Attachment – PUBLIC

General Information on MDR/IVDR Application

Dear Customer,

Thank you for being interested in the certification service of TÜV SÜD Product Service GmbH. With this document, we inform you about the Terms and Conditions for our services. It includes obligations, rights and duties for the regulations for medical devices and in-vitro diagnostics.

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1 Terms and Conditions, Testing and Certification Regulation

General Terms and Conditions of Business of TÜV SÜD Product Service GmbH, Testing, Certification, Validation and Verification Regulation TÜV SÜD Group and TÜV SÜD Code of Conduct can be found here:

www.tuvsud.com/de-de/ueber-uns/unsere-gesellschaften/product-service/geschaeftsbedingungen

The General Terms and Conditions of Business of TÜV SÜD Product Service GmbH and the Testing, Certification, Validation and Verification Regulation of the TÜV SÜD Group, which, in accordance with the quotation submitted by TÜV SÜD Product Service GmbH, form the basis of this contract.

Applicants that do not yet have the status of partners in the certification scheme of TÜV SÜD Product Service GmbH will automatically become partners in this scheme upon certificate issue.

2 Information on MDR Application

2.1 Overview: Conformity assessment procedures

Conformity Assessment Procedure		**Applied for devices of**
Annex IX	**Chapter I&III** (Quality Management System)	Class I devices in sterile condition, with measuring function or reusable surgical instruments
		Systems and procedure packs sterilised in accordance with the manufacturer's instructions, Article 22(3)
		Class IIa, Class IIb devices and Class IIb implantable devices limited to exempted devices according to Art. 52
		Class III and Class IIb implantable devices other than exempted ones according to Art. 52.
	Chapter II (Assessment of Technical Documentation)	
	Chapter I (Quality Management System)	Class III implantable custom-made devices
Annex XI	**Part A** (Production Quality Assurance)	Class I devices in sterile condition, with measuring function or reusable surgical instruments
		Systems and procedure packs sterilised in accordance with the manufacturer's instructions, Article 22(3)
	Part B (Product Verification)	Class IIa devices
	Part A (Production Quality Assurance)	Class III implantable custom-made devices and Class IIa devices
	Part A (Production Quality Assurance) or **Part B** (Product Verification)	Class III and Class IIb devices
Annex X (Type Examination)		

2.2 Obligations of the manufacturer

The manufacturer undertakes to comply with all the requirements arising from Regulation (EU) 2017/745 on medical devices. The manufacturer is obliged to enable the notified body to act as required under Regulation (EU) 2017/745 on medical devices.

This includes but is not limited to the following obligations:

General Information on MDR/IVDR Application

Obligation *Reference to Regulation (EU) 2017/745 on medical devices*	**Conformity Assessment Route**			
	Annex IX Chapters I & III	**Annex IX Chapter II**	**Annex X**	**Annex XI**
In case the device presents a serious risk, the manufacturer declares to immediately inform, where applicable, the notified body that issued a certificate for the device in accordance with Article 56, in particular, of the non-compliance and of any corrective action taken. *Article 10, 12*	**Yes**	**Yes**	**Yes**	**Yes**
The manufacturer declares that if in the course of the post-market surveillance a need for preventive or corrective action or both is identified, to implement appropriate measures and to inform, where applicable, TÜV SÜD Product Service GmbH. *Article 83, 4*	**Yes**	**Yes**	**Yes**	**Yes**
In case of manufacturing class III or implantable devices, the manufacturer declares to submit PSURs by means of the electronic system referred to in Article 92 to TÜV SÜD Product Service GmbH in accordance with Article 52. *Article 86, 2*	**Yes**	**Yes**	**Yes**	**Yes**
The manufacturer declares to inform TÜV SÜD Product Service GmbH of vigilance reports information (referred to in Article *92, 1a -e*): • The reports by manufacturers on serious incidents and field safety corrective actions referred to in *Article 87(1) and Article 89(5)*; • The periodic summary reports by manufacturers referred to in *Article 87(9)*; • The reports by manufacturers on trends referred to in *Article 88*; • The field safety notices by manufacturers referred to in *Article 89(8)*; The information shall be submitted via the electronic system on vigilance and post market surveillance referred to in *Article 92*. In case the electronic system is not functional, TÜV SÜD Product Service GmbH shall be informed directly and simultaneously to the relevant competent authority of every abovementioned vigilance information. The reporting shall be done immediately, i.e. without culpable hesitation, but no later than 15 calendar days in case of serious incidents, 10 calendar days in case of death incidents or unanticipated serious deterioration in a person's state of health and 2 calendar days in case of serious public health threat, starting from the date the manufacturer became aware of the serious incident. Every field safety corrective action or field safety notice shall be reported to the notified body immediately and in advance of the field safety corrective action being undertaken. *Article 87, 3-5, 8* All reporting shall be done using the formal templates and forms which have been made available by the Commission. Every vigilance information or related documents must be submitted to the notified body in English and/or in German.	**Yes**	**Yes**	**Yes**	**Yes**

