

## DECLARATION

### **under Art. 5 (5) EU Regulation on in vitro diagnostic medical devices (EU) 2017/746 (IVDR) for in-house production of IVD in health institutions**

We declare under our sole responsibility that the product listed below and  
manufactured by us by way of in-house production

Product name: **CLDN6 IHC Assay**

Health institution: **University Medical Center Hamburg Eppendorf,  
Hamburg, Germany**

complies with all requirements of the IVD Regulation (EU) 2017/746, Annex I  
'General Safety and Performance Requirements', which apply to it.

The following requirements do not apply: **Please see Appendix 1**

The product was manufactured by us in our own premises on a non-  
industrial scale and is operated solely in our healthcare institution.

Device classification according to Annex VIII: **Class C**

Place and date of issue of this declaration:

Managing Director:

*Prof. Dr. Ronald Simon*



Date 01.07.2025

Quality Manager

*Christin Brennecke*



Date 01.07.2025

## Appendix 1 – Compliance with Annex I of IVD Regulation (EU) 2017/746

### Checklist of general safety and performance requirements

**Device name:** CLDN6 IHC Assay  
**Manufacturer:** University Medical Center Hamburg Eppendorf (UKE), Dept. of Pathology  
**Date:** 11 June 2025

Prof. Dr. Ronald Simon  
Date 11.06.2025



Christin Brennecke  
Date 11.06.2025



These general safety and performance requirements (GSPR) are focussed on CLAUDIN-6 (CLDN6) IHC clinical trial assay and staining protocol for use within a single health institution per IVDR Article 5(5). Other components required to perform the test are:

Device / reagent	Provider/ Manufacturer	Serial Number / Catalogue number
Leica BOND-RX	Leica Biosystems	3213753
Tissue-Tek Prisma Plus	Sakura	61720253 & 61720260
Tissue-Tek Film	Sakura	47421737 & 47421736
BOND Dewax Solution	Leica Biosystems	AR9222
BOND Epitope Retrieval 2 (ER2) Solution	Leica Biosystems	AR9640
Antibody Diluent	Dako REAL	S2022
BOND Wash Solution	Leica Biosystems	AR9590
BOND Polymer Refine Detection Kit	Leica Biosystems	DS9800
anti-CLDN6, clone 3H11, primary antibody (RUO)	TORL Bio	N/A
Mouse IgG2a, stock: 0.5 mg/ml	Abcam	ab18413

### Matrix of General safety and performance requirements per IVDR Annex I

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/ comment in case of deviation
CHAPTER I, GENERAL REQUIREMENTS				

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/ comment in case of deviation
1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.	Yes	ISO 15189, Section 4.14 – risk management	Validation study report entitled “CLDN6 Validation Summary Report_09JUNE25.pdf” approved 2025-06-10.	These sections are not covered by ISO 14971 as this LDT test is developed, manufactured and used as an in-house assay under IVDR Article 5(5) and will not be placed on the market. Use of the assay will be in the context of this clinical study only. Post market surveillance is not applicable.
2. The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.	Yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1
3. Manufacturers shall establish, implement, document and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:	yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1
(a) establish and document a risk management plan for each device;	yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1
(b) identify and analyse the known and foreseeable hazards associated with each device;	yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1
(c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;	yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1
(d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;	yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1	See 1

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/ comment in case of deviation
			Risk and opportunity assessment	
(e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and	no	Device is for in-house use only per IVDR Article 5(5) (laboratory developed test)		
(f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.	no	Device is for in-house use only per IVDR Article 5(5)(laboratory developed test)		
4. Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority: (a) eliminate or reduce risks as far as possible through safe design and manufacture; (b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and (c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users. Manufacturers shall inform users of any residual risks	yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1
5. In eliminating or reducing risks related to use error, the manufacturer shall: (a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment 2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	See 1
6. The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in	yes	ISO 15189, Section 4.14 – risk management  ISO 17020 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU) 4.2.4_1 Risk and opportunity assessment CLDN6 IHC assay validation report	See 1

