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| 1 | 2020-06-05 | |

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| 1 | Regulation (EU) 2017/746 | N/A | N/A |

## Abbreviations and Terms

| Abbreviation/Term | Definition |
|---|---|
| CS | Common Specifications (formerly Common Technical Specifications CTS) |
| DHF | Design History File |
| GSPR | General Safety and Performance Requirements (per IVDR Annex I) |
| IFU | Instructions for Use |
| IVDR | In Vitro Diagnostic Medical Device Regulation 2017/746 |
| N/A | Not Applicable |
| REF | Catalogue Number |
| SMN | Siemens Material Number |
| TFS | Team Foundation Server |

## TABLE OF CONTENTS

# 1 Purpose and Scope

This Checklist (a) presents the evidence that the products listed below comply with each applicable General Safety and Performance Requirement (GSPR) established in Annex I of the IVDR, and (b) documents the standards, common specifications, guidelines, and regulations relevant to that evidence. This fulfills the requirements of IVDR Article 5 (2) and Annex II (4).

| Product Name/Configuration | Product REF | SMN | Legacy P/N |
|---|---|---|---|
| IMMULITE ANTI-TPO KIT 100T | LKTO1 | 10381618 | N/A |
| IMMULITE FREE T3 KIT 100T | LKF31 | 10381626 | N/A |
| IML FREE T4 KIT 100T | LKFT41 | 10381622 | N/A |
| IML.PTH (M/P) KIT 100T | LKPP1 | 10381399 | N/A |

## 2 General Safety and Performance Requirements (IVDR Annex I)

Note: If the answer to Applicable (Yes/No) is “No”, then it is not necessary to input text into the Documentary Evidence or Storage Location of Evidence columns. These may be left blank.

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| CHAPTER I GENERAL REQUIREMENTS | | | | | | |
| 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 | EN 13532:2002 EN ISO 14971:2019 EN 62366-1:2015 EN 13641:2002 | | | |
| 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. | Yes | EN ISO 14971:2019 | | | |
| 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: | Yes | EN ISO 14971:2019 | | | |
| 3(a) | establish and document a risk management plan for each device; | Yes | EN ISO 14971:2019 | | | |
| 3(b) | identify and analyse the known and foreseeable hazards associated with each device; | Yes | EN ISO 14971:2019 | | | |

