BIOSYNEX EASY DIAGNOSTICS FOR LIFE SWISS	DOC 2_ESSENTIAL REQUIREMENTS Checklist according to Directive 98 / 79 / EC, Annex I (Incl. EEA-Requirements (Directive 98/79/EC: 11/01/2012))		
	Reference : F-QUA-334	Version : 04	Date : 09/09/2020

PRODUCT DESIGNATION	REFERENCE
BIOSYNEX AUTOTEST Antigénique COVID-19 Ag	859256/859257/859258

Essential Requirements	Applicable	Standard/ Guideline/ Requirements *	Reference to / Documentation	Results/Remarks
A. GENERAL REQUIREMENTS				
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.	Yes	EN ISO 14971 EN ISO 18113-2 EN 13641 EN 13532	DOC 3 Risk Analysis QSP-1000 Design Control Procedure	Certification of quality system according to EN ISO 13485 A risk analysis, risk estimate and a risk evaluation according to EN ISO 14971 of the product were carried out. All risks were found to be acceptable and no ways of further risk reductions could be found.
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 measures adopted.	Yes	EN ISO 14971 EN ISO 18113-1 EN ISO 18113-2 EN 13641 EN ISO 23640 EN ISO 15223-1 EN 13532	DOC 1 Device description DOC 5 Analytical and clinical performance, stability DOC 3 + 3A Risk Analysis Instructions for use QSP-1000 Design Control Procedure	Certification of quality system according to EN ISO 13485 A risk analysis, risk estimate and a risk evaluation according to EN ISO 14971 of the product were carried out. All risks were found to be acceptable and no ways of further risk reductions could be found. Safety principles: • C-line formation • Safe set up with dropper bottles Layman users will receive all warnings and notes for safe use of the device in the IFU.
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, 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.	Yes	EN ISO 13485 EN 13612 EN ISO 14971 EN 13532	DOC 5 Analytical and clinical performance, stability DOC 3 + DOC 3A Risk Analysis QSP-1000 Design Control Procedure	Certification of quality system according to EN ISO 13485 Risk analysis demonstrates that the test is suitable for its intended use taking into consideration the results of the studies. Studies addressing the listed points are included in the technical file. They include studies on analytical performances and a clinical study with patient samples. Batch Release Certificate can be delivered with every Batch / Lot.
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.	Yes	EN 13612 EN 13975	DOC 5 Analytical and clinical performance, stability	Specific control materials are used for calibrating the assay and for QC of incoming goods. No controls are included in the kit.
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	Yes	EN ISO 23640 EN ISO 14971	DOC3 Risk Analysis	

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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.			DOC 5: Analytical and clinical performance, stability QSP-1000 Design Control Procedure	Accelerated stability indicates no loss of performance for at least 24 months (when the kit is stored at 2-30°C) from the date of manufacture. A real time stability study is in process to confirm the assigned shelf life in real time conditions.
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.	Yes	EN ISO 23640 EN ISO 14971 EN ISO 13485 EN ISO 18113-1 EN ISO 18113-2	DOC 5: Analytical and clinical performance, stability DOC3 Risk Analysis QSP-1000 Design Control Procedure	Test shows good temperature tolerance – see Stability and shipping stability studies. Risk Analysis rates hazards coming from transportation. Packaging of the tests (foil coated aluminum pouches with desiccant inside) protects tests from mechanical damages and humidity.
B. DESIGN AND MANUFACTURING REQUIREMENTS		EN ISO 13485		
1. Chemical and physical properties				
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.	Yes	EN ISO 13485 EN ISO 14971 EN ISO 23640 EN 13612	DOC 5: Analytical and clinical performance, stability DOC3 + DOC3A Risk Analysis QSP-1000 Design Control Procedure	Certification of quality system according to EN ISO 13485 There was no cross-reaction with the following pathogens: *Respiratory syncytial virus Type A* *Respiratory syncytial virus Type B* *Novel influenza A H1N1 virus (2019)* *Seasonal influenza A H1N1 virus* *Influenza A H3N2 virus* *Influenza A H5N1 virus* *Influenza B Yamagata* *Influenza B Victoria* *Rhinovirus* *Adenovirus 3* *Adenovirus 7* *EV-A71* *Mycobacterium tuberculosis* *Mumps virus* *Human coronavirus 229E* *Human coronavirus OC43* *Human coronavirus NL63* *Human coronavirus HKU1* *Parainfluenza virus 1* *Parainfluenza virus 2*