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/comment in case of deviation
accordance with the manufacturer's instructions.				
7. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.	Yes	ISO 15189, Section 4.14 – risk management  ISO 17020 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU) CLDN6 IHC assay validation report	Device is for in-house use only (laboratory developed test) and not intended to be packaged or transported. Assessment of stability is relevant to the device (see 1).
8. All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.	yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1
<b>CHAPTER II, REQUIREMENTS REGARDING PERFORMANCE, DESIGN AND MANUFACTURE</b>				
<b>9. Performance characteristics</b>				
9.1 Devices shall be designed and manufactured in such a way that they are suitable for the purposes referred to in point (2) of Article 2, as specified by the manufacturer, and suitable with regard to the performance they are intended to achieve, taking account of the generally acknowledged state of the art. They shall achieve the performances, as stated by the manufacturer and in particular, where applicable:  (a) the analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross-reactions; and	yes	ISO 17020/15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU) CLDN6 IHC assay validation report	N/A
(b) the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations.	Clinical performance has not been established. This is not a device for clinical performance study.			

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/ comment in case of deviation
9.2 The performance characteristics of the device shall be maintained during the lifetime of the device as indicated by the manufacturer.	yes	ISO 17020/15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A
9.3 Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures and/or suitable reference materials of a higher metrological order. Where available, metrological traceability of values assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement procedures	no	The test does not require use of calibrator or control materials that have metrological value.		
9.4 The characteristics and performances of the device shall be specifically checked in the event that they may be affected when the device is used for the intended use under normal conditions:  (a) for devices for self-testing, performances obtained by laypersons;  (b) for devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances).	no	The device is not used for self-testing or near-patient testing. Device is for in-house use only (laboratory developed test)		
10. Chemical, physical and biological properties				
10.1 Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to the possibility of impairment of analytical performance due to physical and/or chemical incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device.	yes	ISO 15189, Section 4.14 – risk management	Validation study report entitled “CLDN6 Validation Summary Report_09JUNE25.pdf” approved 2025-06-10. 4.2.4_1 Risk and opportunity assessment	See 1
10.2 Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.	Yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1
10.3 Devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks posed by substances or particles, including wear debris, degradation products and	Yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/ comment in case of deviation
processing residues, that may be released from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.				
10.4 Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended to be used.	Yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1
<b>11. Infection and microbial contamination</b>				
11.1. Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall: (a) allow easy and safe handling, (b) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and where necessary (c) prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen.	Yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1
11.2. Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition or microbial state is damaged	no	The device is non-sterile and has no specified microbial state.		
11.3. Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.	no	The test is not sterile.		
11.4 Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.	no	Product is not intended to be sterile		
11.5 Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system	no	The test does not need to be sterilised before use. Device is for in-house use only (laboratory developed test)		



General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/comment in case of deviation
shall be suitable taking account of the method of sterilisation indicated by the manufacturer.				
11.6 The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.	no	The test is not sterile. Device is for in-house use only (laboratory developed test)		
<b>12. Devices incorporating materials of biological origin</b> Where devices include tissues, cells and substances of animal, human or microbial origin, the selection of sources, the processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be carried out so as to provide safety for user or other person. In particular, safety with regard to microbial and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This might not apply to certain devices if the activity of the microbial and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.	Yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1 Device does not contain any microbial and other transmissible agents
<b>13 Construction of devices and interaction with their environment</b>				
13.1 If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use.	yes	ISO 15189, Section 4.14 – risk management	Validation study report entitled "CLDN6 Validation Summary Report_09JUNE25.pdf" approved 2025-06-10. 2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	See 1
13.2 Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible: (a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	No	The reagent is not under pressure, and does not introduce any other risks in connection to the physical features.		
(b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;	yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1
(c) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including	No	This reagent does not come into contact with materials, liquids, and substances, including gases		



General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/comment in case of deviation
gases, to which it is exposed during normal conditions of use;				
(d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;	yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1
(e) the risks of accidental ingress of substances into the device;	No	There is no risk of accidental ingress of substances into the device		
(f) the risk of incorrect identification of specimens and the risk of erroneous results due to, for example, confusing colour and/or numeric and/or character codings on specimen receptacles, removable parts and/or accessories used with devices in order to perform the test or assay as intended	yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1
(g) the risks of any foreseeable interference with other devices.	No	There is no known risk of any foreseeable interference with other devices.		
13.3 Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.	No	The device is not flammable or combustible.		
13.4 Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.	No	The test does not require adjustment, calibration, or maintenance.		
13.5 Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.	Yes	ISO 15189, Section 4.14 – risk management	4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1
13.6 Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by users, or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.	yes	ISO 15189, Section 4.14 – risk management	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU) 4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1
13.7 The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the	No	Not applicable for a reagent product (antibody for IHC). The device does not have measuring, monitoring or display scale.		