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|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 3(c) | estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse; | Yes | EN ISO 14971:2019 | | | |
| 3(d) | eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4; | Yes | EN ISO 14971:2019 | | | |
| 3(e) | 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, the benefit-risk ratio and risk acceptability; and | Yes | EN ISO 14971:2019 | | | |
| 3(f) | 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 | EN ISO 14971:2019 | | | |
| 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, the 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: | Yes | EN 13532:2002 EN ISO 14971:2019 EN 62366-1:2015 EN 13641:2002 | | | |
| 4(a) | eliminate or reduce risks as far as possible through safe design and manufacture; | Yes | EN 13532:2002 EN 13641:2002 EN ISO 14971:2019 EN 62366-1:2015 | | | |
| 4(b) | where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and | Yes | EN 13532:2002 EN 13641:2002 EN ISO 14971:2019 EN 62366-1:2015 | | | |
| 4(c) | provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users. Manufacturers shall inform users of any residual risks. | Yes | EN ISO 14971:2019 EN ISO 15223-1:2016 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 18113-4:2011 | | | |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 5 | In eliminating or reducing risks related to use error, the manufacturer shall: | No | | | | |
| 5(a) | 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 | EN ISO 14971:2019 EN 62366-1:2015 | | | |
| 5(b) | 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 | EN ISO 14971:2019 EN 62366-1:2015 | | | |
| 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 | EN 13532:2002 EN 13612:2002 EN ISO 14971:2019 EN ISO 23640:2015 EN 62366-1:2015 | | | |
| 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. | Yes | EN 13532:2002 EN 13612:2002 EN ISO 14971:2019 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 18113-4:2011 EN ISO 23640:2015 EN 62366-1:2015 | | | |
| 8 | All known and foreseeable risks, and any undesirable effects shall be minimised and be acceptable when weighed against the evaluated potential benefits to the patients and/or the user arising from the intended performance of the device during normal conditions of use. | Yes | EN ISO 14971:2019 EN 62366-1:2015 | | | |
| CHAPTER II REQUIREMENTS REGARDING PERFORMANCE, DESIGN AND MANUFACTURE | | | | | | |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 9 | Performance characteristics | No | | | | |
| 9.1 | Devices shall be designed and manufactured in such a way that they are suitable for the purposes referred to in point (2) of Article 2, as specified by the manufacturer, and suitable with regard to the performance they are intended to achieve, taking account of the generally acknowledged state of the art. They shall achieve the performances, as stated by the manufacturer and in particular, where applicable: | Yes | EN 13612:2002 EN 14136:2004 EN ISO 14971:2019 EN ISO 17511:2003 EN ISO 18153:2003 EN 62366-1:2015 | | | |
| 9.1(a) | the analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross- reactions; and | Yes | EN 13612:2002 EN 14136:2004 EN ISO 17511:2003 EN ISO 18153:2003 EN 62366-1:2015 CTS 2002/364/EC CTS 2009/886/EC CTS 2011/869/EU CTS 2019/1244/EC | | | |
| 9.1(b) | the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations. | Yes | EN 13612:2002 EN 14136:2004 EN 62366-1:2015 CTS 2002/364/EC CTS 2009/886/EC CTS 2011/869/EU CTS 2019/1244/EC | | | |
| 9.2 | The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the manufacturer. | Yes | EN ISO 23640:2015 | | | |
| 9.3 | Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures and/or suitable reference materials of a higher metrological order. Where available, metrological traceability of values assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement procedures. | Yes | EN ISO 17511:2003 EN ISO 18153:2003 | | | |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 9.4 | The characteristics and performances of the device shall be specifically checked in the event that they may be affected when the device is used for the intended use under normal conditions: | No | | | | |
| 9.4(a) | for devices for self-testing, performances obtained by laypersons; | Yes | EN 13532:2002 EN 13612:2002 EN 62366-1:2015 | | | |
| 9.4(b) | for devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances). | Yes | EN 13532:2002 EN 62366-1:2015 | | | |
| 10 | Chemical, physical and biological properties | No | | | | |
| 10.1 | Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to the possibility of impairment of analytical performance due to physical and/or chemical incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device. | Yes | EN ISO 14971:2019 EN ISO 23640:2015 EN 62366-1:2015 | | | |
| 10.2 | Devices shall be designed, manufactured and packaged in such a way as to minimise 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. | Yes | EN 13532:2002 EN ISO 14971:2019 EN 62366-1:2015 ISTA 1- ,2- ,3- series | | | |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 10.3 | Devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1), and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (2). | Yes | EN ISO 14971:2019 2006/1907/EC (REACH) 2008/1272/EC (CLP) | | | |
| 10.4 | 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. | Yes | EN ISO 14971:2019 EN 62366-1:2015 | | | |
| 11 | Infection and microbial contamination | No | | | | |
| 11.1 | Devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or, where applicable, other persons. The design shall: | Yes | EN 13641:2002 EN 13612:2002 EN ISO 14971:2019 EN 62366-1:2015 | | | |
| 11.1(a) | allow easy and safe handling; | Yes | EN 13641:2002 EN 13612:2002 EN ISO 14971:2019 EN 62366-1:2015 | | | |
| 11.1(b) | reduce as far as possible any microbial leakage from the device and/or microbial exposure during use; and, where necessary | Yes | EN ISO 14971:2019 2008/1272/EC (CLP) EN 62366-1:2015 IATA Dangerous Goods Regulations ED 43 | | | |
| 11.1(c) | prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen. | Yes | EN ISO 14971:2019 EN 62366-1:2015 EN 13612:2002 EN 13641:2002 | | | |