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				Parainfluenza virus 3 *Parainfluenza virus 4* *Haemophilus influenzae* *Streptococcus pyogenes* *Streptococcus pneumoniae* *Candida albicans* *Bordetella pertussis* *Mycoplasma pneumoniae* *Chlamydia pneumoniae* *Legionella pneumophila* *Pooled human nasal wash.* There was no interference (positive or negative) with the following substances: human blood (with EDTA anticoagulant), Mucin, Antiviral Drugs (Oseltamivir phosphate, Ribavirin), Antibiotics (Levofloxacin, Azithromycin, Meropenem, Tobramycin), nasal sprays or drops (Phenylephrine, Oxymetazoline, Alkalol nasal wash, 0. 9% NaCl), nasal corticosteroids (Beclomethasone, Hexadecadrol, Flunisolide, Triamcinolone, Budesonide, Mometasone, Fluticasone, Fluticasone propionate). Hazards from this have been rated in Risk Analysis.
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.	Yes	EN ISO 14971	DOC3 + DOC3A Risk Analysis QSP-1000 Design Control Procedure	The possible risk posed by product leakage, contaminants and residues to the persons involved in the transport, storage and use of the devices was evaluated and minimized to residual risk. The risk of escaping materials was analyzed according to EN ISO 14971 and is rated as low because of the low quantities, the structure of the test and the type of usage (IVD). Primary packaging prevents unwanted leakage for tests (pouches) and for liquids (pre-filles bottles sealed with aluminium) during transport and usage.
2. Infection and microbial contamination				
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 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.	Yes	EN ISO 14971 EN ISO 18113-2	DOC3 + DOC3A Risk Analysis DOC 4 Design and manufacturing information	A risk analysis was carried out. The test contains no biological material of human origin. The biological materials contained in the test are in a dried form. The test is designed with a plastic housing. The handling of the device by the layman user was evaluated in the layman study.

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			DOC 15: Laymen study	Instructions for disposal of used material are detailed in the IFU.
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.	Yes	EN ISO 14971	DOC 3 + DOC3A Risk Analysis	The biological substances used were subjected to a risk analysis according to EN ISO 14971 and have a negligible risk of infection (notably because of their dry form). Sources of materials of biological origin are carefully selected to minimize hazards.
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.	No	NA	NA	The kit is not sterile, nor is in a special microbiological state. There is a sterile swab supplied within the kit as an accessory, its packaging is under the responsibility of its legal manufacturer.
2.4. Devices labelled either as 'STERILE` or as having a special microbiological state must have been processed by an appropriate, validated method.	No	NA	NA	The test device is not sterile, nor is in a special microbiological state. There is a sterile swab supplied within the kit as an accessory, the sterilization process is under the responsibility of its legal manufacturer.
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 sterilised prior to use, reduce as far as possible the risk of microbial contamination.	Yes	EN ISO 13485 EN ISO 14971	DOC3 + DOC3A Risk Analysis	The cleanliness of the product (test cassette) is ensured by sealing it in a pouch made of coated aluminum foil. The product is not intended to be sterilized prior to use.
Steps must be taken to reduce as far as possible 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.	Yes	EN ISO 13485	ISO 13485 certificate DOC3+DOC3A Risk Analysis DOC 4 Design and Manufacturing Information	QMS defines measures to ensure correct handling of raw materials and manufacturing processes.
2.6. Devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions.	No	NA	NA	The product is not intended to be sterilized prior to use.
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.	Yes	EN ISO 13485	DOC3 + DOC3A Risk Analysis DOC 4 Design and Manufacturing Information	The product is packed in a pouch made of coated aluminum foil. The product is not intended to be sterilized prior to use.
3. Manufacturing and environmental properties				