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/ comment in case of deviation
environmental conditions in which the devices are intended to be used				
14 Devices with a measuring function				
14.1 Devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide appropriate analytical performance in accordance with point (a) of Section 9.1 of Annex I, taking into account the intended purpose of the device.	no	Not applicable for a reagent product (antibody for IHC). Device does not have a measuring function, monitoring or display scale.		
14.2 The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC	no	Device does not have a measuring function		
15. Protection against radiation				
15.1. Devices shall be designed, manufactured and packaged in such a way that exposure of users or other persons to radiation (intended, unintended, stray or scattered) is reduced as far as possible and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes.	no	Device does not emit radiation.		
15.2 When devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall as far as possible be: (a) designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and (b) fitted with visual displays and/or audible warnings of such emissions.	no	Device does not emit hazardous or potentially hazardous radiation		
15.3 The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.	no	Device does not emit hazardous or potentially hazardous radiation		
16. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves				
16.1 Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition,	No	The device does not incorporate an electronic programmable system.		

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/ comment in case of deviation
appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.				
16.2 For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.	No	The device does not incorporate software.		
16.3 Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).	No	The device does not incorporate software that is intended to be used in combination with mobile computing platforms.		
16.4 Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.	No	The device does not incorporate software.		
<b>17. Devices connected to or equipped with an energy source</b>				
17.1 For devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.	No	The device is not connected to an energy source		
17.2 Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.	no	The device or safety of the patient does not depend on an internal power supply of the device		
17.3 Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.	No	The device does not create electromagnetic interference.		
17.4 Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.	No	The device is not susceptible to electromagnetic interference.		

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/ comment in case of deviation
17.5 Devices shall be designed and manufactured in such a way as to avoid as far as possible the risk of accidental electric shocks to the user, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.	No	The device does not generate electricity.		
18. Protection against mechanical and thermal risks				
18.1 Devices shall be designed and manufactured in such a way as to protect users and other persons against mechanical risks.	No	There are no mechanical risks associated with the device		
18.2 Devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses inherent to the foreseen working environment, and to retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.	No	The device is not subject to mechanical stresses		
18.3. Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means shall be incorporated. Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.	yes	ISO 15189, Section 4.14 – risk management	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU) 4.2.4 risk and opportunity management / 4.2.4_1 Risk and opportunity assessment	See 1
18.4 Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance	no	Device does not produce vibration		
18.5 Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	no	Device does not generate or emit noise		
18.6 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.	no	Device has no such parts to be handled by the user and is not connected to energy supplies.		

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/comment in case of deviation
18.7 Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.	No			The device does not have fitting parts and does not need to be assembled
18.8 Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.	no			Device does not contain such assessable parts
<b>19. Protection against the risks posed by devices intended for self-testing or near-patient testing</b>				
19.1 Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in order to correctly interpret the result provided by the device and to avoid misleading information. In the case of near-patient testing, the information and the instructions provided by the manufacturer shall make clear the level of training, qualifications and/or experience required by the user.	no			Device is not for self-testing or near-patient testing and is for in-house use only (laboratory developed test)
19.2 Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to: (a) ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after appropriate training and/or information; and	no			Device is not for self-testing or near-patient testing and is for in-house use only (laboratory developed test)
(b) reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results	no			Device is not for self-testing or near-patient testing and is for in-house use only (laboratory developed test)
19.3 Devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended user: (a) can verify that, at the time of use, the device will perform as intended by the manufacturer; and	no			Device is not for self-testing or near-patient testing and is for in-house use only (laboratory developed test)
(b) be warned if the device has failed to provide a valid result.	no			Device is not for self-testing or near-patient testing and is for in-house use only (laboratory developed test)

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/comment in case of deviation
<b>CHAPTER III, REQUIREMENTS REGARDING INFORMATION SUPPLIED WITH THE DEVICE</b>				
<b>20. Label and instructions for use</b>				
<b>20.1. General requirements regarding the information supplied by the manufacturer</b>				
Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following: a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.	Yes	ISO 17020/15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	Device is for in-house use only (laboratory developed test)
b) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit. If individual full labelling of each unit is not practicable, the information shall be set out on the packaging of multiple devices.	Yes	ISO 17020/15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	Device is for in-house use only (laboratory developed test)
c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification or bar codes.	Yes	ISO 17020/15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	Device is for in-house use only (laboratory developed test)
d) Instructions for use shall be provided together with devices. However, in duly justified and exceptional cases instructions for use shall not be required or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.	yes	ISO 17020/15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	Device is for in-house use only (laboratory developed test)
e) Where multiple devices, with the exception of devices intended for self-testing or near-patient testing, are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any	no	Device is for in-house use only (laboratory developed test). All laboratory users will be trained on the use of the assay as per internal training protocols.		