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|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 11.2 | Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition or microbial state is damaged. | Yes | EN ISO 14971:2019 EN ISO 15223-1:2016 EN 13641:2002 | | | |
| 11.3 | Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods. | Yes | | | | |
| 11.4 | Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities. | Yes | | | | |
| 11.5 | Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer. | Yes | EN ISO 14971:2019 ISTA 1- ,2- ,3- series | | | |
| 11.6 | The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile. | No | | N/A | N/A | N/A |
| 12 | Devices incorporating materials of biological origin | No | | | | |
| | Where devices include tissues, cells and substances of animal, human or microbial origin, the selection of sources, the processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be carried out so as to provide safety for user or other person. | Yes | EN 13612:2002 EN 13641:2002 EN ISO 14971:2019 | | | |

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| | In particular, safety with regard to microbial and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This might not apply to certain devices if the activity of the microbial and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device. | Yes | EN 13641:2002 EN ISO 14971:2019 | | | |
| 13 | Construction of devices and interaction with their environment | No | | | | |
| 13.1 | If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. | Yes | EN 13532:2002 EN 13612:2002 EN ISO 15223-1:2016 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 18113-4:2011 EN ISO 14971:2019 EN 62366-1:2015 | | | |
| 13.2 | Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible: | No | | | | |
| 13.2.a | the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; | Yes | EN 13532:2002 EN ISO 14971:2019 EN 62366-1:2015 | | | |
| 13.2.b | 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; | Yes | EN 13532:2002 EN ISO 14971:2019 | | | |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 13.2.c | 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; | Yes | EN ISO 14971:2019 | | | |
| 13.2.d | the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts; | Yes | | | | |
| 13.2.e | the risks of accidental ingress of substances into the device; | Yes | EN ISO 14971:2019 EN 62366-1:2015 | | | |
| 13.2.f | the risk of incorrect identification of specimens and the risk of erroneous results due to, for example, confusing colour and/or numeric and/or character codings on specimen receptacles, removable parts and/or accessories used with devices in order to perform the test or assay as intended; | Yes | EN ISO 14971:2019 EN 62366-1:2015 | | | |
| 13.2.g | the risks of any foreseeable interference with other devices. | Yes | EN ISO 14971:2019 | | | |
| 13.3 | Devices shall be designed and manufactured in such a way as to minimise 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. | Yes | EN 13532:2002 EN ISO 14971:2019 | | | |
| 13.4 | Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively. | Yes | EN 13612:2002 EN ISO 14971:2019 EN 62366-1:2015 | | | |
| 13.5 | Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe. | Yes | EN 13532:2002 EN 13612:2002 EN 62366-1:2015 | | | |

