Corporate Answers to Essential Requirements IVD CheckList - Directive 98/79/EC - Annex I - en

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Section	Essential Requirements (Annex 1 Directive 98/79 EC)	Essential Requirements applicability	Technical Standards (corresponding clauses/sub-clauses)	Procedure	Output data	Location	Comments
A - General requirements							
A-1	The device 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.	All		000840 PDP Product Development Process Directive - Design Control for Product and Service	Product Requirements Document (PRD) Traceability matrix	Design History File (DHF)	
			EN ISO 14971:2012 (all clauses)	001622 Safety risk management of bioMerieux products	Risk Management File	Design History File (DHF) Site Quality Assurance department	
			EN 62366:2008 IEC 62366-1:2015	001622 Safety risk management of bioMerieux products 009943 Commercial Software Development Process Procedure 047074 – Usability engineering process 003170 - Requirements for Information Supplied with bioMerieux Products	“Usability engineering file” and/or “Risk Management File” Labels and/or package insert	Design History File (DHF) Site Quality Assurance department	
			EN ISO 13485:2016	000253 Global Quality Management System Manual	ISO EN 13485 Certificate	Quality Management System (corporate)	
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: - eliminate or reduce risks as far as possible (inherently safe design and construction), - where appropriate take adequate protection measures in relation to risks that cannot be eliminated, - inform users of the residual risks due to any shortcomings of the protection methods adopted.	All		000840 PDP Product Development Process Directive - Design Control for Product and Service	Product Requirements Document (PRD) Traceability matrix	Design History File (DHF)	
			EN ISO 14971:2012 (all clauses)	001622 Safety risk management of bioMerieux products	Risk Management File	Design History File (DHF) Site Quality Assurance department	
			EN 62366:2008 IEC 62366-1:2015	001622 Safety risk management of bioMerieux products 009943 Commercial Software Development Process Procedure 003170 - Requirements for Information Supplied with bioMerieux Products 047074 – Usability engineering process	“Usability engineering file” and/or “Risk Management File” Labels and/or package insert	Design History File (DHF) Site Quality Assurance department Product Labeling & Documentation department	
			EN ISO 13485:2016	000253 Global Quality Management System Manual	ISO EN 13485 Certificate	Quality Management System (corporate)	
A-3	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 in terms of analytical sensitivity, specificity, accuracy, repeatability, reproducibility, including mastery of known interference, and limits of detection, stated by the manufacturer. 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.	All	EN 12322:1999/A1:2001	000840 PDP Product Development Process Directive - Design Control for Product and Service	Product Requirements Document (PRD) Traceability matrix	Design History File (DHF)	
			EN 13612:2002/AC:2002 (4.2, 4.4, 4.5)	000262 Corporate Procedure to Conduct Clinical Trials	Validation report	Design History File (DHF)	
				000848 - Product Provision Directive	Control Procedures	Device Master Record (DMR)	
			EN ISO 17511:2003 (4, 5, 6, 7, 8)	010834 - Raccordement Metrologique d un Test Immunoessais	Verification report	Design History File (DHF)	010834 is applicable for Immunoassay only (Marcy site). For others product range output data demonstrate conformity when applicable.