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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.	Yes	EN ISO 13485 EN ISO 14971 EN ISO 18113-2	DOC 1: Device Description DOC 3 + DOC 3A Risk Analysis	The kit contains a sterile swab as an accessory which is intended for sample collection. The package insert describes the instructions for the use of the swab. The device is not intended to be used with other devices or Equipments..
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.	Yes	EN ISO 13485 EN ISO 14971 EN ISO 18113-1 EN ISO 18113-2	DOC3 + DOC 3A Risk Analysis Instructions for use QSP-1000 Design Control Procedure	The test is used as an aid for the diagnosis of SARS-CoV-2 infection. This implies that the sample material (nasal swabs) is potentially infectious. This cannot be changed. Warnings for personal protection and proper disposal are given in the IFU. Risk has been discussed in Risk Analysis.
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 fields, 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.	Yes	EN ISO 14971 EN ISO 23640 EN 13612	DOC3 + DOC3A Risk Analysis DOC 5C Stability QSP-1000 Design Control Procedure	The product was analyzed according to EN ISO 14971 regarding the risks indicated on the **left.** Because of the type, size and weight of the product, the risk of injury due to physical causes is improbable. Possible environmental influences include temperature, moisture: Failure of the product due to moisture is prevented by sealing it in a protective pouch and by the use of a desiccant. At temperatures of +2-+30°C, no failure of the product over the shelf life is assumed. Since these temperatures correspond to the usual ambient conditions, this risk is low. See Stability data in DOC 5C No risk by electromagnetic disturbance – rapid test
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.	No	NA	NA	No risks of fire or explosion during normal use or in single fault condition.
3.5. Devices must be designed and manufactured in such a way as to facilitate the management of safe waste disposal.	Yes	EN ISO 14971 EN ISO 18113-2	DOC3 + DOC3A Risk Analysis	Sample Material is of potentially infectious character. Sampling and disposal of sample material should be done according to local regulations. Respective warnings are given in the IFU.
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.	Yes	EN ISO 13485 EN ISO 18113-2	DOC1 Device description	C-line and T-line which are visual indicators for the interpretation of the test are placed in an area that can be well seen by the user.

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			DOC3 + DOC3A Risk Analysis Instructions for use QSP-1000 Design Control Procedure	Interpretation of results is explained in the IFU in a dedicated section. The possibility of variability of the T-line intensity according to the concentration of the searched antigen is described. Risk for false results due to mixing up lines, overlooking faint lines was discussed in Risk Analysis.
4. Devices which are instruments or apparatus with a measuring function				
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.	No	NA	NA	The device is not an instrument nor an apparatus with a measuring function.
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 (1).	No	NA	NA	The device is not an instrument nor an apparatus with a measuring function.
5. Protection against radiation				
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.	No	NA	NA	The test does not contain any energy and/or radiation sources and does not generate any.
5.2. When devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must as far as possible be:	No	NA	NA	The test does not contain any energy and/or radiation sources and does not generate any.
- 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,	No	NA	NA	The test does not contain any energy and/or radiation sources and does not generate any.
- fitted with visual displays and/or audible warnings of such emissions.	No	NA	NA	The test does not contain any energy and/or radiation sources and does not generate any.
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.	No	NA	NA	The test does not contain any energy and/or radiation sources and does not generate any.
6. Requirements for medical devices connected to or equipped with an energy source				
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.	No	NA	NA	The test does not have any programmable electronic system.
According 2007/47 /EC: For devices which incorporate **software** or which are medical software in themselves, the software must be validated.	No	NA	NA	Test does not incorporate any software.