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/ comment in case of deviation
case may request further copies to be provided free of charge.				
f) When the device is intended for professional use only, instructions for use may be provided to the user in non-paper format (e.g. electronic), except when the device is intended for near-patient testing.	no	Device is for in-house use only by qualified professionals (laboratory developed test). All laboratory users will be trained on the use of the assay as per internal training protocols		
g) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.	Yes	ISO 15189, Section 4.14 – risk management	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	See 1 Device is for in-house use only (laboratory developed test)
h) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols, taking into account the intended users. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.	no	Device is for in-house use only (laboratory developed test)		
i) In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant hazard pictograms and labelling requirements of Regulation (EC) No 1272/2008 shall apply. Where there is insufficient space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the label and the other information required by Regulation (EC) No 1272/2008 shall be given in the instructions for use	no	Device is for in-house use only (laboratory developed test). All information relevant for the users will be available in the CLDN6 IHC assay IFU.		
j) The provisions of Regulation (EC) No 1907/2006 on the safety data sheet shall apply, unless all relevant information, as appropriate, is already made available in the instructions for use	no	Device is for in-house use only (laboratory developed test). All information relevant for the users will be available in the CLDN6 IHC assay IFU.		
20.2 Information on the label				
The label shall bear all of the following particulars: (a) the name or trade name of the device;	no	Device is for in-house use only (laboratory developed test)		
(b) the details strictly necessary for a user to identify the device and, where it is not	no	Device is for in-house use only (laboratory developed test)		



General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/comment in case of deviation
obvious for the user, the intended purpose of the device;				
(c) the name, registered trade name or registered trademark of the manufacturer and the address of its registered place of business;	no	Device is for in-house use only (laboratory developed test)		
(d) if the manufacturer has its registered place of business outside the Union, the name of its authorised representative and the address of the registered place of business of the authorised representative	no	Device is for in-house use only (laboratory developed test). The single health institution is based in the EU (Hamburg, Germany).		
(e) an indication that the device is an in vitro diagnostic medical device, or if the device is a 'device for performance study', an indication of that fact;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	Device is for in-house use only (laboratory developed test)
(f) the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay on Leica Bond RX	Device is for in-house use only (laboratory developed test)
(g) the UDI carrier as referred to in Article 24 and Part C of Annex VI;	no	Device is for in-house use only (laboratory developed test)		
(h) an unambiguous indication of the time limit for using the device safely, without degradation of performance, expressed at least in terms of year and month and, where relevant, the day, in that order;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay on Leica Bond RX	Device is for in-house use only (laboratory developed test)
(i) where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;	no	N/A	N/A	Device is for in-house use only (laboratory developed test)
(j) where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of thereof, or other terms which accurately reflect the contents of the package;	no	Device is for in-house use only (laboratory developed test)		
(k) an indication of any special storage and/or handling condition that applies;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	Device is for in-house use only (laboratory developed test)

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/comment in case of deviation
				only (laboratory developed test)
(l) where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement indicating any special microbial state or state of cleanliness;	no	The device is not sterile and does not indicate any special microbial or clean state. Device is for in-house use only (laboratory developed test)		
(m) warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device or to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;	no	The device does not contain any components that could pose a danger to the user or other persons. Device is for in-house use only (laboratory developed test)		
(n) if the instructions for use are not provided in paper form in accordance with point (f) of Section 20.1, a reference to their accessibility (or availability), and where applicable the website address where they can be consulted;	no	The IFU will be provided in paper form. Device is for in-house use only (laboratory developed test)		
(o) where applicable, any particular operating instructions;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	Device is for in-house use only (laboratory developed test)
(p) if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;	no	The dispenser is not intended for single use. Device is for in-house use only (laboratory developed test)		
(q) if the device is intended for self-testing or near-patient testing, an indication of that fact;	no	The device is not for self-testing or near-patient testing. Device is for in-house use only (laboratory developed test)		
(r) where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof;	no	The test is not a rapid assay. Device is for in-house use only (laboratory developed test)		
(s) where device kits include individual reagents and articles that are made available as separate devices, each of those devices shall comply with the labelling requirements contained in this Section and with the requirements of this Regulation;	no	The reagents and articles of the kits are not made available as separate devices.		
(t) the devices and separate components shall be identified, where applicable in terms of batches, to allow all appropriate	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	Device is for in-house use