				000840 PDP Product Development Process Directive - Design Control for Product and Service	Verification report	Design History File (DHF)	
			EN ISO 20776-1:2006	000840 PDP Product Development Process Directive - Design Control for Product and Service	Verification report	Design History File (DHF)	
			CTS: Commission decision 2009/886/EC + corrigenda + Commission Decision 2011/869/EU + Commission Decision 2019/1244/EU [1]		Verification report / CTS report	Design History File (DHF)	
			EN ISO 13485:2016	000253 Global Quality Management System Manual	ISO EN 13485 Certificate	Quality Management System (corporate)	
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.	All	EN 13612:2002/AC:2002 (4.5) [1]	000262 Corporate Procedure to Conduct Clinical Trials	Validation report	Design History File (DHF)	
			EN ISO 23640:2015 [2]	001791 Stability testing	Stability report(s)	Design History File (DHF) Site Quality Assurance department	
			EN ISO 14971:2012 (all clauses)	001622 Safety risk management of bioMerieux products	Risk Management File	Design History File (DHF) Site Quality Assurance department	
			EN 62366:2008 IEC 62366-1:2015	001622 Safety risk management of bioMerieux products 009943 Commercial Software Development Process Procedure 047074 – Usability engineering process 003170 - Requirements for Information Supplied with bioMerieux Products	“Usability engineering file” and/or “Risk Management File” Labels and/or package insert	Design History File (DHF) Site Quality Assurance department	
			EN ISO 13485:2016	000253 Global Quality Management System Manual	ISO EN 13485 Certificate	Quality Management System (corporate)	
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.	All	EN ISO 14971:2012 (all clauses)	001622 Safety risk management of bioMerieux products	Risk Management File	Design History File (DHF) Site Quality Assurance department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
			EN 62366:2008 IEC 62366-1:2015	001622 Safety risk management of bioMerieux products 009943 Commercial Software Development Process Procedure 003170 - Requirements for Information Supplied with bioMerieux Products 047074 – Usability engineering process	“Usability engineering file” and/or “Risk Management File” Labels and/or package insert	Design History File (DHF) Site Quality Assurance department Product Labeling & Documentation department	
			EN ISO 13485:2016	000253 Global Quality Management System Manual	ISO EN 13485 Certificate	Quality Management System (corporate)	

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B. Design and manufacture requirements							
B-1	**1.Chemical and physical properties**						
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 specimen (such as biological tissues, cells, body fluids and micro-organisms) intended to be used with the device, taking account of its intended purpose.	All	EN ISO 14971:2012 (all clauses)	001622 Safety risk management of bioMerieux products	Risk Management File	Design History File (DHF) Site Quality Assurance department	
			EN ISO 20776-1:2006	000840 PDP Product Development Process Directive - Design Control for Product and Service	Verification report	Design History File (DHF)	
			EN 62366:2008 IEC 62366-1:2015	001622 Safety risk management of bioMerieux products 009943 Commercial Software Development Process Procedure 047074 – Usability engineering process 003170 - Requirements for Information Supplied with bioMerieux Products	"Usability engineering file" and/or "Risk Management File" Labels and/or package insert	Design History File (DHF) Site Quality Assurance department	
			CTS: Commission decision 2009/886/EC + corrigenda + Commission Decision 2011/869/EU (1)		Verification report / CTS report	Design History File (DHF)	
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.	All	EN 62366:2008 IEC 62366-1:2015	001622 Safety risk management of bioMerieux products 009943 Commercial Software Development Process Procedure 003170 - Requirements for Information Supplied with bioMerieux Products 047074 – Usability engineering process	"Usability engineering file" and/or "Risk Management File" Labels and/or package insert	Design History File (DHF) Site Quality Assurance department Product Labeling & Documentation department	
B-2	**2. Infection and microbial contamination**						
B-2.1	The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce to a minimum the risk of infection to the user or other persons. The design must allow easy handling and, where necessary, reduce as far as possible contamination of, and leakage from the device during use, and, in the case of specimen receptacles, the risk of contamination of the specimen. The manufacturing processes must be appropriate for these purposes.	All except software		000840 PDP Product Development Process Directive - Design Control for Product and Service	Product Requirements Document (PRD) Traceability matrix	Design History File (DHF)	
			EN 62366:2008 IEC 62366-1:2015	001622 Safety risk management of bioMerieux products 009943 Commercial Software Development Process Procedure 047074 – Usability engineering process 003170 - Requirements for Information Supplied with bioMerieux Products	"Usability engineering file" and/or "Risk Management File" Labels and/or package insert	Design History File (DHF) Site Quality Assurance department	
			EN ISO 13485:2016	000253 Global Quality Management System Manual	ISO EN 13485 Certificate	Quality Management System (corporate)	