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|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 13.6 | Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by users, or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use. | Yes | 2008/1272/EC (CLP) | | | |
| 13.7 | The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the en-vironmental conditions in which the devices are intended to be used. | Yes | EN 13532:2002 EN 62366-1:2015 | | | |
| 14 | Devices with a measuring function | No | | | | |
| 14.1 | Devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide appropriate analytical performance in accordance with point (a) of Section 9.1 of Annex I, taking into account the intended purpose of the device. | Yes | | | | |
| 14.2 | The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (1). | Yes | | | | |
| 15 | Protection against radiation | No | | | | |
| 15.1 | Devices shall be designed, manufactured and packaged in such a way that exposure of users or other persons to radiation (intended, unintended, stray or scattered) is reduced as far as possible and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes. | No | | N/A | N/A | N/A |
| 15.2 | When devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall as far as possible be: | No | | N/A | N/A | N/A |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 15.2.a | designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and | No | | N/A | N/A | N/A |
| 15.2.b | fitted with visual displays and/or audible warnings of such emissions. | No | | N/A | N/A | N/A |
| 15.3 | 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 user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified. | No | | N/A | N/A | N/A |
| 16 | Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves | No | | | | |
| 16.1 | 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. | No | | N/A | N/A | N/A |
| 16.2 | 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. | No | | N/A | N/A | N/A |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 16.3 | 16.3. 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 | N/A | N/A |
| 16.4 | 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. | No | | N/A | N/A | N/A |
| 17 | Devices connected to or equipped with an energy source | No | | | | |
| 17.1 | For devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks. | No | | N/A | N/A | N/A |
| 17.2 | 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 | N/A | N/A |
| 17.3 | 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 | N/A | N/A |
| 17.4 | Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electro- magnetic interference such that is adequate to enable them to operate as intended. | No | | N/A | N/A | N/A |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
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| 17.5 | 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 user, or 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 | N/A | N/A |
| 18 | Protection against mechanical and thermal risks | No | | | | |
| 18.1 | Devices shall be designed and manufactured in such a way as to protect users and other persons against mechanical risks. | No | | N/A | N/A | N/A |
| 18.2 | Devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses inherent to the foreseen working environment, and to retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer. | No | | N/A | N/A | N/A |
| 18.3 | Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means shall be incorporated. Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer. | No | | N/A | N/A | N/A |
| 18.4 | 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. | No | | N/A | N/A | N/A |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 18.5 | 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. | No | | N/A | N/A | N/A |
| 18.6 | 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 minimise all possible risks. | No | | N/A | N/A | N/A |
| 18.7 | 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. The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk. | No | | N/A | N/A | N/A |
| 18.8 | Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use. | No | | N/A | N/A | N/A |
| 19 | Protection against the risks posed by devices intended for self-testing or near-patient testing | No | | | | |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 19.1 | Devices intended for self-testing or near-patient testing 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 the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in order to correctly interpret the result provided by the device and to avoid misleading information. In the case of near-patient testing, the information and the instructions provided by the manufacturer shall make clear the level of training, qualifications and/or experience required by the user. | No | | N/A | N/A | N/A |
| 19.2 | Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to: | No | | | | |
| 19.2.a | 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; and | No | | N/A | N/A | N/A |
| 19.2.b | reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results. | No | | N/A | N/A | N/A |
| 19.3 | Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended user: | No | | | | |
| 19.3.a | can verify that, at the time of use, the device will perform as intended by the manufacturer; and | No | | N/A | N/A | N/A |
| 19.3.b | be warned if the device has failed to provide a valid result. | No | | N/A | N/A | N/A |
| CHAPTER III REQUIREMENTS REGARDING INFORMATION SUPPLIED WITH THE DEVICE | | | | | | |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 20 | Label and instructions for use | No | | | | |