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Obligation *Reference to Regulation (EU) 2017/745 on medical devices*	**Conformity Assessment Route**			
	Annex IX Chapters I & III	**Annex IX Chapter II**	**Annex X**	**Annex XI**
The manufacturer declares to inform TÜV SÜD Product Service GmbH of any plans for significant changes to the quality management system or the device-range covered. *Annex IX, 2.4 and Annex XI, Part A, 6.4*	**Yes**	**Yes**	–	**Yes** (in case of Part A)
The manufacturer declares to inform TÜV SÜD Product Service GmbH of any planned change to the approved type or its intended purpose and conditions of use. *Annex X, 5.1*	–	–	**Yes**	–
The manufacturer declares to inform TÜV SÜD Product Service GmbH of plans to introduce changes to the approved device which could affect the safety and performance of the device, or the conditions prescribed for use of the device. *Annex IX, 4.10*	–	**Yes**	–	–
The manufacturer declares to inform TÜV SÜD Product Service GmbH of any planned changes with respect to an ancillary substance incorporated in a device, if applicable, in particular related to its manufacturing process. *Annex IX, 5.2f*	–	**Yes** (if 5.2 is applicable)	–	–
The manufacturer declares to inform TÜV SÜD Product Service GmbH of any intended change with respect to non-viable tissues or cells of human origin incorporated in a device, if applicable, in particular related to its donation, testing or procurement. *Annex IX, 5.3.1 d*	–	**Yes** (if 5.3.1 is applicable)	–	–
The manufacturer declares to inform TÜV SÜD Product Service GmbH of the release of the batch of devices following Annex IX 5.4, if applicable, and to send to TÜV SÜD Product Service GmbH the official certificate concerning the release of the batch of human blood or plasma derivate used in the device. *Annex IX, Ch. II, 6 and Annex XI, Part A, 8 and Part B, 16*	–	**Yes**	–	**Yes**

2.3 Obligations of the Authorised Representative

This section is applicable if the manufacturer is not established in a member state of the European Union. The mandate of the authorised representative (see Article 11) shall enable the authorised representative to comply with all the requirements related to authorised representatives arising from Regulation (EU) 2017/745 on medical devices.

This includes but is not limited to the following obligation:

Obligation *Reference to Regulation (EU) 2017/745 on medical devices*	**Conformity Assessment Route**			
	Annex IX Chapters I & III	**Annex IX Chapter II**	**Annex X**	**Annex XI**
An authorised representative who terminates its mandate on the ground referred to in point (h) of paragraph 3 shall immediately inform, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor. *Article 11, 6*	**Yes**	**Yes**	**Yes**	**Yes**

2.4 Rights and duties of the Notified Bodies

2.4.1 General

TÜV SÜD Product Service GmbH may suspend, restrict or withdraw certificates issued (Regulation (EU) 2017/745 on medical devices, Annex VII, 4.3) under the circumstances described in the Testing and Certification Regulation TÜV SÜD Group.

TÜV SÜD Product Service GmbH may impose restrictions to the intended purpose of a device to certain groups of patients or require manufacturers to undertake specific PMCF studies pursuant to Part B of Annex XIV (Regulation (EU) 2017/745 on medical devices, Article 56, 3).

2.4.2 Information obligation towards third parties

The manufacturer accepts that TÜV SÜD Product Service GmbH…

- may exchange information (with the Commission and/or Member States), may disseminate warnings and may provide information under criminal law.

  Article 109,3

- submits data to as well as gets data from the European database on medical devices following the requirements of Regulation (EU) 2017/745 on medical devices.

  Article 31,2; Article 32,1; Article 53; Article 57; Article 92,2; Annex VI, Part A 2.2; Annex VII, 4.3

- makes available and submits upon request all relevant documentation, including the manufacturer´s documentation to the authority responsible for notified bodies.

  Article 36, 2

- conducts clinical audits on the quality management system and its outputs for manufacturers of high-risk products such as class III, implantable and active Class IIb (rule 12) devices. A clinical audit is an element of the risk-based overall surveillance prom and takes place at least once in a 3-year period. These audits are conducted by specifically qualified and trained auditors.