B-2.2	Where a device incorporates biological substances, the risks of infection must be reduced to a minimum by selecting appropriate donors and appropriate substances and by using appropriate, validated inactivation, conservation, test and control procedures.	Not applicable for instruments and software	EN 12322:1999/A1:2001	000840 PDP Product Development Process Directive - Design Control for Product and Service	Product Requirements Document (PRD) Traceability matrix	Design History File (DHF)	
				000840 PDP Product Development Process Directive - Design Control for Product and Service	Product Requirements Document (PRD) Traceability matrix	Design History File (DHF)	
			EN ISO 20776-1:2006	000840 PDP Product Development Process Directive - Design Control for Product and Service	Verification report	Design History File (DHF)	
B-2.3	Devices labeled 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.	"Not applicable - bioMerieux does not manufacture device STERILE or having a special microbiological state".	N/A	N/A	N/A	N/A	
B-2.4	Devices labeled either as « STERILE » or as having a special microbiological state must have been processed by an appropriate, validated method.	"Not applicable - bioMerieux does not manufacture device STERILE or having a special microbiological state".	N/A	N/A	N/A	N/A	
B-2.5	Packaging systems for devices other than those referred to in Section 2.3 must keep the product without deterioration at the level of cleanliness indicated by the manufacturer and, if the devices are to be sterilized prior to use, reduce as far as possible the risk of microbial contamination. Steps must be taken to reduce microbial contamination during selection and handling of raw materials, manufacture, storage and distribution where the performance of the device can be adversely affected by such contamination.	Not applicable - bioMerieux does not manufacture devices intended to be sterilized	N/A	N/A	N/A	N/A	

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B-2.6	Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	Not applicable - bioMerieux does not manufacture devices intended to be sterilized	N/A	N/A	N/A	N/A	
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 sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	Not applicable - bioMerieux does not manufacture devices intended to be sterilized	N/A	N/A	N/A	N/A	
B-3	**3. Manufacturing and environmental properties**						
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 or in the instructions for use.	All	EN ISO 18113-2:2011 (7.7)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 62366:2008 IEC 62366-1:2015	001622 Safety risk management of bioMerieux products 009943 Commercial Software Development Process Procedure 003170 - Requirements for Information Supplied with bioMerieux Products 047074 – Usability engineering process	“Usability engineering file” and/or “Risk Management File” Labels and/or package insert	Design History File (DHF) Site Quality Assurance department Product Labeling & Documentation department	
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.	All except software		000253 Global Quality Management System Manual 000840 PDP Product Development Process Directive - Design Control for Product and Service	Product Requirements Document (PRD) Traceability matrix Risk Management File	Design History File (DHF) Site Quality Assurance department	
B-3.3	Devices must be designed and manufactured in such a way as to remove or reduce as far as possible: - the risk of injury linked to their physical features (in particular aspects of volume x pressure, dimension and, where appropriate, ergonomic features); - risks linked to reasonably foreseeable external influences, such as magnetic field, external electrical effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure or acceleration or accidental penetration of substances into the device. Devices must be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity of electromagnetic disturbance to enable them to operate as intended.	All	EN 61010-2-101:2002	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 62366:2008 IEC 62366-1:2015	001622 Safety risk management of bioMerieux products 009943 Commercial Software Development Process Procedure 003170 - Requirements for Information Supplied with bioMerieux Products 047074 – Usability engineering process	“Usability engineering file” and/or “Risk Management File” Labels and/or package insert	Design History File (DHF) Site Quality Assurance department Product Labeling & Documentation department	
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.	All except software	EN 61010-2-101:2002	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 62366:2008 IEC 62366-1:2015	001622 Safety risk management of bioMerieux products 009943 Commercial Software Development Process Procedure 047074 – Usability engineering process 003170 - Requirements for Information Supplied with bioMerieux Products	“Usability engineering file” and/or “Risk Management File” Labels and/or package insert	Design History File (DHF) Site Quality Assurance department	
B-3.5	Devices must be designed and manufactured in such a way to facilitate the management of safe waste disposal.	All	EN 62366:2008 IEC 62366-1:2015	001622 Safety risk management of bioMerieux products 009943 Commercial Software Development Process Procedure 003170 - Requirements for Information Supplied with bioMerieux Products 047074 – Usability engineering process	“Usability engineering file” and/or “Risk Management File” Labels and/or package insert	Design History File (DHF) Site Quality Assurance department Product Labeling & Documentation department	