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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.	No	NA	NA	No electromagnetic perturbations are to be expected when using the device.
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.	No	NA	NA	No electric shocks are to be expected when using the device.
6.4. Protection against mechanical and thermal risks				
6.4.1. Devices must be designed and manufactured in such a way 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.	No	NA	NA	There are no mechanical or thermal risks associated with the devices
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.	No	NA	NA	There are no mechanical or thermal risks associated with the devices
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.	No	NA	NA	There are no mechanical or thermal risks associated with the devices
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.	No	NA	NA	There are no vibrations risks associated with the device
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.	No	NA	NA	There are no noise risks associated with the devices.
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.	No	NA	NA	There are no connections to electricity, gas or hydraulic or pneumatic energy supplies associated with the devices
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.	No	NA	NA	There are no thermal risks associated with the devices
7. Requirements for devices for self-testing				
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	Yes	ISO 14971 EN 13612 EN 13532	DOC 3A + 3 Risk analysis DOC 15 Layman user study	A layman user study was carried out to evaluate the handling of the test by laymen users. Data and instructions are understandable.

Essential Requirements	Applicable	Standard/ Guideline/ Requirements *	Reference to / Documentation	Results/Remarks
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.			DOC 4 Design and manufacturing	
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.	Yes	ISO 14971 EN 13612 EN 13532	DOC 3A + 3 Risk analysis DOC 15 Layman user study DOC 4 Design and manufacturing	The layman user study confirms the easy use. Procedure is really short. The risk analysis indicated an acceptable risk for the danger of incorrect handling and wrong results interpretation.
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.	Yes	ISO 14971 EN 13612 EN 13532	DOC 3A + 3 Risk analysis DOC 15 Layman user study DOC 4 Design and manufacturing	The risk analysis indicated an acceptable risk for the danger of incorrect handling. Under usual circumstances no misinterpretation. All warnings are noted.
8. Information supplied by the manufacturer				
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 in the instructions for use.	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use Labeling	The primary and secondary packaging (including labeling) and instruction for use of the test were designed according to the standards and guidelines listed at left side. Manufacturer is given on primary packaging, outer container, IFU. IFU describes how to use assay, gives background information, precautions, performance data etc.
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.	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use Labeling	Labeling of primary packaging of the test (pouch) and of the kit show the symbols according to EN ISO 15223-1 and provide at least : Device name, LOT, Expiry, IVD, Storage Temperature, Observe Instructions, Single Use, CE mark, name and address of manufacturer. A leaflet with detailed IFU is also provided with each kit.
Instructions for use must accompany or be included in the packaging of one or more devices.	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use Labeling	Instructions for use will be provided with each kit.
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.	No	NA	NA	Instructions for use will be provided with each kit.
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.	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use Labeling	Symbols are used according with EN ISO 15223-1 In case users are not familiar with symbols a table with explanations is given in IFU.
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	No	2001/58/EC and REACH REGULATION	DOC 10 MSDS	An MSDS is available for this product.