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/ comment in case of deviation
action to detect any potential risk posed by the devices and detachable components. As far as practicable and appropriate, the information shall be set out on the device itself and/or, where appropriate, on the sales packaging;				only (laboratory developed test)
(u) the label for devices for self-testing shall bear the following particulars: (i) the type of specimen(s) required to perform the test (e.g. blood, urine or saliva); (ii) the need for additional materials for the test to function properly; (iii) contact details for further advice and assistance The name of devices for self-testing shall not reflect an intended purpose other than that specified by the manufacturer.	no	The device is not for self-testing.		
20.3 Information on the packaging which maintains the sterile condition of a device ('sterile packaging'):				
The following particulars shall appear on the sterile packaging: (a) an indication permitting the sterile packaging to be recognised as such,	no	The device is not sterile.		
(b) a declaration that the device is in a sterile condition,	no	The device is not sterile		
c) the method of sterilisation,	no	The device is not sterile		
d) the name and address of the manufacturer,	no	The device is not sterile		
e) a description of the device,	no	The device is not sterile		
f) the month and year of manufacture,	no	The device is not sterile		
g) an unambiguous indication of the time limit for using the device safely, expressed at least in terms of year and month and, where relevant, the day, in that order,	no	The device is not sterile		
h) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.	no	The device is not sterile		
20.4. Information in the instructions for use				
20.4.1. The instructions for use shall contain all of the following particulars: (a) the name or trade name of the device;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A
(b) the details strictly necessary for the user to uniquely identify the device;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/comment in case of deviation
(c) the device's intended purpose: (i) what is detected and/or measured; (ii) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic); (iii) the specific information that is intended to be provided in the context of: — a physiological or pathological state; — congenital physical or mental impairments; — the predisposition to a medical condition or a disease; — the determination of the safety and compatibility with potential recipients; — the prediction of treatment response or reactions; — the definition or monitoring of therapeutic measures; (iv) whether it is automated or not; (v) whether it is qualitative, semi-quantitative or quantitative; (vi) the type of specimen(s) required; (vii) where applicable, the testing population; and	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU) CLDN6 IHC Assay Validation Report	N/A
(viii) for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for which it is a companion test.	No	The test is an investigational device.		
(d) an indication that the device is an in vitro diagnostic medical device, or, if the device is a 'device for performance study', an indication of that fact;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A
(e) the intended user, as appropriate (e.g. self-testing, near patient and laboratory professional use, healthcare professionals);	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A
(f) the test principle;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A
(g) a description of the calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A
(h) a description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/comment in case of deviation
(i) a list of materials provided and a list of special materials required but not provided;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A
(j) for devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment:  — information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics, and/or — information on any known restrictions to combinations of devices and equipment.	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A
(k) an indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions which apply;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A
(l) in-use stability which may include the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A
(m) if the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event of the sterile packaging being damaged before use;	no	The device is not sterile.		
(n) information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. That information shall cover, where appropriate:  (i) warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance,  (ii) warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/comment in case of deviation
(iii) warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,	No	This device does not pose risk of interference.		
(iv) precautions related to materials incorporated into the device that contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the patient or user,	No	The device does not contain CMR substances, or endocrine disrupting substances.		
(v) if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union,	No	The device is not for single use only.		
(vi) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilisation. Information shall be provided to identify when the device should no longer be reused, such as signs of material degradation or the maximum number of allowable reuses;	No	The device has limited/no risk for contamination. Only the quantity of device required for the intended number of tests per day is dispensed.		
(o) any warnings and/or precautions related to potentially infectious material that is included in the device;	no	The device does not contain potentially infectious material.		
(p) where relevant, requirements for special facilities, such as a clean room environment, or special training, such as on radiation safety, or particular qualifications of the intended user;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A
(q) conditions for collection, handling, and preparation of the specimen;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A
(r) details of any preparatory treatment or handling of the device before it is ready for use, such as sterilisation, final assembly, calibration, etc., for the device to be used as intended by the manufacturer;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A
(s) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:	no	The device does not require installation.		