B-3.6	The measuring, monitoring or display scale (including color change and other visual indicators) must be designed and manufactured in line with ergonomic principles, taking account of the intended purpose of the device.	All	EN 62366:2008 IEC 62366-1:2015	001622 Safety risk management of bioMerieux products 009943 Commercial Software Development Process Procedure 047074 – Usability engineering process 003170 - Requirements for Information Supplied with bioMerieux Products	“Usability engineering file” and/or “Risk Management File” Labels and/or package insert	Design History File (DHF) Site Quality Assurance department	
B-4	**4. Devices which are instruments or apparatus with a measuring function**						
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.	Applicable only for instruments and software	EN 13612:2002/AC:2002 (4.5) (1)	000262 Corporate Procedure to Conduct Clinical Trials	Validation report	Design History File (DHF)	
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.	Applicable only for instruments and software		000840 PDP Product Development Process Directive - Design Control for Product and Service	Product Requirements Document (PRD) Traceability matrix	Design History File (DHF)	
B-5	**5. Protection against radiation**						
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 minimized.	Applicable only for instruments	EN 61010-2-101:2002	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 14971:2012 (all clauses)	001622 Safety risk management of bioMerieux products	Risk Management File	Design History File (DHF) Site Quality Assurance department	
B-5.2	When devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must as far as possible be: - designed and manufactured in such as way as to ensure that their characteristics and the quality of radiation emitted can be controlled and/or adjusted; - fitted with visual displays and/or audible warnings of such emissions.	Applicable only for instruments	EN 61010-2-101:2002	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
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.	Applicable only for instruments	EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert Test Report	Product Labeling & Documentation department	
B-6	**6. Requirements for medical devices connected to or equipped with an energy source.**						
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.	Applicable only for instruments and software	EN 13612:2002/AC:2002 (4.5) (1)	000262 Corporate Procedure to Conduct Clinical Trials	Validation report Verification report	Design History File (DHF)	
			EN 62304:2006/AC:2008	009943 commercial software development procedure 001622 Safety Risk Management of bioMerieux Products	Design & Development Plan Risk Management File	Design History File (DHF)	
B-6.2	Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic perturbation which could impair the operation of other devices or equipment in the usual environment.	Applicable only for instruments and software	EN 61326-2-6:2006	000840 PDP Product Development Process Directive- Design Control for Product and Service 003170 - Requirements for Information Supplied with bioMerieux Products	Product Requirements Document (PRD) Traceability matrix Labels and/or package insert Test Report	Design History File (DHF) Product Labeling & Documentation department	
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.	Applicable only for instruments	EN 61010-2-101:2002	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	

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B-6.4 Protection against mechanical and thermal risks							
B-6.4.1	Devices must be designed and manufactured in such as to protect the user against mechanical risks. 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. 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. 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.	Applicable only for instruments	EN 61010-2-101:2002	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 62366:2008 IEC 62366-1:2015	001622 Safety risk management of bioMerieux products 009943 Commercial Software Development Process Procedure 047074 – Usability engineering process 003170 - Requirements for Information Supplied with bioMerieux Products	“Usability engineering file” and/or “Risk Management File” Labels and/or package insert	Design History File (DHF) Site Quality Assurance department	
B-6.4.2	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.	Applicable only for instruments	EN 61010-2-101:2002	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
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.	Applicable only for instruments	EN 61010-2-101:2002	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
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 minimize all possible risks.	Applicable only for instruments	EN 61010-2-101:2002	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
B-6.4.5	Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	Applicable only for instruments	EN 61010-2-101:2002	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
B-7	**7. Requirements for devices for self-testing**						
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.	Requirement not applicable as there is no bioMérieux device for self-testing	N/A	N/A	N/A	N/A	