| 20.1 | General requirements regarding the information supplied by the manufacturer | No | | | | |
| | 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: | No | | N/A | N/A | N/A |
| 20.1(a) | 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. | No | | N/A | N/A | N/A |
| 20.1(b) | 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. If individual full labelling of each unit is not practicable, the information shall be set out on the packaging of multiple devices. | No | | N/A | N/A | N/A |
| 20.1.c | Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification or bar codes. | No | | N/A | N/A | N/A |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 20.1.d | Instructions for use shall be provided together with devices. However, in duly justified and exceptional cases instructions for use shall not be required or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use. | No | | N/A | N/A | N/A |
| 20.1.e | Where multiple devices, with the exception of devices intended for self-testing or near-patient testing, 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 | N/A | N/A |
| 20.1.f | When the device is intended for professional use only, instructions for use may be provided to the user in non-paper format (e.g. electronic), except when the device is intended for near-patient testing. | No | | N/A | N/A | N/A |
| 20.1.g | 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. | No | | N/A | N/A | N/A |
| 20.1.h | Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols, taking into account the intended users. 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 | N/A | N/A |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 20.1.i | In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant hazard pictograms and labelling requirements of Regulation (EC) No 1272/2008 shall apply. Where there is insufficient space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the label and the other information required by Regulation (EC) No 1272/2008 shall be given in the instructions for use. | No | | N/A | N/A | N/A |
| 20.1.j | The provisions of Regulation (EC) No 1907/2006 on the safety data sheet shall apply, unless all relevant information, as appropriate, is already made available in the instructions for use. | No | | N/A | N/A | N/A |
| 20.2 | Information on the label. The label shall bear all of the following particulars: | No | | | | |
| 20.2.a | the name or trade name of the device; | No | | N/A | N/A | N/A |
| 20.2.b | the details strictly necessary for a user to identify the device and, where it is not obvious for the user, the intended purpose of the device; | No | | N/A | N/A | N/A |
| 20.2.c | the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business; | No | | N/A | N/A | N/A |
| 20.2.d | if the manufacturer has its registered place of business outside the Union, the name of its authorised rep-resentative and the address of the registered place of business of the authorised representative; | No | | N/A | N/A | N/A |
| 20.2.e | an indication that the device is an in vitro diagnostic medical device, or if the device is a 'device for performance study', an indication of that fact; | No | | N/A | N/A | N/A |
| 20.2.f | 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 | N/A | N/A |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 20.2.g | the UDI carrier as referred to in Article 24 and Part C of Annex VI; | No | | N/A | N/A | N/A |
| 20.2.h | an unambiguous indication of the time limit for using the device safely, without degradation of performance, expressed at least in terms of year and month and, where relevant, the day, in that order; | No | | N/A | N/A | N/A |
| 20.2.i | 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; | No | | N/A | N/A | N/A |
| 20.2.j | where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of thereof, or other terms which accurately reflect the contents of the package; | No | | N/A | N/A | N/A |
| 20.2.k | an indication of any special storage and/or handling condition that applies; | No | | N/A | N/A | N/A |
| 20.2.l | where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement indicating any special microbial state or state of cleanliness; | No | | N/A | N/A | N/A |
| 20.2.m | warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device or 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; | No | | N/A | N/A | N/A |
| 20.2.n | if the instructions for use are not provided in paper form in accordance with point (f) of Section 20.1, a reference to their accessibility (or availability), and where applicable the website address where they can be consulted; | No | | N/A | N/A | N/A |
| 20.2.o | where applicable, any particular operating instructions; | No | | N/A | N/A | N/A |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 20.2.p | 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 | N/A | N/A |
| 20.2.q | if the device is intended for self-testing or near-patient testing, an indication of that fact; | No | | N/A | N/A | N/A |
| 20.2.r | where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof; | No | | N/A | N/A | N/A |
| 20.2.s | where device kits include individual reagents and articles that are made available as separate devices, each of those devices shall comply with the labelling requirements contained in this Section and with the requirements of this Regulation; | No | | N/A | N/A | N/A |
| 20.2.t | the devices and separate components shall be identified, where applicable in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. As far as practicable and appropriate, the information shall be set out on the device itself and/or, where appropriate, on the sales packaging; | No | | N/A | N/A | N/A |