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and the form under which they are present, relevant danger symbols and labeling 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. 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.		(1907/2006 CE + Commission Regulation EU No 109/2012		
8.4. The label must bear the following particulars which may take the form of symbols as appropriate:				
(a) the name or trade name and address of the manufacturer. 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;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Labeling	Biosynex Swiss SA is responsible manufacturer for the device. No authorized representative is involved. Manufacturer address is given on outer container behind the applicable symbol. The kit contains a sterile swab as accessory, its responsible manufacturer is indicated on the primary packaging of the swab.
(b) the details strictly necessary for the user to uniquely identify the device and the contents of the packaging;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Labeling	Product name and reference are given on outer container, as well as number of tests contained in the kit. Inner container states abbreviation of test and gives amount of devices inside the pouch after the content symbol. IFU also lists kit components.
(c) where appropriate, the word 'STERILE` or a statement indicating any special microbiological state or state of cleanliness;	No	NA	NA	The kit is not supplied as sterile, nor is in a special microbiological state. The kit contains a sterile swab as accessory, its sterility is under the responsibility of its legal manufacturer.
(d) the batch code, preceded by the word 'LOT`, or the serial number;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Labeling	Primary and outer containers both give LOT# behind the relevant symbol.
(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;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Labeling	Primary and outer container both give expiry date behind the according symbol.
(f) in case of devices for performance evaluation, the words 'for performance evaluation only`;	No	NA	NA	The product is not intended for performance evaluation.
(g) where appropriate, a statement indicating the in vitro use of the device;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Labeling	IVD symbol on primary packaging and outer container. IFU explains symbol and also states IVD use in wording.

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(h) any particular storage and/or handling conditions;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Labeling	Storage temperature is given on primary packaging and outer container after the relevant symbol. IFU explains symbol and describes storage conditions also in wording.
(i) where applicable, any particular operating instructions;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Labeling	Not on primary packaging or outer container. The primary packaging and outer container indicate to refer to the IFU (which describes the particular operating instructions) through the appropriate symbol.
(j) appropriate warnings and/or precautions to take;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Labeling	Not on primary packaging or outer container. The primary packaging and outer container indicate to refer to the IFU through the appropriate symbol. IFU gives warnings/precautions in order to avoid user mistakes.
(k) if the device is intended for self-testing, that fact must be clearly stated.	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Labeling	Self-testing destination is clearly stated on outer labeling
8.5. 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.	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Labeling	The intended use is explained in the IFU. The label of the outer packaging refers to the IFU through the appropriate symbol.
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.	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Labeling	A batch number is present on the kit and is also indicated on the individual pouches. The buffers and sterile swab have separate batch numbers indicated on their primary packaging.
8.7. Where appropriate, the instructions for use must contain the following particulars:				
(a) the details referred to in section 8.4 with the exception of points (d) and (e);	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	See section 8.4
(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;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	IFU section gives description of detection method and what active components are involved.
(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;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	IFU gives storage and stability conditions. This is indicated by the respective symbol. IFU gives info that user should remove the test cassette from the sealed pouch just prior to testing ; the test cassette must be used within one hour after opening the pouch.

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Essential Requirements	Applicable	Standard/ Guideline/ Requirements *	Reference to / Documentation	Results/Remarks
(d) the performances referred to in section 3 of part A;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	Performance data is included in the IFU. Concise description in order to be accessible for layman user.
(e) an indication of any special equipment required including information necessary for the identification of that special equipment for proper use;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	Section Materials gives information about material provided and material required but not provided. The only material required and not provided is a timer – this is indicated in the 1st step of the description of the procedure.
(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;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	Specimen collection, preparation and storage conditions are described in the IFU. A dedicated section of the IFU gives information on the collection of the specimen (using the sterile swab). The procedure for the self-test implicates that the specimen is used immediately – no storage.
(g) a detailed description of the procedure to be followed in using the device;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	Detailed operating instructions are described in the IFU
(h) the measurement procedure to be followed with the device including as appropriate:	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	The process is described concisely and as simply as possible in the instruction for use. Pictures included facilitating procedure and resulting interpretation.
- the principle of the method,	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	Instruction for use describes the principle of the test in a concise manner in order to be accessible to the layman user.
- 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,	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	The IFU gives analytical performance data and diagnostic performance characteristics. The IFU gives limitations of the assay e.g. the warning that the diagnosis should not be based on the result of a single rapid test etc. This information are given in a concise manner in order to be accessible for the layman user.
- the details of any further procedure or handling needed before the device can be used (for example, reconstitution, incubation, dilution, instrument checks, etc.),	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	Instruction for use describe the collection and preparation of sample needed before the test can be carried out.
- the indication whether any particular training is required;	No	NA	NA	There are no restrictions that personal must be trained before using the test.
(i) the mathematical approach upon which the calculation of the analytical result is made;	No	NA	NA	The result is qualitative only.