B-7.1	Devices for self-testing must be designed and manufactured in such a way as to: - ensure that the device is easy to use by the intended lay user at all stages of the procedure, and - reduce as far as practicable the risk of user error in the handling of the device and in the interpretation of the results.		N/A	N/A	N/A	N/A	
B-7.2	Devices for self-testing must, where reasonably possible, include user control, i.e. a procedure by which the user can verify that, at the time of use, the product will perform as intended.		N/A	N/A	N/A	N/A	
B-8	**8. Information supplied by the manufacturer**						
B-8.1	Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the data on the label and the instructions for use. 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 labeling 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. 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. The decision with regard to translation of the package insert and label into one or several languages of the European Union is left to Member States subject to the condition that, in case of devices intended for self testing, the package insert and label include a translation of the official language(s) of the Member State in which the device for self testing is supplied to the end user.	All	EN ISO 18113-1:2011 (4.1, 4.2.1, 4.6)	003170 Requirements for Information Supplied with bioMerieux Product 044085 - Procedure for Global eIFU Process Management	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-2:2011 (5, 6, 7)	003170 Requirements for Information Supplied with bioMerieux Product 044085 - Procedure for Global eIFU Process Management	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011 (5, 6, 7)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 14971:2012 (all clauses)	001622 Safety risk management of bioMerieux products	Risk Management File	Design History File (DHF) Site Quality Assurance department	
B-8.2	Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification color used must conform to the harmonized standards. In areas for which no standards exist, the symbols and color used must be described in the documentation supplied with the device.	All	EN ISO 15223-1:2016 (4.2, Clause 5)	003170 Requirements for Information Supplied with bioMerieux Product 004398 Symbols and marks used for the labelling of bioMerieux products	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-1:2011 (4.3)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.3	In the case of devices containing a substance 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 labeling requirements of Directive 67/548/EEC and Directive 88/379/EEC 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. The provisions of the aforementioned Directives on the safety data sheet shall apply unless all relevant information as appropriate is already made available by the instructions for use.	All	EN ISO 18113-1:2011 (all clauses)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-2:2011 (5.8, 6.8, 7.10)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	

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B-8.4	**8.4 The label must bear the following particulars which may take the form of symbols as appropriate:**						
B-8.4-a)	The name or trade name and address of the manufacturer. For devices imported into the Community with a view of their distribution in the Community, the label, the outer packaging, or instructions for use, shall contain in addition the name and address of the authorized representative of the manufacturer;	All	EN ISO 18113-2:2011 (5.1, 6.2)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011 (7.1)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 15223-1:2016 (5.1.1, 5.1.2)	003170 Requirements for Information Supplied with bioMerieux Product 004398 Symbols and marks used for the labelling of bioMerieux products	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.4-b)	The details strictly necessary for the user to identify the device and the contents of the packaging;	All	EN ISO 18113-2:2011(5.2.1, 5.3, 6.3.1, 6.4)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011(5.2.1)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 15223-1:2016 (5.1.3, 5.1.6, 5.5.2, 5.5.3, 5.5.4, 5.5.5)	003170 Requirements for Information Supplied with bioMerieux Product 004398 Symbols and marks used for the labelling of bioMerieux products	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.4-c)	Where appropriate, the word "STERILE" or a statement indicating any special microbiological state or state of cleanliness;	Applicable only for sterile devices	EN ISO 15223-1:2016 (5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9)	003170 Requirements for Information Supplied with bioMerieux Product 004398 Symbols and marks used for the labelling of bioMerieux products	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-1:2011 (4.5)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
B-8.4-d)	The batch code, preceded by the word "LOT" or the serial number;	All	EN ISO 18113-2:2011 (5.2.2, 6.3.2)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 15223-1:2016 (5.1.5, 5.1.7)	003170 Requirements for Information Supplied with bioMerieux Product 004398 Symbols and marks used for the labelling of bioMerieux products	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011 (5.2.2)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
