






EXPLORING THE RELATIONSHIP BETWEEN THE IVDR AND THE IVDD

General Safety and Performance Requirements Versus Essential Requirements

This tool clarifies the corresponding relationships between the general safety and performance requirements, as defined in Annex I of the EU in vitro diagnostic medical device regulation 2017/746 (IVDR) and the Essential Requirements defined in Annex I of the EU Directive 98/79/EC for in vitro diagnostic medical devices (IVDD). Use this tool to ensure your in vitro diagnostic medical devices satisfy all the applicable general safety and performance requirements to demonstrate conformity with the IVDR.

- > IVDR requirements highlighted in **green** are either identical, or very similar, to a corresponding IVDD requirement.
- > IVDR requirements highlighted in **yellow** are more stringent than the corresponding IVDD requirement, so make sure to check the differences in the wording of both requirements as evidence originally created to satisfy the essential requirements may not be sufficient.
- > Requirements highlighted in **orange** are specific to the IVDR, and do not have an equivalent or similar counterpart in the IVDD. You will need to provide new information that satisfies these requirements.

COLOR INTERPRETATION		
Green		Requirements between the IVDD and IVDR are either identical, or very similar
Yellow		IVDR requirements are more stringent than IVDD requirement
Orange		IVDR requirement has no equivalent in the IVDD



IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
CHAP 1	GENERAL REQUIREMENTS	A	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.	A.1	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise, directly or indirectly, the clinical condition or the safety of the patients, the safety or health of users or, where applicable, other persons, or the safety of property. Any risks which may be associated with their use must be acceptable when weighed against the benefits to the patient and be compatible with a high level of protection of health and safety.
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.		New to IVDR
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:		New to IVDR
3(a)	Establish and document a risk management plan for each device;		New to IVDR
3(b)	Identify and analyse the known and foreseeable hazards associated with each device;		New to IVDR
3(c)	Estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;		New to IVDR
3(d)	Eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;		New to IVDR
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		New to IVDR
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.		New to IVDR
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:	A.2	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order...



IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
4(a)	Eliminate or reduce risks as far as possible through safe design and manufacture;	A.2 Bullet 1	...eliminate or reduce risks as far as possible (inherently safe design and construction) ...
4(b)	Where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and	A.2 Bullet 2	...where appropriate take adequate protection measures in relation to risks that cannot be eliminated...
4(c)	Provide information for safety (warnings/precautions/ contra-indications) and, where appropriate, training to users.		New to IVDR
4	Manufacturers shall inform users of any residual risks.	A.2 Bullet 3	...inform users of the residual risks due to any shortcomings of the protection measures adopted...
5	In eliminating or reducing risks related to use error, the manufacturer shall:		New to IVDR
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		New to IVDR
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).		New to IVDR
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.	A.4	The characteristics and performances referred to in sections 1 and 3 must not be adversely affected to such a degree that the health or the 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. When no lifetime is stated, the same applies for the lifetime reasonably to be expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.
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.	A.5	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under storage and transport conditions (temperature, humidity, etc.) taking account of the instructions and information provided by the manufacturer.
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.		New to IVDR

IVDR REF		REQUIREMENT	IVDD REF	REQUIREMENT
CHAP II		REQUIREMENTS REGARDING PERFORMANCE, DESIGN AND MANUFACTURE	A	DESIGN AND MANUFACTURING REQUIREMENTS
9		PERFORMANCE CHARACTERISTICS		
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;	A.3	<p>The devices must be designed and manufactured in such a way that they are suitable for the purposes referred to in Article 1(2)(b), as specified by the manufacturer, taking account of the generally acknowledged state of the art. They must achieve the performances, in particular, where appropriate, in terms of analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference, and limits of detection, stated by the manufacturer.</p> <p>The traceability of values assigned to calibrators and/or control materials must be assured through available reference measurement procedures and/or available reference materials of a higher order.</p>
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	A.3	See ER A.3 above
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.	A.3	See ER A.3 above
9.2		The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the manufacturer.		New to IVDR
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.	A.3	See ER A.3 above
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:		New to IVDR

IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
9.4(a)	For devices for self-testing, performances obtained by laypersons;		New to IVDR
9.4(b)	For devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances).		New to IVDR
10	CHEMICAL, PHYSICAL AND BIOLOGICAL PROPERTIES	B.1	CHEMICAL AND PHYSICAL PROPERTIES
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.	B.1.1	The devices must be designed and manufactured in such a way as to achieve the characteristics and performances referred to in section A on the 'General requirements'. Particular attention must be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens (such as biological tissues, cells, body fluids and micro-organisms) intended to be used with the device, taking account of its intended purpose.
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.	B.1.2	The devices must be designed, manufactured and packed in such a way as to reduce as far as possible the risk posed by product leakage, contaminants and residues to the persons involved in the transport, storage and use of the devices, taking account of the intended purpose of the products.
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).		New to IVDR
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.		New to IVDR

IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
11	INFECTION AND MICROBIAL CONTAMINATION	B.2	INFECTION AND MICROBIAL CONTAMINATION
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:	B.2.1	The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or other persons. The design... The manufacturing processes must be appropriate for these purposes.
11.1(a)	Allow easy and safe handling;	B.2.1	...must allow easy handling...
11.1(b)	Reduce as far as possible any microbial leakage from the device and/or microbial exposure during use;	B.2.1	...and, where necessary, reduce as far as possible contamination of, and leakage from, the device during use...
11.1(c)	And, where necessary Prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen.	B.2.1	...and, in the case of specimen receptacles, the risk of contamination of the specimen...
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.	B.2.3	Devices labelled either as 'STERILE' or as having a special microbiological state must be designed, manufactured and packed in an appropriate pack, according to procedures suitable for ensuring that they remain in the appropriate microbiological state indicated on the label when placed on the market, under the storage and transport conditions specified by the manufacturer, until the protective packaging is damaged or opened.
11.3	Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.	B.2.4	Devices labelled either as 'STERILE' or as having a special microbiological state must have been processed by an appropriate, validated method.
11.4	Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.	B.2.6	Devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions.
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.	B.2.7	Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilisation indicated by the manufacturer.
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.		New to IVDR

IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
12	DEVICES INCORPORATING MATERIALS OF BIOLOGICAL ORIGIN		
12	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.	B.2.2	Where a device incorporates biological substances, the risks of infection must be reduced as far as possible by selecting appropriate donors and appropriate substances and by using appropriate, validated inactivation, conservation, test and control procedures.
13	CONSTRUCTION OF DEVICES AND INTERACTION WITH THEIR ENVIRONMENT	B.3	MANUFACTURING AND ENVIRONMENTAL PROPERTIES
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.	B.3.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label and/or in the instructions for use.
13.2	Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:	B.3.3	Devices must be designed and manufactured in such a way as to remove or reduce as far as possible...
13.2(a)	The risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	B.3.3 Bullet 1	...the risk of injury linked to their physical features (in particular aspects of volume x pressure, dimension and, where appropriate, ergonomic features)...
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;	B.3.3 Bullet 2	...risks linked to reasonably foreseeable external influences, such as magnetic fields, external electrical effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure or acceleration or accidental penetration of substances into the device.
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;	B.3.2	Devices must be designed and manufactured in such a way as to reduce as far as possible the risks linked to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use.
13.2(d)	The risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;		New to IVDR
13.2(e)	The risks of accidental ingress of substances into the device;		New to IVDR
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;		New to IVDR

IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
13.2(g)	The risks of any foreseeable interference with other devices.		New to IVDR
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.	B.3.4	Devices must be designed and manufactured in such a way as to reduce as far as possible the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.
13.4	Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.		New to IVDR
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.		New to IVDR
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.	B.3.5	Devices must be designed and manufactured in such a way as to facilitate the management of safe waste disposal.
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 environmental conditions in which the devices are intended to be used.	B.3.6	The measuring, monitoring or display scale (including colour change and other visual indicators) must be designed and manufactured in line with ergonomic principles, taking account of the intended purpose of the device.
14	DEVICES WITH A MEASURING FUNCTION	B.4	DEVICES WHICH ARE INSTRUMENTS OR APPARATUS WITH A MEASURING FUNCTION
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.	B.4.1	Devices which are instruments or apparatus having a primary analytical measuring function must be designed and manufactured in such a way as to provide adequate stability and accuracy of measurement within appropriate accuracy limits, taking into account the intended purpose of the device and of available and appropriate reference measurement procedures and materials. The accuracy limits have to be specified by the manufacturer.
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 (3).	B.4.2	When values are expressed numerically, they must be given in legal units conforming to the provisions of Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement.

IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
15	PROTECTION AGAINST RADIATION	B.5	PROTECTION AGAINST RADIATION
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.	B.5.1	Devices shall be designed, manufactured and packaged in such a way that exposure of users and other persons to the emitted radiation is minimised.
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:	B.5.2	When devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must as far as possible be...
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	B.5.2 Bullet 1	...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...
15.2(b)	Fitted with visual displays and/or audible warnings of such emissions.	B.5.2 Bullet 2	...fitted with visual displays and/or audible warnings of such emissions.
15.2	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.	B.5.3	The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the user, and on ways of avoiding misuse and of eliminating the risks inherent in installation.
16	ELECTRONIC PROGRAMMABLE SYSTEMS — DEVICES THAT INCORPORATE ELECTRONIC PROGRAMMABLE SYSTEMS AND SOFTWARE THAT ARE DEVICES IN THEMSELVES		
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.	B.6.1	Devices incorporating electronic programmable systems, including software, must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use.
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.		New to IVDR
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).		New to IVDR

IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
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.		New to IVDR
17	DEVICES CONNECTED TO OR EQUIPPED WITH AN ENERGY SOURCE	B.6	REQUIREMENTS FOR MEDICAL DEVICES CONNECTED TO OR EQUIPPED WITH AN ENERGY SOURCE
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.		New to IVDR
17.2	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.		New to IVDR
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.	B.6.2	Devices must be designed and manufactured in such a way as to minimise the risks of creating electromagnetic perturbation which could impair the operation of other devices or equipment in the usual environment.
17.4	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.		New to IVDR
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.	B.6.3	Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained correctly.
18	PROTECTION AGAINST MECHANICAL AND THERMAL RISKS	B6.4	PROTECTION AGAINST MECHANICAL AND THERMAL RISKS
18.1	Devices shall be designed and manufactured in such a way as to protect users and other persons against mechanical risks.	B.6.4.1 P1	Devices must be designed and manufactured in such a way as to protect the user against mechanical risks...
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. 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.	B.6.4.1 P1 & 3	<p>Devices must be sufficiently stable under the foreseen operating conditions. They must be suitable to withstand stresses inherent in the foreseen working environment, and to retain this resistance during the expected life of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.</p> <p>Any guards or other means included with the device to provide protection, in particular against moving parts, must be secure and must not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.</p>

IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
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.	B.6.4.1 P 2	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 must be incorporated.
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.	B6.4.2	Devices must 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.
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.	B.6.4.3	Devices must be designed and manufactured in such a way as to reduce as far as possible 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.
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.	B.6.4.4	Terminals and connectors to electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and manufactured in such a way as to minimise all possible risks.
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.		New to IVDR
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.	B.6.4.5	Accessible parts of the devices (excluding the parts of areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.
19	PROTECTION AGAINST THE RISKS POSED BY DEVICES INTENDED FOR SELF-TESTING OR NEAR-PATIENT TESTING	B.7	REQUIREMENTS FOR DEVICES FOR SELF-TESTING
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.	B.7	Devices for self-testing must 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 users and the influence resulting from variation that can reasonably be anticipated in users' technique and environment. The information and instructions provided by the manufacturer should be easily understood and applied by the user.

IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
19.2	Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to:	B.7.1	Devices for self-testing must be designed and manufactured in such a way as to...
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	B.7.1 Bullet 1	...ensure that the device is easy to use by the intended lay user at all stages of the procedure, and...
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.	B.7.1 Bullet 2	...reduce as far as practicable the risk of user error in the handling of the device and in the interpretation of the results.
19.3	Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended user:	B.7.2	Devices for self-testing must, where reasonably possible, include user control, i.e. a procedure...
19.3(a)	Can verify that, at the time of use, the device will perform as intended by the manufacturer; and	B.7.2	...by which the user can verify that, at the time of use, the product will perform as intended.
19.3(b)	Be warned if the device has failed to provide a valid result.		New to IVDR
CHAP III	REQUIREMENTS REGARDING INFORMATION SUPPLIED WITH THE DEVICE	B.8	INFORMATION SUPPLIED BY THE MANUFACTURER
20	LABEL AND INSTRUCTIONS FOR USE		
20.1	General requirements regarding the information supplied by the manufacturer		
20.1	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:	B.8.1 P1 & 2	Each device must be accompanied by the information needed to use it safely and properly... and to identify the manufacturer. This information comprises the data on the label and in the instructions for use.
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.	B.8.1 P1	...taking account of the training and knowledge of the potential users...
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.	B.8.1 P3	As far as practicable and appropriate, the information needed to use the device safely and properly must be set out on the device itself and/or, where appropriate, on the sales packaging. If individual full labelling of each unit is not practicable, the information must be set out on the packaging and/or in the instructions for use supplied with one or more devices. Instructions for use must accompany or be included in the packaging of one or more devices.

IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
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.		New to IVDR
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.	B.8.1 P4&5	Instructions for use must accompany or be included in the packaging of one or more devices. In duly justified and exceptional cases no such instructions for use are needed for a device if it can be used properly and safely without them.
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.		New to IVDR
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.		New to IVDR
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.		New to IVDR
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.	B.8.2	Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colour used must be described in the documentation supplied with the device.
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.	B.8.3	In the case of devices containing or a preparation 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 danger symbols and labelling requirements of Directive 67/548/EEC (2) and Directive 88/379/EEC (3) shall apply. Where there is insufficient space to put all the information on the device itself or on its label, the relevant danger symbols shall be put on the label and the other information required by those Directives shall be given in the instructions for use.
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.		New to IVDR

IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
20.2	Information on the label		
20.2	The label shall bear all of the following particulars:	B.8.4	The label must bear the following particulars which may take the form of symbols as appropriate...
20.2(a)	The name or trade name of the device;	B.8.4(a)	The name or trade name...
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;	B.8.4(b) & B.8.5	The details strictly necessary for the user to uniquely identify the device and the contents of the packaging; If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state the intended purpose in the instructions for use and, if appropriate, on the label.
20.2(c)	The name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;	B.8.4(a)	The name or trade name and address of the manufacturer...
20.2(d)	If the manufacturer has its registered place of business outside the Union, the name of its authorised representative and the address of the registered place of business of the authorised representative;	B.8.4(a)	...For devices imported into the Community with a view to their distribution in the Community, the label, the outer packaging, or the instructions for use shall contain in addition the name and address of the authorised representative of the manufacturer;
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;	B.8.4(f) & (g)	In case of devices for performance evaluation, the words 'for performance evaluation only'; Where appropriate, a statement indicating the in vitro use of the device;
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;	B.8.4(d)	The batch code, preceded by the word 'LOT', or the serial number;
20.2(g)	The UDI carrier as referred to in Article 24 and Part C of Annex VI;		New to IVDR
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;	B.8.4(e)	If necessary, an indication of the date by which the device or part of it should be used, in safety, without degradation of performance, expressed as the year, the month and, where relevant, the day, in that order;
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;		New to IVDR
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;		New to IVDR
20.2(k)	An indication of any special storage and/or handling condition that applies;	B.8.4(h)	Any particular storage and/or handling conditions;

IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
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;	B.8.4(c)	Where appropriate, the word 'STERILE' or a statement indicating any special microbiological state or state of cleanliness;
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;	B.8.4(j)	Appropriate warnings and/or precautions to take;
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;		New to IVDR
20.2(o)	Where applicable, any particular operating instructions;	B.8.4(i)	Where applicable, any particular operating instructions;
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;		New to IVDR
20.2(q)	If the device is intended for self-testing or near-patient testing, an indication of that fact;	B.8.4(k)	If the device is intended for self-testing, that fact must be clearly stated.
20.2(r)	Where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof;		New to IVDR
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;		New to IVDR
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;	B.8.6	Wherever reasonable and practicable, the devices and separate components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.
20.2(u)	The label for devices for self-testing shall bear the following particulars:		New to IVDR
20.2(u)(i)	The type of specimen(s) required to perform the test (e.g. blood, urine or saliva);		New to IVDR
20.2(u)(ii)	The need for additional materials for the test to function properly;		New to IVDR
20.2(u)(iii)	Contact details for further advice and assistance.		New to IVDR
20.2(u)	The name of devices for self-testing shall not reflect an intended purpose other than that specified by the manufacturer.		New to IVDR
20.3	Information on the packaging which maintains the sterile condition of a device('sterile packaging')		
20.3	The following particulars shall appear on the sterile packaging:		New to IVDR
20.3(a)	An indication permitting the sterile packaging to be recognised as such,		New to IVDR

IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
20.3(b)	A declaration that the device is in a sterile condition,		New to IVDR
20.3(c)	The method of sterilisation,		New to IVDR
20.3(d)	The name and address of the manufacturer,		New to IVDR
20.3(e)	A description of the device,		New to IVDR
20.3(f)	The month and year of manufacture,		New to IVDR
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,		New to IVDR
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.		New to IVDR
20.4	Information in the instructions for use		
20.4.1	The instructions for use shall contain all of the following particulars:	B.8.7 & B.8.7(a)	Where appropriate, the instructions for use must contain the following particulars...the details referred to in section 8.4 with the exception of points (d) and (e);
20.4.1(a)	The name or trade name of the device;	B.8.4(a)	See above
20.4.1(b)	The details strictly necessary for the user to uniquely identify the device;	B.8.4(b)	See above
20.4.1(c)	The device's intended purpose:	B.8.5	See above
20.4.1(c)(i)	What is detected and/or measured;		New to IVDR
20.4.1(c)(ii)	Its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);		New to IVDR
20.4.1(c)(iii)	The specific information that is intended to be provided in the context of: <ul style="list-style-type: none"> —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; 		New to IVDR
20.4.1(c)(iv)	Whether it is automated or not;		New to IVDR
20.4.1(c)(v)	Whether it is qualitative, semi-quantitative or quantitative;		New to IVDR
20.4.1(c)(vi)	The type of specimen(s) required;	B.8.7(f)	The type of specimen to be used...
20.4.1(c)(vii)	Where applicable, the testing population; and		New to IVDR

IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
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.		New to IVDR
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;	B.8.4(f) & (g)	See above
20.4.1(e)	The intended user, as appropriate (e.g. self-testing, near patient and laboratory professional use, healthcare professionals);		New to IVDR
20.4.1(f)	The test principle;	B.8.7(h) Bullet 1	The measurement procedure to be followed with the device including as appropriate... the principle of the method...
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);		New to IVDR
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;	B.8.7(b)	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;
20.4.1(i)	A list of materials provided and a list of special materials required but not provided;	B.8.7(e)	An indication of any special equipment required including information necessary for the identification of that special equipment for proper use;
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.	B.8.7(m)	If the device must be used in combination with or installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe and proper combination;
20.4.1(k)	An indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply;	B.8.4(h)	See above
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;	B.8.7(c)	The storage conditions and shelf life following the first opening of the primary container, together with the storage conditions and stability of working reagents;
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;	B.8.4(c)	See above
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:	B.8.4(j)	See above

IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
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,		New to IVDR
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 electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,	B.8.7(r)	Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;
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,		New to IVDR
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,		New to IVDR
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,		New to IVDR
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-sterilisation. 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;	B.8.7(q)	If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and re-sterilisation or decontamination, and any restriction on the number of reuses;
20.4.1(o)	Any warnings and/or precautions related to potentially infectious material that is included in the device;		New to IVDR
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;		New to IVDR
20.4.1(q)	Conditions for collection, handling, and preparation of the specimen;	B.8.7(f)	...any special conditions of collection, pre-treatment and, if necessary, storage conditions and instructions for the preparation of the patient;
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;	B.8.7(o)	Details of any further treatment or handling needed before the device can be used (for example, sterilisation, final assembly, etc.);

IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
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:/ —details of the nature, and frequency, of preventive and regular maintenance, including cleaning and 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; —methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.	B.8.7(n)	All the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely; information about safe waste disposal;
20.4.1(t)	Where applicable, recommendations for quality control procedures;	B.8.7(k) Bullet 1	Information appropriate to users on... internal quality control including specific validation procedures,
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;	B.8.7(k) Bullet 2	Information appropriate to users on... the traceability of the calibration of the device;
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;	B.8.7(g)	A detailed description of the procedure to be followed in using the device;
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;	B.8.7(h) Bullet 2	...the specific analytical performance characteristics (e.g. sensitivity, specificity, accuracy, repeatability, reproducibility, limits of detection and measurement range, including information needed for the control of known relevant interferences), limitations of the method and information about the use of available reference measurement procedures and materials by the user...
20.4.1(x)	Clinical performance characteristics as defined in Section 9.1 of this Annex;	B.8.7(d)	The performances referred to in section 3 of part A; (see IVDR Section 9)
20.4.1(y)	The mathematical approach upon which the calculation of the analytical result is made;	B.8.7(i)	The mathematical approach upon which the calculation of the analytical result is made;
20.4.1(z)	Where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic specificity, positive and negative predictive value;	B.8.7(d)	See above
20.4.1(aa)	Where relevant, reference intervals in normal and affected populations;	B.8.7(l)	The reference intervals for the quantities being determined, including a description of the appropriate reference population;

IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
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;		New to IVDR
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:	B.8.7(s)	Precautions to be taken against any special, unusual risks related to the use or disposal of the device including special protective measures; where the device includes substances of human or animal origin, attention must be drawn to their potential infectious nature;
20.4.1(ac)(i)	Infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human origin;		New to IVDR
20.4.1(ac)(ii)	Environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation);		New to IVDR
20.4.1(ac)(iii)	Physical hazards such as explosion.		New to IVDR
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;	B.8.4(a)	See above
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;	B.8.7(u)	Date of issue or latest revision of the instructions for use.
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;		New to IVDR
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;		New to IVDR
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.		New to IVDR
20.4.2	In addition, the instructions for use for devices intended for self-testing shall comply with all of the following principles:	B.8.7(t)	Specifications for devices for self-testing
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;		New to IVDR

IVDR REF	REQUIREMENT	IVDD REF	REQUIREMENT
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;	B.8.7(t) Bullet 2	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,
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;		New to IVDR
20.4.2(d)	The results shall be expressed and presented in a way that is readily understood by the intended user;	B.8.7(t) Bullet 1	The results need to be expressed and presented in a way that is readily understood by a lay person;
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;	B.8.7(t) Bullet 1	...information needs to be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result) and on the possibility of false positive or false negative result
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;	B.8.7(t) Bullet 3	The information provided must include a statement clearly directing that the user should not take any decision of medical relevance without first consulting his or her medical practitioner,
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.	B.8.7(t) Bullet 4	The information must also specify that when the device for self-testing is used for the monitoring of an existing disease, the patient should only adapt the treatment if he has received the appropriate training to do so;



ROBYN MEURANT

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Robyn Meurant has more than 30 years of experience in the field of IVDs, as a laboratory scientist and as a regulator with the Australian Therapeutic Goods Administration (TGA) and with World Health Organization (WHO) Prequalification. Ms. Meurant began her career working in several large diagnostic laboratories in the role of senior scientist. In her position at TGA, Ms. Meurant assisted in developing the new regulatory framework for IVDs. With WHO, she served as the lead technical officer for application evaluation and dossier assessment, and as lead for the development of guidance and technical specifications for IVDs in the scope of WHO Prequalification. In addition, she has contributed to standards development and has been a source of expert advice to the Australian government on IVDs. In 2009 she was awarded the Distinguished Service Award by the Australian Society for Microbiology.

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