirements for active implantable devices | No | n/a | The device is software that is not implantable so the principle of this requirement is not applicable. |
| 20 | Protection against mechanical and thermal risks | No | n/a | The device is software, which practically do not have any associated mechanical and thermal risks, so the principle of this requirement is not applicable. |
| 21 | Protection against the risks posed to the patient or user by devices supplying energy or substances. | No | n/a | The device is software, which does not supply energy nor substances, so the principle of this requirement is not applicable. |
| 22 | Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons. | No | n/a | The device is not intended for use by lay persons so the principle of this requirement is not applicable. |
|  |  |  |  |  |
| 23 | Label and instructions for use |  |  |  |
| 23.1 | General requirements regarding the information supplied by the manufacturer. Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following: | - | The eFI2 is an algorithm and corresponding code list- therefore there is no label or packaging. However, instructions for use will be made available on a public eFI2 GitHub. | - |
| .1a | The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. | Yes | The eFI2 is intended for use by clinicians. All instructions and labels will be reviewed by the multi-disciplinary development team of statisticians, clinicians and software developers. Instructions will be made available on the eFI2 GitHub for users. Instructions will also be provided to the software companies who are responsible for implementing the eFI2 and incorporated eFI+ algorithms into primary care records. | n/a |
| 23.1b | The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices. | Yes | n/a | The device is an algorithm. Instructions will be made available on the eFI2 GitHub. |
| 23.1c | Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification (‘RFID’) or bar codes. | Yes | n/a | The device is an algorithm. Instructions will be made available on the eFI2 GitHub. |
| 23.1d | Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section. | No | n/a | The device is an algorithm. Instructions will be made available on the eFI2 GitHub. |
| 23.1e | Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge. | No | n/a | Multiple devices will not be supplied to a single user and/or location so the principle of this requirement is not applicable. |
| 23.1f | Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation. | Yes | **eFI2 instructions** will be made available on the eFI2 GitHub with the option to download as a PDF and print. | n/a |
| 23.1g | 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. | Yes | Instructions will be made available on the eFI2 GitHub along with the **Hazard Log** and **Risk Management Plan.** The instructions will state that the eFI2 score should be used in conjunction with clinical assessment and judgement. | n/a |
| 23.1h | Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device. | No | n/a | None of the information being supplied will take the form of symbols so the principle of this requirement is not applicable. |
| 23.2 | Information on the label The label shall bear all of the following particulars: |  |  |  |
| 23.2a | the name or trade name of the device; | Yes | n/a | The eFI2 is an algorithm and does not have an information label |
| 23.2b | the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device; | Yes | n/a | The eFI2 is an algorithm and does not have an information label |
| 23.2c | the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business; | Yes | n/a | The eFI2 is an algorithm and does not have an information label |
| 23.2d | if the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative; | Yes | n/a | The eFI2 is an algorithm and does not have an information label |
| 23.2e | where applicable, an indication that the device contains or incorporates: — a medicinal substance, including a human blood or plasma derivative, or — tissues or cells, or their derivatives, of human origin, or — tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 | No | n/a | The device is software, which does not contain or incorporate any of the listed substances or derivatives, so the principle of this requirement is not applicable. |
| 23.2f | where applicable, information labelled in accordance with Section 10.4.5; | No | n/a | The device is software, which does not contain substances referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0,1 % weight by weight (w/w), so the principle of this requirement is not applicable. |
| 23.2g | the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate; | No | n/a | The device is software which does not have an accompanying lot umber nor serial number, so the principle of this requirement is not applicable. |
| 23.2h | the UDI carrier referred to in Article 27(4) and Part C of Annex VII; | No | - | We will include a UDI from 26 May 2025, in accordance with the grace period noted in MDR Article 123 paragaph 3f for class I devices. |
| 23.2i | an unambiguous indication of the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant; | No | n/a | The device is software that is not in continuous use so the principle of this requirement is not applicable. |
| 23.2j | where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable; | Yes | The date on which a version of the eFI2 is published will be used as the date of manufacture. Information about these dates will be made available on the produce website, in accordance with the version control noted in 23.1f. All instructions and labels will be reviewed by the multi-disciplinary development team of statisticians, clinicians and software developers. | n/a |
| 23.2k | an indication of any special storage and/or handling condition that applies; | No | n/a | The device is software without any special storage and/or handling condition, so the principle of this requirement is not applicable. |
| 23.2l | if the device is supplied sterile, an indication of its sterile state and the sterilisation method; | No | n/a | The device is software so the principle of this requirement is not applicable. |
| 23.2m | warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users; | Yes | The eFI2 is an algorithm and does not have an information label. However a **Hazard Log** and **Risk Management Plan** will be available on the eFI2 GitHub. | n/a |
| 23.2n | if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union; | No | n/a | The device is software that is not intended for single use. |
| 23.2o | if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles; | No | n/a | The device is software that is not intended for single use. |
| 23.2p | if the device is custom-made, the words ‘custom-made device | No | n/a | The device is software that is not custom-made. |
| 23.2q | an indication that the device is a medical device. If the device is intended for clinical investigation only, the words ‘exclusively for clinical investigation'; | Yes | n/a | The eFI2 is an algorithm and does not have an information label. |
| 23.2r | in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action; | No | n/a | The device is software, which is not intended to be introduced into the human body, so the principle of this requirement is not applicable. |
| 23.2s | for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number; | No | n/a | The device is software, which is not implantable, so the principle of this requirement is not applicable. |
| 23.3 | Information on the packaging which maintains the sterile condition of a device (‘sterile packaging’)The following particulars shall appear on the sterile packaging: | No | n/a | The device is software so the principle of this requirement is not applicable. |