B-8.4-e)	If necessary, an indication of the date by which the device or a part of it should be used, in safety, expressed as the year, the month and, where relevant, the day, in that order;	All	EN ISO 15223-1:2016 (5.1.4)	003170 Requirements for Information Supplied with bioMerieux Product 004398 Symbols and marks used for the labelling of bioMerieux products	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-2:2011 (5.7, 6.7)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
B-8.4-f)	In cases of devices for performance evaluation, the words « for performance evaluation only »;	Devices for performance evaluation only		003170 Requirements for Information Supplied with bioMerieux Product 004398 Symbols and marks used for the labelling of bioMerieux products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.4-g)	Where appropriate, statement indicating the in-vitro use of the device ;	All	EN ISO 18113-2:2011 (5.5, 6.5)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011 (5.2.3)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 15223-1:2016 (5.5.1)	003170 Requirements for Information Supplied with bioMerieux Product 004398 Symbols and marks used for the labelling of bioMerieux products	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.4-h)	Any particular storage and/or handling conditions;	All	EN ISO 18113-2:2011 (5.6, 6.6)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 15223-1:2016 (5.3.1, 5.3.2,5.3.3,5.3.4, 5.3.5, 5.3.6, 5.3.7, 5.3.8, 5.3.9)	003170 Requirements for Information Supplied with bioMerieux Product 004398 Symbols and marks used for the labelling of bioMerieux products	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.4-i)	Where applicable, any particular operating instructions;	All	EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.4-j)	Appropriate warnings and/or precautions to take;	All		000840 PDP Product Development Process Directive - Design Control for Product and Service	Product Requirements Document (PRD) Traceability matrix	Design History File (DHF)	
			EN ISO 18113-1:2011 (4.8)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-2:2011 (5.8, 6.8)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 15223-1:2016 (5.2.6, 5.2.8, 5.4.1, 5.4.2, 5.4.4, 5.4.5)	003170 Requirements for Information Supplied with bioMerieux Product 004398 Symbols and marks used for the labelling of bioMerieux products	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.4-k)	if the device is intended for self-testing, thaf fact should be cearly stated.	Essential requirement not applicable as bioMérieux does not manufacture devices for self-testing	N/A	N/A	N/A	N/A	
B-8.5	If the intended purpose of the device is not obvious to the user, the manufacgturer must clearly state the intended purpose in the instructions for use and, if appropriate, on the label.	All	EN ISO 18113-2:2011 (5.4, 7.3)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011(7.3)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.6	Wherever reasonable and praticable, the devices and separate component 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.	All	EN ISO 15223-1:2016 (5.1.5, 5.1.7)	003170 Requirements for Information Supplied with bioMerieux Product 004398 Symbols and marks used for the labelling of bioMerieux products	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-2:2011 (5.2.2, 6.3.2)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	

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Section	Essential Requirements (Annex 1 Directive 98/79 EC)	Essential Requirements applicability	Technical Standards (corresponding clauses/sub-clauses)	Procedure	Output data	Location	Comments
B-8.7	**Where appropriate, the instructions for use must contain the following particulars:**						
B-8.7-a)	The details refered to in Section 8.4 with the exception of point (d) and (e);	All	EN ISO 18113-2:2011 (7.1, 7.2, 7.9, 7.10)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011 (7.1, 7.2.1, 7.3, 7.4, 7.5, 7.12)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
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;	All	EN ISO 18113-2:2011 (7.9)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
B-8.7-c)	The storage conditions and shelf life following the first opening of the primary container, together with the storge conditions and stability of working reagents;	All	EN ISO 18113-2:2011 (7.9)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
B-8.7-d)	The performances referred to in Section 3 of Part A; *(General requirement A-3 above)*	All	EN ISO 18113-2:2011 (7.16)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011 (7.9)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.7-e)	An indication of any special equipment required including information necessary for the indentification of that special equipment for proper use;	All	EN ISO 18113-2:2011 (7.7)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011 (7.2.2, 7.11, 7.12)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.7-f)	The type of specimen to be used, any special conditions of collection, pre-treatment and, if necessary, storage conditions and instructions for the preparation of the patient;	All	EN ISO 18113-2:2011 (7.11)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011(7.11, 7.12)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.7-g)	A detailed description of the procedure to be followed in using the device;	All	EN ISO 18113-2:2011 (7.12)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011 (7.12, 7.15, 7.17)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.7-h)	The measurement procedure to be followed with the device including as