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EU Conformity Assessment Checklist (Annex III)

Product Name(s):	Atellica CH 930
Catalogue Number (REF):	11067000
Siemens Material Number (SMN):	11067000

	Document Identifier:	**Version:**
Essential Requirements Checklist:	DX009766	3.0
EU Declaration of Conformity:	DoC_Atellica CH 930	1.0

Conformance to Directive 98/79/EC (IVD Directive)

This certifies that that the above-mentioned Essential Requirements Checklist and EU Declaration of Conformity have been reviewed and reflect all current European harmonized standards in effect. The product meets the criteria for CE marking as per the Conformity Assessment to the Requirements of Annex III of the IVD Directive (98/79/EC), as described below.

NOTE: Compliance with ISO 13485:2003 does not provide a presumption of conformity with all the aspects of Annex III. While some Annex III requirements are covered by ISO 13485:2003, others are not covered or are only partially covered (as outlined in EN ISO 13485:2012 Annex ZC.2). The demonstration of compliance to those Annex III requirements not fully covered by ISO 13485:2003, as outlined below, supports conformance to EN ISO 13485:2012.

Requirement of Directive 98/79/EC (IVD Directive) Annex III	**Evidence of Conformity**
1. The EC declaration of conformity is the procedure whereby the manufacturer or his authorised representative who fulfils the obligations imposed by section 2 to 5 and additionally, in the case of devices for self-testing, the obligations imposed by section 6, ensures and declares that the products concerned meet the provisions of this Directive which apply to them. The manufacturer must affix the CE marking in accordance with Article 16.	N/A. Procedural Requirement.
2. The manufacturer must prepare the technical documentation described in section 3 and ensure that the manufacturing process follows the principles of quality assurance as set out in section 4.	*The relevant manufacturing and process control documents are listed in the device master record.*
3. The technical documentation must allow assessment of the conformity of the product with the requirements of the Directive. It must include in particular:	Complies. See below.
— a general description of the product, including any variants planned, (Annex III, Section 3, Indent 1)	*Descriptions of the product and associated variants are located in the associated Essential Requirements Checklist.*
— the documentation of the quality system, (Annex III, Section 3, Indent 2)	This requirement is met through conformance to ISO 13485:2003, and the legal requirements for the EU are outlined in DQSP-00001: Global Quality Manual and DQSP-00069: Conformity to European Directives and Regulations.

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Requirement of Directive 98/79/EC (IVD Directive) Annex III	Evidence of Conformity
— design information, including the determination of the characteristics of the basic materials, characteristics and limitation of the performance of the devices, methods of manufacture and, in the case of instruments, design drawings, diagrams of components, sub-assemblies, circuits, etc., (Annex III, Section 3, Indent 3)	This requirement is met through conformance to ISO 13485:2003. *The relevant manufacturing and process control documents are listed in the device master record.*
— in the case of devices containing tissues of human origin or substances derived from such tissue, information on the origin of such material and on the conditions in which it was collected, (Annex III, Section 3, Indent 4)	*Not applicable. Does not contain tissues of human origin or substances derived from such tissue.*
— the descriptions and explanations necessary to understand the abovementioned characteristics, drawings and diagrams and the operation of the product, (Annex III, Section 3, Indent 5)	*Information regarding the technology and operation of the device is detailed in the Operator Manual.*
— the results of the risk analysis and, where appropriate, a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if the standards referred to in Article 5 have not been applied in full, (Annex III, Section 3, Indent 6)	*The risk report is referenced in the IVDD Essential Requirements Checklist. The risk analysis meets the requirements of EN ISO 14971:2012.*
— in the case of sterile products or products with a special microbiological state or state of cleanliness, a description of the procedures used, (Annex III, Section 3, Indent 7)	N/A. Not a sterile product.
— the results of the design calculations and of the inspections carried out, etc., (Annex III, Section 3, Indent 8)	This requirement is met through conformance to ISO 13485:2003.
— if the device is to be combined with other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when combined with any such device(s) having the characteristics specified by the manufacturer, (Annex III, Section 3, Indent 9)	See technical documentation for Atellica CH reagents, calibrators, controls, and other consumables.
— the test reports, (Annex III, Section 3, Indent 10)	This requirement is met through conformance to ISO 13485:2003.
— adequate performance evaluation data showing the performances claimed by the manufacturer and supported by a reference measurement system (when available), with information on the reference methods, the reference materials, the known reference values, the accuracy and measurement units used; such data should originate from studies in a clinical or other appropriate environment or result from relevant biographical references, (Annex III, Section 3, Indent 11)	*See performance data for the relevant assays.*
— the labels and instructions for use, (Annex III, Section 3, Indent 12)	*The relevant documents for labels and instructions for use are listed in the Essential Requirements Checklist.*
— the results of stability studies.	*Not applicable. Not a reagent, calibrator,*