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/comment in case of deviation
<ul style="list-style-type: none"> <li>— details of the nature, and frequency, of preventive and regular maintenance, including cleaning and disinfection;</li> <li>— identification of any consumable components and how to replace them;</li> <li>— information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;</li> <li>— methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.</li> </ul>				
(t) where applicable, recommendations for quality control procedures;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A
(u) the metrological traceability of values assigned to calibrators and control materials, including identification of applied reference materials and/or reference measurement procedures of higher order and information regarding maximum (self-allowed) batch to batch variation provided with relevant figures and units of measure;	no	The device does not have assigned values.		
(v) assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing shall be considered; where applicable, the instructions for use shall be accompanied by information regarding batch to batch variation provided with relevant figures and units of measure;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A
(w) analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and measurement range, (information needed for the control of known relevant interferences, cross-reactions and limitations of the method), measuring range, linearity and information about the use of available reference measurement procedures and materials by the user;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU) CLDN6 IHC Assay validation report	N/A
(x) clinical performance characteristics as defined in Section 9.1 of this Annex;	no	Clinical performance characteristics are not application for this device. Device is for in-house use only (laboratory developed test)		
(y) the mathematical approach upon which the calculation of the analytical result is made;	Yes	ISO15189 accreditation	2.3.7_4 CLDN6 IHC scoring form	N/A
(z) where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic specificity, positive and negative predictive value;	no	Clinical performance characteristics are not application for this device. Device is for in-house use only (laboratory developed test).		
(aa) where relevant, reference intervals in normal and affected populations;	no	Reference intervals in normal and affected populations not applicable to IHC products		



General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/comment in case of deviation
(ab) information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen) that may affect the performance of the device;	Yes	ISO15189 accreditation	CLDN6 IHC Assay validation report	N/A
(ac) warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the consumables used with it, if any. This information shall cover, where appropriate:  (i) infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human origin;  (ii) environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation;  (iii) physical hazards such as explosion.	no	The device is not contaminated with potentially infectious substances of human origin. The device does not include the use of batteries or emit radiation. The device is not an explosion hazard.		
(ad) the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business at which he can be contacted and its location be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU) CLDN6 IHC Assay validation report	N/A
(ae) date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use, with a clear indication of the introduced modifications;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU)	N/A
(af) a notice to the user that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established;	Yes	ISO15189 accreditation	2.3.7_2 CLDN6 IHC Assay Instructions for use (IFU) Safety recording and reporting plan	Device is for in-house use only (laboratory developed test)
(ag) where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the instructions for use requirements contained in this Section and with the requirements of this Regulation;	no	The individual reagents and articles are not available as separate tests		
(ah) for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.	no	The device does not incorporate software.		

General safety and performance requirement (GSPR)	Does GSPR apply to the device for performance study? (Yes/No)	Standards and common specifications used in full or in part	Evidence of conformance, documentation	Justification/comment in case of deviation
20.4.2 In addition, the instructions for use for devices intended for self-testing shall comply with all of the following principles: (a) details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation and information on how to run the test and interpret the results;	no	The device is not intended for self-testing and is for professional use only.		
(b) specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device;	no	The device is not intended for self-testing and is for professional use only.		
(c) the device's intended purpose shall provide sufficient information to enable the user to understand the medical context and to allow the intended user to make a correct interpretation of the results;	no	The device is not intended for self-testing and is for professional use only.		
(d) the results shall be expressed and presented in a way that is readily understood by the intended user;	no	The device is not intended for self-testing and is for professional use only.		
(e) information shall be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false negative result. Information shall also be provided as to any factors that can affect the test result such as age, gender, menstruation, infection, exercise, fasting, diet or medication;	no	The device is not intended for self-testing and is for professional use only.		
(f) the information provided shall include a statement clearly directing that the user should not take any decision of medical relevance without first consulting the appropriate healthcare professional, information on disease effects and prevalence, and, where available, information specific to the Member State(s) where the device is placed on the market on where a user can obtain further advice such as national helplines, websites;	no	The device is not intended for self-testing and is for professional use only.		
(g) for devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition, the information shall specify that the patient should only adapt the treatment if he has received the appropriate training to do so.	no	The device is not intended for self-testing and is for professional use only.		