  Annex VII, 4.5.1, 4.5.2., 4.5.5

- makes available and submits upon request assessments of the manufacturer´s technical documentation, in particular the clinical evaluation documentation, to the authority responsible for notified bodies.

  Article 45, 1

TÜV SÜD Product Service GmbH…

- informs the manufacturers concerned at the latest within 10 days, if the designation of TÜV SÜD Product Service GmbH has been suspended, restricted, or fully or partially withdrawn.

  Article 46, 5

- informs the manufacturers concerned as soon as possible and in the case of a planned cessation one year before ceasing its conformity assessment activities.

  Article 46, 3

- ensures publicly availability of information according to the requirements of Regulation (EU) 2017/745 on medical devices.

  Articles 37,3; Article 50; Annex VII, 1.2.5, 4.2;

- ensures to inform of the requirements related to subcontractors and/or external experts involved in conformity assessment activities.

  Annex VII, 3.4.2

- informs as outlined in the Testing and Certification Regulation TÜV SÜD Group.

2.5 Documentation to be submitted within conformity assessment

The following sections define the minimum content of documentation required for the respective conformity assessment procedure, the time limits of documentation submission and the respective reference to Regulation (EU) 2017/745 on medical devices.

Accessibility requirements

The manufacturer must submit the documentation being part of the respective conformity assessment either in English and/or in German. A ‘read only’ access to the documentation only via manufacturers electronic data platform (e.g. IT-systems, cloud) is not permitted.

If necessary, further documents apart from the ones listed within these sections may be requested during the assessment.

Time limits of submission

The following points in time exist for the submission of documentation:

1. “Lodge of Application”, i.e. documentation to be submitted together with this application.
2. “Assessment of the quality management system”, i.e. documentation to be submitted to enable the assessment of the quality management system during an audit and/or during technical documentation assessment.

Provisions of providing the technical documentation

In case the conformity assessment procedure applied for is linked to assessment of technical documentation for devices selected on a representative basis, the manufacturer is obliged to provide the technical documentation as referred to in Annexes II and III without undue delay.

In case the amending Regulation (EU) 2023/607 to the MDR Regulation (EU) 2017/745 applies and the defined conditions are fulfilled, a timeline should be provided for possible submission of the individual technical documentation and any other relevant information.

2.5.1 Annex IX Chapter I & III – Quality Management System

Timepoint 1: Lodge of application

Documentation to be submitted until Lodge of Application	*MDR reference*
Draft of an EU declaration of conformity for the device model covered by this application	*Annex IX Ch. I Sec. 2.1 indent 4*
Documentation on the quality management system such as quality programs, procedures, quality plans and quality manuals including	
↳ The documentation on the manufacturer's quality management system	*Annex IX Ch. I Sec. 2.1 indent 5*
↳ A documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under the MDR and the undertaking by the manufacturer to apply those procedures.	*Annex IX Ch. I Sec. 2.1 indent 6*
↳ A description of the procedures in place to ensure that the quality management system remains adequate and effective and the undertaking by the manufacturer to apply those procedures.	*Annex IX Ch. I Sec. 2.1 indent 7*
↳ The documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92	*Annex IX Ch. I Sec. 2.1 indent 8*
↳ A description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92 as well as the undertaking by the manufacturer to apply those procedures.	*Annex IX Ch. I Sec. 2.1 indent 9*
↳ A documentation on the clinical evaluation plan and a description of the procedures in place to keep it up to date, taking into account the state of the art.	*Annex IX Ch. I Sec. 2.1 indent 10 & 11*

Timepoint 2: Assessment of Quality Management System

Documentation to be submitted until assessment of Quality Management System	*MDR reference*
The manufacturer's quality objectives	*Annex IX Ch. I Sec. 2.2 (a)*
The organisation of the business including in particular	*Annex IX Ch. I Sec. 2.2 (b)*
↳ The organisational structures with the assignment of staff responsibilities in relation to critical procedures, the responsibilities of the managerial staff and their organisational authority.	*Annex IX Ch. I Sec. 2.2 (b) Indent 1*
↳ The methods of monitoring whether the operation of the quality management system is efficient and in particular the ability of that system to achieve the desired design and device quality, including control of devices which fail to conform.	*Annex IX Ch. I Sec. 2.2 (b) Indent 2*
↳ where the design, manufacture and/or final verification and testing of the devices, or parts of any of those processes, is carried out by another party: the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party	*Annex IX Ch. I Section 2.2 (b) Indent 3*