| 23.4 | Information in the instructions for use The instructions for use shall contain all of the following particulars: |  |  |  |
| 23.4a | the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2; | Yes | The **eFI2 instructions** will include the name of the device (eFI2) and the address and contact info of the lead researcher on the development team. The other points are not applicable to the eFI2 as the device is an algorithm and corresponding code list. | n/a |
| 23.4b | the device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate; | Yes | The instructions will provide a clear purpose along with information on the patient target group (those aged 65+). | n/a |
| 23.4c | where applicable, a specification of the clinical benefits to be expected; | Yes | The instructions will provide a specification of the clinical benefits. | n/a |
| 23.4d | where applicable, links to the summary of safety and clinical performance referred to in Article 32; | Yes | The instructions will link to an academic peer reviewed paper which highlight the clinical performance of the algorithms. | n/a |
| 23.4e | the performance characteristics of the device; | Yes | The instructions will link to an academic peer reviewed paper which highlight the clinical performance of the algorithms. | n/a |
| 23.4f | where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories; | Yes | The instructions will state the eFI2 algorithm is to be used in patients aged 65+. Clinically, the algorithm will be supplied automatically to this age group by the software companies. | n/a |
| 23.4g | any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard; | Yes | The instructions will refer to the **Hazard Log** and **Risk Management Plan** | n/a |
| 23.4h | specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it; | Yes | All instructions will be reviewed by the multi-disciplinary development team of statisticians, clinicians and software developers. | n/a |
| 23.4i | details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection; | Yes | n/a | The device if software so the principle of this requirement is not applicable. |
| 23.4j | any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons; | Yes | n/a | The device if software so the principle of this requirement is not applicable. |
| 23.4k | 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: — details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection, — identification of any consumable components and how to replace them, — information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime, and— methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices; | Yes | n/a | n/ The device if software so the principle of this requirement is not applicable. |
| 23.4l | if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use; | No | n/a | The device if software so the principle of this requirement is not applicable. |
| 23.4m | if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation; | No | n/a | The device if software so the principle of this requirement is not applicable. |
| 23.4n | if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation appropriate to the Member State or Member States in which the device has been placed on the market. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses; | No | n/a | The device if software so the principle of this requirement is not applicable. |
| 23.4o | an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements; | No | n/a | The device if software so the principle of this requirement is not applicable. |
| 23.4p | 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. If in accordance with point (d) of Section 23.1. no instructions for use are required, this information shall be made available to the user upon request; | No | n/a | The device if software that is not intended for single us so the principle of this requirement is not applicable. |
| 23.4q | for devices intended for use together with other devices and/or general purpose equipment: — information to identify such devices or equipment, in order to obtain a safe combination, and/or — information on any known restrictions to combinations of devices and equipment; | No | n/a | The device is software that is not intended to be used together with other devices and/or general purpose equipment, so the principle of this requirement is not applicable. |
| 23.4r | if the device emits radiation for medical purposes: — detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation, — the means of protecting the patient, user, or other person from unintended radiation during use of the device; | No | n/a | The device is software, which does not emit radiation, so the principle of this requirement is not applicable. |
| 23.4s | 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 in the event of malfunction of the device or changes in its performance that may affect safety, — warnings, precautions and/or measures to be taken as regards the exposure to 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, or temperature, — 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, — if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered, — warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and — precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user; | Yes | The instructions will highlight that the algorithms are designed for use in conjunction with clinical assessment and judgement. | n/a |
| 23.4t | in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contra- indications, undesirable side-effects and risks relating to overdose; | No | n/a | The device is software, which is not composed of substances or of combinations of substances that are intended to be introduced into the human body, so the principle of this requirement is not applicable. |
| 23.4u | in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed; | No | n/a | The device is software, which is not implantable, so the principle of this requirement is not applicable. |
| 23.4v | warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information shall cover, where appropriate: — infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and — physical hazards such as from sharps.If in accordance with the point (d) of Section 23.1 no instructions for use are required, this information shall be made available to the user upon request; | No | n/a | The device is software so the principle of this requirement is not applicable. |
| 23.4w | for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional; | No | n/a | The device is not intended for use by lay persons so the principle of this requirement is not applicable. |
| 23.4x | for the devices covered by this Regulation pursuant to Article 1(2), information regarding the absence of a clinical benefit and the risks related to use of the device; | Yes | The instructions will link to the **Hazard Log**  and the **Risk Management Plan** | n/a |
| 23.4y | date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use; | Yes | The instructions will be clearly labelled with the date and version. | n/a |
| 23.4z | a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established; | Yes | The instructions will link to the **Hazard Log**  and the **Risk Management Plan** | n/a |
| 23.4aa | information to be supplied to the patient with an implanted device in accordance with Article 18; | No | n/a | The device is software, which is not implantable, so the principle of this requirement is not applicable. |
| 23.4ab | for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended. | Yes | The eFI2 algorithms will be implemented within the primary care electronic health records, which have existing IT security specifications. | n/a |