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Requirement of Directive 98/79/EC (IVD Directive) Annex III			Evidence of Conformity
		(Annex III, Section 3, Indent 13)	*control, or other consumable.*
4.		The manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured. The system shall address:	Complies. See below.
	—	the organisational structure and responsibilities,	N/A. Procedural Requirement.
	—	the manufacturing processes and systematic quality control of production,	*The relevant manufacturing and process control documents are listed in the device master record.*
	—	the means to monitor the performance of the quality system.	N/A. Procedural Requirement.
5.		The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product. He shall notify the competent authorities of the following incidents immediately on learning of them:	Siemens Healthcare Diagnostics maintains procedures for complaint handling and corrective actions.
	(i)	any malfunction, failure or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to, or might have led to, the death of a patient or user or other persons or to a serious deterioration in his or their state of health;	See #5
	(ii)	any technical or medical reason connected with the characteristics or the performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.	See #5
6.		For devices for self-testing the manufacturer shall lodge an application for examination of the design with a notified body.	*N/A. Not a Self-Test Device.*
6.1		The application shall enable the design of the device to be understood and shall enable conformity with the design-related requirements of the directive to be assessed. It shall include:	*N/A. Not a Self-Test Device.*
	—	test reports including, where appropriate, results of studies carried out with lay persons,	*N/A. Not a Self-Test Device.*
	—	data showing the handling suitability of the device in view of its intended purpose for self-testing,	*N/A. Not a Self-Test Device.*
	—	the information to be provided with the device on its label and its instructions for use.	*N/A. Not a Self-Test Device.*
6.2		The notified body shall examine the application and, if the design conforms to the relevant provisions of this Directive shall issue the applicant with an EC design-examination certificate. The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the design-related requirements of the Directive. The certificate shall contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design and, where appropriate, a description of the intended purpose of the product.	*N/A. Not a Self-Test Device.*
6.3		The applicant shall inform the notified body which issued the EC design-examination certificate of any significant change made to the approved design. Changes to the approved design must receive	*N/A. Not a Self-Test Device.*

Requirement of Directive 98/79/EC (IVD Directive) Annex III	Evidence of Conformity
further approval from the notified body which issued the EC design-examination certificate wherever the changes could affect conformity with the essential requirements of the Directive or with the conditions prescribed for use of the product. This additional approval shall take the form of a supplement to the EC design-examination certificate.	

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Conformance to the RoHS Directive (2011/65/EU)

This certifies that that the above-mentioned EU Declaration of Conformity has been reviewed and reflects all current European harmonized standards in effect. The product meets the criteria for CE marking as per the Conformity Assessment procedure outlined in Annex II, Module A (internal production control) of Decision No 768/2008/EC, required by Article 7 of the RoHS Directive (2011/65/EU), as described below.

Requirement of Decision No 768/2008/EC, Annex II, Module A	**Evidence of Conformity**
1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.	N/A. Procedural Requirement.
2. Technical Documentation The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain at least the following elements:	Complies. See below.
— a general description of the product, (Annex II, Module A, Section 2, Indent 1)	*Descriptions of the product and associated variants are located in the associated Essential Requirements Checklist.*
— conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc., (Annex II, Module A, Section 2, Indent 2)	*The relevant manufacturing and process control documents are listed in the device master record.*
— descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product, (Annex II, Module A, Section 2, Indent 3)	*Information regarding the technology and operation of the device is detailed in the Operator Manual.*
— a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonized standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied, (Annex II, Module A, Section 2, Indent 4)	Appropriate harmonized standards are referenced in the Essential Requirements Checklist.
— results of design calculations made, examinations carried out, etc., and (Annex II, Module A, Section 2, Indent 5)	Supplier declarations and/or contractual agreements, material declarations, and analytical test results are included in the technical documentation.
— test reports. (Annex II, Module A, Section 2, Indent 6)	Analytical test results are included in the technical documentation.

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Requirement of Decision No 768/2008/EC, Annex II, Module A		Evidence of Conformity
3.	The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the legislative instruments that apply to them.	Supplier declarations and/or contractual agreements, material declarations, and analytical test results are included in the technical documentation.
4.	Conformity marking and declaration of conformity	Complies. See below.
	4.1 The manufacturer shall affix the required conformity marking set out in the legislative instrument to each individual product that satisfies the applicable requirements of the legislative instrument.	The CE-mark is affixed to the device and the EU Declaration of Conformity.
	4.2 The manufacturer shall draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product for which it has been drawn up. A copy of the declaration of conformity shall be made available to the relevant authorities upon request.	EU Declaration of Conformity *(Referenced on page 1)*
5.	Authorised representative The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.	The manufacturer is responsible for conformity marking and the EU Declaration of Conformity.

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Date
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