appropriate: - the principle of the method, - the specific analytical performance characteristics (e.g. sensitivity, specificity, accuracy, repetability, 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, - the details of any further procedure or handling needed before the device can be used (for example reconstitution, incubation, dilution, instrument checks, etc...). - the indication whether any particular training is required;	All	EN ISO 18113-2:2011 (7.4, 7.8, 7.16, 7.18)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011 (7.7, 7.8, 7.9, 7.10, 7.11, 7.12)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.7-i)	The mathematical approach upon which the calculation of the analytical result is made;	All	EN ISO 18113-2:2011 (7.14, 7.15)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011 (7.14)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.7-j)	Measures to be taken in the event of changes in the analytical peformance of the device;	All	EN ISO 18113-2:2011 (7.13, 7.18)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011(7.20)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.7-k)	Information appropriate to users on: - internal quality control including specific validation procedures, - the traceability of the calibration of the device;	All	EN ISO 17511:2003 (8)	010834 - Raccordement Metrologique d un Test Immunoessais	Verification report	Design History File (DHF)	010834 is applicable for Immunoassay only (Marcy site). For others product range output data demonstrate conformity when applicable.
			EN ISO 18113-2:2011 (7.5, 7.13)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011 (7.13)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.7-l)	The reference intervals for the quantities being determined, including a description of the appropriate reference population;	All	EN ISO 18113-2:2011 (7.17)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
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;	All	EN ISO 18113-2:2011(7.7)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011 (7.6, 7.11, 7.12)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
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 calbration needed to ensure that the device operates properly and safely, information about safe waste disposal;	All	EN ISO 18113-3:2011 (7.6, 7.11, 7.12, 7.13, 7.18, 7.19)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	

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B-8.7-o)	Details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc..);	All	EN ISO 18113-2:2011 (7.8)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011 (7.11)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.7-p)	The necessary instructions in the event of damage to the protective packaging and details of appropriate methods of resterilization or decontamination;	All	EN ISO 18113-3:2011 (7.19)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.7-q)	If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and resterilization or decontamination and any restriction on the number of reuses;	Applicable only for instruments and software		000840 PDP Product Development Process Directive - Design Control for Product and Service	Product Requirements Document (PRD) Traceability matrix	Design History File (DHF)	
			EN ISO 18113-3:2011 (7.19)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
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...	Applicable only for instruments and software	EN ISO 18113-2:2011 (7.10)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011 (7.5, 7.6.3, 7.11)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.7-s)	Precautions to be taken against any special, unusual risks related to the use or 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;	All		000840 PDP Product Development Process Directive - Design Control for Product and Service	Product Requirements Document (PRD) Traceability matrix	Design History File (DHF)	
			EN ISO 18113-2:2011 (7.10)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN ISO 18113-3:2011 (7.5, 7.18)	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
			EN 61010-2-101:2002	003170 - Requirements for Information Supplied with bioMerieux Products	Labels and/or package insert	Product Labeling & Documentation department	
B-8.7-t)	Specifications for devices for self-testing; - the results need to be expressed and presented in a way that is readily understood by a lay person: 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. - 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. - 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, - 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;	Requirement not applicable as there is no bioMérieux device for self-testing	N/A	N/A	N/A	N/A	
B-8.7-u)	Date of issue or latest revision of the instructions for use.	All	N/A	003170 Requirements for Information Supplied with bioMerieux Product	Labels and/or package insert	Product Labeling & Documentation department	
(1)	*The performance characteristics of the device have not yet been established. Thus, the concerned essential requirement is not satisfied regarding EN 13612:2002/AC:2002 standard and CTS requirements for devices which are intended for performance evaluation.*						
(2)	*The stability studies are ongoing during design and developpement phases. Thus, the concerned essential requirement is not satisfied regarding N ISO 23640:2013 standards for devices which are intended for performance evaluation.*						