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Documentation to be submitted until assessment of Quality Management System	***MDR reference***
↳ where the manufacturer does not have a registered place of business in a Member State: The draft mandate for the designation of an authorised representative and a letter of intention from the authorised representative to accept the mandate	*Annex IX Ch. I Sec. 2.2 (b) Indent 4*
The procedures and techniques for monitoring, verifying, validating and controlling the design of the devices and the corresponding documentation as well as the data and records arising from those procedures and techniques. Those procedures and techniques shall specifically cover:	*Annex IX Ch. I Sec. 2.2 (c)*
↳ The strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence, choice of and compliance with conformity assessment procedures.	*Annex IX Ch. I Sec. 2.2(c) Indent 1*
↳ Identification of applicable general safety and performance requirements and solutions to fulfil those requirements, taking applicable CS and, where opted for, harmonised standards or other adequate solutions into account.	*Annex IX Ch. I Sec. 2.2 (c) Indent 2*
↳ Risk management as referred to in Section 3 of Annex I	*Annex IX Ch. I Sec. 2.2 (c) Indent 3*
↳ Clinical evaluation, including post-market clinical follow-up pursuant to Article 61 and Annex XIV	*Annex IX Ch. I Sec. 2.2 (c) Indent 4*
↳ Solutions for fulfilling the applicable specific requirements regarding design and construction, including appropriate pre-clinical evaluation, in particular the requirements of Chapter II of Annex I.	*Annex IX Ch. I Sec. 2.2 (c) Indent 5*
↳ Solutions for fulfilling the applicable specific requirements regarding the information to be supplied with the device, in particular the requirements of Annex I Chapter III	*Annex IX Ch. I Sec. 2.2 (c) Indent 6*
↳ The device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture	*Annex IX Ch. I Sec. 2.2 (c) Indent 7*
↳ Management of design or quality management system changes	*Annex IX Ch. I Sec. 2.2 (c) Indent 8*
The verification and quality assurance techniques at the manufacturing stage and in particular the processes and procedures which are to be used, particularly as regards sterilisation and the relevant documents.	*Annex IX Ch. I Sec. 2.2 (d)*
The appropriate tests and trials which are to be carried out before, during and after manufacturing, the frequency with which they are to take place, and the test equipment to be used; it shall be possible to trace back adequately the calibration of that test equipment.	*Annex IX Ch. I Sec. 2.2 (e)*
In case of **Class IIb active devices intended to administer and/or remove medicinal products**	

Documentation to be submitted until assessment of Quality Management System	*MDR reference*
↳ Technical documentation as referred to in Annexes II and III including clinical data and clinical evaluation	*Annex IX Ch. II Sec. 5.1 (a)*
In case of **Class IIa implantable devices** and **Class IIb implantable devices limited to** sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors	
↳ Technical documentation as referred to in Annexes II and III including clinical data and clinical evaluation	*Annex IX Ch. II Sec. 4.2*
↳ Draft of the summary of safety and clinical performance (according to Article 32,1))	*Article 32,1*

2.5.2 Annex IX Chapter II – Technical documentation

Timepoint 1: Lodge of application

Documentation to be submitted until lodge of application	MDR reference
Technical documentation as referred to in Annexes II and III including clinical data and clinical evaluation	*Annex IX Ch. II Sec. 4.2*
Draft of the summary of safety and clinical performance (according to Article 32,1))	*Article 32,1*

2.5.3 Annex X – Type examination

Timepoint 1: Lodge of application

Documentation to be submitted until lodge of application	*MDR reference*
Technical documentation as referred to in Annexes II and III including clinical data and clinical evaluation	*Annex X Sec. 2 Indent 2*
Information about the representative sample of the device production envisaged ('type') made available to TÜV SÜD Product Service GmbH (Please note: TÜV SÜD Product Service GmbH may request additional samples as necessary)	*Annex X Sec. 2 Indent 2*
In case of **Class III devices** and **implantable device**	
↳ Draft of the summary of safety and clinical performance (according to Article 32,1))	*Article 32,1*

2.5.4 Annex XI Part A – Production quality assurance

Timepoint 1: Lodge of application

Documentation to be submitted until lodge of application	MDR reference
Draft of an EU declaration of conformity for the device model covered by this application	*Annex XI Part A 5.*
Documentation on the quality management system such as quality programs, procedures, quality plans and quality manuals including	*Annex XI Part A Sec. 6.1 Indent 1*
↳ The documentation on the manufacturer's quality management system	*Annex XI Part A Sec. 6.1 Indent 1*