| 20.2.u | the label for devices for self-testing shall bear the following particulars: | No | | | | |
| 20.2.u(i) | the type of specimen(s) required to perform the test (e.g. blood, urine or saliva); | No | | N/A | N/A | N/A |
| 20.2.u(ii) | the need for additional materials for the test to function properly; | No | | N/A | N/A | N/A |
| 20.2.u(iii) | contact details for further advice and assistance. The name of devices for self-testing shall not reflect an intended purpose other than that specified by the manufacturer. | No | | N/A | N/A | N/A |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 20.3 | Information on the packaging which maintains the sterile condition of a device ('sterile packaging'): The following particulars shall appear on the sterile packaging: | No | | | | |
| 20.3.a | an indication permitting the sterile packaging to be recognised as such, | No | | N/A | N/A | N/A |
| 20.3.b | a declaration that the device is in a sterile condition, | No | | N/A | N/A | N/A |
| 20.3.c | the method of sterilisation, | No | | N/A | N/A | N/A |
| 20.3.d | the name and address of the manufacturer, | No | | N/A | N/A | N/A |
| 20.3.e | a description of the device, | No | | N/A | N/A | N/A |
| 20.3.f | the month and year of manufacture, | No | | N/A | N/A | N/A |
| 20.3.g | an unambiguous indication of the time limit for using the device safely, expressed at least in terms of year and month and, where relevant, the day, in that order, | No | | N/A | N/A | N/A |
| 20.3.h | an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use. | No | | N/A | N/A | N/A |
| 20.4 | Information in the instructions for use | No | | | | |
| 20.4.1 | The instructions for use shall contain all of the following particulars: | No | | | | |
| 20.4.1.a | the name or trade name of the device; | No | | N/A | N/A | N/A |
| 20.4.1.b | the details strictly necessary for the user to uniquely identify the device; | No | | N/A | N/A | N/A |
| 20.4.1.c | the device's intended purpose: | No | | | | |
| 20.4.1.c(i) | what is detected and/or measured; | No | | N/A | N/A | N/A |
| 20.4.1.c(ii) | its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic); | No | | N/A | N/A | N/A |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 20.4.1.c(iii) | the specific information that is intended to be provided in the context of: — a physiological or pathological state; — congenital physical or mental impairments; — the predisposition to a medical condition or a disease; — the determination of the safety and compatibility with potential recipients; — the prediction of treatment response or reactions; — the definition or monitoring of therapeutic measures; | No | | N/A | N/A | N/A |
| 20.4.1.c(iv) | whether it is automated or not; | No | | N/A | N/A | N/A |
| 20.4.1.c(v) | whether it is qualitative, semi-quantitative or quantitative; | No | | N/A | N/A | N/A |
| 20.4.1.c(vi) | the type of specimen(s) required; | No | | N/A | N/A | N/A |
| 20.4.1.c(vii) | where applicable, the testing population; and | No | | N/A | N/A | N/A |
| 20.4.1.c(viii) | for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for which it is a companion test. | No | | N/A | N/A | N/A |
| 20.4.1.d | an indication that the device is an in vitro diagnostic medical device, or, if the device is a ‘device for performance study’, an indication of that fact; | No | | N/A | N/A | N/A |
| 20.4.1.e | the intended user, as appropriate (e.g. self-testing, near patient and laboratory professional use, healthcare professionals); | No | | N/A | N/A | N/A |
| 20.4.1.f | the test principle; | No | | N/A | N/A | N/A |
| 20.4.1.g | a description of the calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only); | No | | N/A | N/A | N/A |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 20.4.1.h | a description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement; | No | | N/A | N/A | N/A |
| 20.4.1.i | a list of materials provided and a list of special materials required but not provided; | No | | N/A | N/A | N/A |
| 20.4.1.j | for devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment: — information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics, and/or — information on any known restrictions to combinations of devices and equipment. | No | | N/A | N/A | N/A |
| 20.4.1.k | an indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply; | No | | N/A | N/A | N/A |
| 20.4.1.l | in-use stability which may include the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant; | No | | N/A | N/A | N/A |
| 20.4.1.m | if the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event of the sterile packaging being damaged before use; | No | | N/A | N/A | N/A |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 20.4.1.n | information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. That information shall cover, where appropriate: | No | | | | |
| 20.4.1.n(i) | warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance, | No | | N/A | N/A | N/A |
| 20.4.1.n(ii) | 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 electro-magnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature, | No | | N/A | N/A | N/A |
| 20.4.1.n(iii) | 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, therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment, | No | | N/A | N/A | N/A |
| 20.4.1.n(iv) | 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, | No | | N/A | N/A | N/A |