BIOSYNEX EASY DIAGNOSTICS FOR LIFE SWISS	DOC 2_ESSENTIAL REQUIREMENTS Checklist according to Directive 98 / 79 / EC, Annex I (Incl. EEA-Requirements (Directive 98/79/EC: 11/01/2012))		
	Reference : F-QUA-334	Version : 04	Date : 09/09/2020

Essential Requirements	Applicable	Standard/ Guideline/ Requirements *	Reference to / Documentation	Results/Remarks
(j) measures to be taken in the event of changes in the analytical performance of the device;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	The product is intended for single use. Therefore it is not to expect that the analytical performance will change during use. If the control line does not appear, it is instructed that the user repeat the process with a new test.
(k) information appropriate to users on:				
- internal quality control including specific validation procedures,	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	Information on the quality control check through the appearance of the control line is explained in the IFU.
- the traceability of the calibration of the device;	No	NA	NA	Test is not calibrated. User is not involved in any calibration steps.
(l) the reference intervals for the quantities being determined, including a description of the appropriate reference population;	No	NA	NA	Not applicable, the test only gives a qualitative result.
(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;	No	NA	NA	The device is not used in combination with or installed with any other medical devices or equipment.
(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;	No	NA	NA	No installation, no maintenance, no calibration. The product has been developed for single use. Proper completion of the test will be displayed by the appearance of the control line. Information on safe disposal is given.
(o) details of any further treatment or handling needed before the device can be used (for example, sterilisation, final assembly, etc.);	No	NA	NA	Details for correct sample collection are given in IFU. Apart from this the test generates the result on its own and no accessories are needed for generation and/or interpretation of results. No further treatment or handling is needed before the device can be used.
(p) the necessary instructions in the event of damage to the protective packaging and details of appropriate methods of resterilisation or decontamination;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	In the IFU, the user is advised not to use the test if the pouch is damaged.
(q) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and resterilisation or decontamination, and any restriction on the number of reuses;	No	NA	NA	Device is for single use. This is indicated by the respective symbol.
(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.;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	Test procedure should take place at room temperature (15-30°C) and tests that have been removed from the primary packaging should be used within one hour. Corresponding instructions / warnings in IFU.

BIOSYNEX EASY DIAGNOSTICS FOR LIFE SWISS	DOC 2_ESSENTIAL REQUIREMENTS Checklist according to Directive 98 / 79 / EC, Annex I (Incl. EEA-Requirements (Directive 98/79/EC: 11/01/2012))		
	Reference : F-QUA-334	Version : 04	Date : 09/09/2020

Essential Requirements	Applicable	Standard/ Guideline/ Requirements *	Reference to / Documentation	Results/Remarks
(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;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	Instruction for use gives instructions for the disposal of used tests that might be potentially infectious. The materials of animal origin that are used involve a negligible infection potential.
(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;	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	The explanation of the results is given in the instruction for use as graphics and text. The result positive/negative/invalid is understandable and requires no further explanation. The user is advised that there is a possibility that technical or procedural errors as well as other factors not listed may interfere with the test and cause false results. No decisions of medical relevance have to be made, it is indicated as a warning that the test does not substitute to a medical consultation and to result of a biological analysis carried out in a medical laboratory.
(u) date of issue or latest revision of the instructions for use.	Yes	EN ISO 15223-1 EN ISO 18113-1 EN ISO 18113-2	Instructions for Use	Instruction for use gives revision number and date of release

* Versions of the standards are available in the following document: SPE-QUA-001 Plan exigences Biosynex

History (changes)

Revision	Date	Part	Reason/Changes
01	2021-02-05	NA	Creation of the document