| 20.4.1.n(v) | 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 | N/A | N/A |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 20.4.1.n(vi) | if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterili- sation. Information shall be provided to identify when the device should no longer be reused, such as signs of material degradation or the maximum number of allowable reuses; | No | | N/A | N/A | N/A |
| 20.4.1.o | any warnings and/or precautions related to potentially infectious material that is included in the device; | No | | N/A | N/A | N/A |
| 20.4.1.p | where relevant, requirements for special facilities, such as a clean room environment, or special training, such as on radiation safety, or particular qualifications of the intended user; | No | | N/A | N/A | N/A |
| 20.4.1.q | conditions for collection, handling, and preparation of the specimen; | No | | N/A | N/A | N/A |
| 20.4.1.r | details of any preparatory treatment or handling of the device before it is ready for use, such as sterilisation, final assembly, calibration, etc., for the device to be used as intended by the manufacturer; | No | | N/A | N/A | N/A |
| 20.4.1.s | 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: | No | | N/A | N/A | N/A |
| 20.4.1.s(i) | — details of the nature, and frequency, of preventive and regular maintenance, including cleaning and disinfection; | No | | N/A | N/A | N/A |
| 20.4.1.s(ii) | — identification of any consumable components and how to replace them; | No | | N/A | N/A | N/A |
| 20.4.1.s(iii) | — information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime; | No | | N/A | N/A | N/A |
| 20.4.1.s(iv) | — methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices. | No | | N/A | N/A | N/A |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 20.4.1.t | where applicable, recommendations for quality control procedures; | No | | N/A | N/A | N/A |
| 20.4.1.u | the metrological traceability of values assigned to calibrators and control materials, including identification of applied reference materials and/or reference measurement procedures of higher order and information regarding maximum (self-allowed) batch to batch variation provided with relevant figures and units of measure; | No | | N/A | N/A | N/A |
| 20.4.1.v | assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing shall be considered; where applicable, the instructions for use shall be accompanied by information regarding batch to batch variation provided with relevant figures and units of measure; | No | | N/A | N/A | N/A |
| 20.4.1.w | analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and measurement range, (information needed for the control of known relevant interferences, cross-reactions and limitations of the method), measuring range, linearity and information about the use of available reference measurement procedures and materials by the user; | No | | N/A | N/A | N/A |
| 20.4.1.x | clinical performance characteristics as defined in Section 9.1 of this Annex; | No | | N/A | N/A | N/A |
| 20.4.1.y | the mathematical approach upon which the calculation of the analytical result is made; | No | | N/A | N/A | N/A |
| 20.4.1.z | where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic specificity, positive and negative predictive value; | No | | N/A | N/A | N/A |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 20.4.1.aa | where relevant, reference intervals in normal and affected populations; | No | | N/A | N/A | N/A |
| 20.4.1.ab | information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen) that may affect the performance of the device; | No | | N/A | N/A | N/A |
| 20.4.1.ac | 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: | No | | N/A | N/A | N/A |
| 20.4.1.ac (i) | infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human origin; | No | | N/A | N/A | N/A |
| 20.4.1.ac (ii) | environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation); | No | | N/A | N/A | N/A |
| 20.4.1.ac (iii) | physical hazards such as explosion. | No | | N/A | N/A | N/A |
| 20.4.1.ad | the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business at which he can be contacted and its location be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance; | No | | N/A | N/A | N/A |
| 20.4.1.ae | 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, with a clear indication of the introduced modifications; | No | | N/A | N/A | N/A |
| 20.4.1.af | a notice to the user that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established; | No | | N/A | N/A | N/A |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 20.4.1.ag | where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the instructions for use requirements contained in this Section and with the requirements of this Regulation; | No | | N/A | N/A | N/A |
| 20.4.1.ah | 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. | No | | N/A | N/A | N/A |
| 20.4.2 | In addition, the instructions for use for devices intended for self-testing shall comply with all of the following principles: | No | | | | |
| 20.4.2.a | details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation and information on how to run the test and interpret the results; | No | | N/A | N/A | N/A |
| 20.4.2.b | specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device; | No | | N/A | N/A | N/A |
| 20.4.2.c | the device's intended purpose shall provide sufficient information to enable the user to understand the medical context and to allow the intended user to make a correct interpretation of the results; | No | | N/A | N/A | N/A |
| 20.4.2.d | the results shall be expressed and presented in a way that is readily understood by the intended user; | No | | N/A | N/A | N/A |

| Point No. | General Safety and Performance Requirements | Applicable (Yes/No) | Applicable Standards, CS and Regulations (or justification) | Documentary Evidence | | |
|---|---|---|---|---|---|---|
| | | | | Title | Identifier | Storage Location |
| 20.4.2.e | information shall be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false negative result. Information shall also be provided as to any factors that can affect the test result such as age, gender, menstruation, infection, exercise, fasting, diet or medication; | No | | N/A | N/A | N/A |
| 20.4.2.f | the information provided shall include a statement clearly directing that the user should not take any decision of medical relevance without first consulting the appropriate healthcare professional, information on disease effects and prevalence, and, where available, information specific to the Member State(s) where the device is placed on the market on where a user can obtain further advice such as national helplines, websites; | No | | N/A | N/A | N/A |
| 20.4.2.g | for devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition, the information shall specify that the patient should only adapt the treatment if he has received the appropriate training to do so. | No | | N/A | N/A | N/A |

# 3 Applied Standards, Common Specifications, Guidelines, and Regulations

The tables below fulfill the requirement in IVDR Annex I Article 29 that the summary of safety and performance include a reference to any harmonised standards and applied Common Specifications

## 3.1 International Standards and Common Specifications

| International Standards | | | Comments |
|---|---|---|---|
| **Number** | **Version** | **Title** | |
| BS EN 13532:2002 | | General requirements for in vitro diagnostic medical devices for self-testing | |
| BS EN ISO 14971:2019 | | Medical devices. Application of risk management to medical devices | |
| BS EN 62366-1:2015 | | Medical devices. Application of usability engineering to medical devices | |
| BS EN 13641:2002 | | Elimination or reduction of risk of infection related to in vitro diagnostic reagents | |
| BS EN ISO 15223-1:2016 | | Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements | |
| BS EN ISO 18113-1:2011 | | In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements | |
| BS EN ISO 18113-2:2011 | | In vitro diagnostic medical Devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents for professional use | |

| International Standards | | | Comments |
|---|---|---|---|
| Number | Version | Title | |
| BS EN ISO 18113-4:2011 | | In vitro diagnostic medical Devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents for self-testing | |
| BS EN 13612:2002 | | Performance evaluation of in vitro diagnostic medical devices | |
| BS EN ISO 23640:2015 | | In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents | |
| BS EN 14136:2004 | | Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures | |
| BS EN ISO 17511:2003 | | In vitro diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials | |
| BS EN ISO 18153:2003 | | In vitro diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials | |
| CTS 2002/364/EC | | CTS 2002/364/EC (for high-risk products, if applicable) | |
| CTS 2009/886/EC | | CTS 2009/886/EC (for high-risk products, if applicable) | |
| CTS 2011/869/EU | | CTS 2011/869/EU (for high-risk products, if applicable) | |

| International Standards | | | Comments |
|---|---|---|---|
| Number | Version | Title | |
| CTS 2019/1244/EC | | CTS 2019/1244/EC (for high-risk products, if applicable) | |
| ISTA 1- ,2- ,3- series | | ISTA 1- ,2- ,3- series | |
| 2006/1907/EC (REACH) | | 2006/1907/EC (REACH) | |
| 2008/1272/EC (CLP) | | 2008/1272/EC (CLP) | |
| IATA Dangerous Goods Regulations ED 43 | | IATA Dangerous Goods Regulations ED 43 | |

## 3.1 International Guidance and Regulations

| Guidance Standards | | | Comments |
|---|---|---|---|
| Number | Version | Title | |