General Information on MDR/IVDR Application

Documentation to be submitted until lodge of application	MDR reference
↳ A documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under the MDR and the undertaking by the manufacturer to apply those procedures.	*Annex XI Part A Sec. 6.1 Indent 1*
↳ A description of the procedures in place to ensure that the quality management system remains adequate and effective and the undertaking by the manufacturer to apply those procedures.	*Annex XI Part A Sec. 6.1 Indent 1*
↳ The documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92	*Annex XI Part A Sec. 6.1 Indent 1*
↳ A description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92 as well as the undertaking by the manufacturer to apply those procedures.	*Annex XI Part A Sec. 6.1 Indent 1*
↳ A documentation on the clinical evaluation plan and a description of the procedures in place to keep it up to date, taking into account the state of the art.	*Annex XI Part A Sec. 6.1 Indent 1*
If the EU-type examination certificates **have been issued by another notified body**	
↳ Technical documentation referred to in the Annexes II and III for the types approved	*Annex XI Part A Sec. 6.1 Indent 2*
↳ copy of the EU-type examination certificates referred to in Section 4 of Annex X	*Annex XI Part A Sec. 6.1 Indent 3*
If the EU-type examination certificates **have been issued by TÜV SÜD Product Service GmbH**	
↳ Reference to the technical documentation and its updates	*Annex XI Part A Sec. 6.1 Indent 2*
↳ Reference to the certificates issued	*Annex XI Part A Sec. 6.1 Indent 3*
In case of **Class IIa implantable devices**	
↳ Technical documentation as referred to in Annexes II and III including clinical data and clinical evaluation	*Annex XI 3.*
↳ Draft of the summary of safety and clinical performance (according to Article 32,1)	*Article 32, 1*

Timepoint 2: Assessment of Quality Management System

Documentation to be submitted until assessment of quality management system	*MDR reference*
The manufacturer's quality objectives	*Annex XI Part A Sec. 6.2*
The manufacturer's quality objectives	*Annex IX Ch. I Sec. 2.2 (a)*

The organisation of the business including in particular	*Annex XI Part A Sec. 6.2*
↳ The organisational structures with the assignment of staff responsibilities in relation to critical procedures, the responsibilities of the managerial staff and their organisational authority.	*Annex XI Part A Sec. 6.2*
↳ The methods of monitoring whether the operation of the quality management system is efficient and in particular the ability of that system to achieve the desired design and device quality, including control of devices which fail to conform.	*Annex XI Part A Sec. 6.2*
↳ where the design, manufacture and/or final verification and testing of the devices, or parts of any of those processes, is carried out by another party: the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party	*Annex XI Part A Sec. 6.2*
↳ where the manufacturer does not have a registered place of business in a Member State: The draft mandate for the designation of an authorised representative and a letter of intention from the authorised representative to accept the mandate	*Annex XI Part A Sec. 6.2*
The verification and quality assurance techniques at the manufacturing stage and in particular the processes and procedures which are to be used, particularly as regards sterilisation and the relevant documents.	*Annex XI Part A Sec. 6.2*
The appropriate tests and trials which are to be carried out before, during and after manufacturing, the frequency with which they are to take place, and the test equipment to be used; it shall be possible to trace back adequately the calibration of that test equipment.	*Annex XI Part A Sec. 6.2*

2.5.5 Annex XI Part B – Product verification

Timepoint 1: Lodge of application

Documentation to be submitted until lodge of application	***MDR reference***
If the EU-type examination certificates **have been issued by another notified body**	
↳ Technical documentation referred to in the Annexes II and III for the types approved	*Annex XI Part B 12.*
↳ Copy of the EU-type examination certificates referred to in Section 4 of Annex X	*Annex XI Part B 12.*
If the EU-type examination certificates **have been issued by TÜV SÜD Product Service GmbH**	
↳ Reference to the technical documentation and its updates	*Annex XI Part B 12.*
↳ Reference to the certificates issued	*Annex XI Part B 12.*
In case of **Class IIa devices**	
↳ Technical documentation referred to in the Annexes II and III	*Annex XI Part B 18.*
In case of **Class IIa implantable devices**	
↳ Draft of the summary of safety and clinical performance (according to Article 32,1)	*Article 32, 1*

2.6 Obligations under MDR Article 120(3) (Directives 93/42/EEC (MDD) or 90/385/EEC (AIMDD))

The manufacturer undertakes to comply with all other requirements following from the Medical Devices Directives (EC Directives) and their transposition into the national law of the EU Member States.

Obligation	**Conformity assessment according to Annex**					
Directive 93/42/EC (MDD)	**II w/o (4)**	**II.4**	**III**	**IV**	**V**	**VI**
Relevant Type of certificate at TÜV SÜD PS GmbH	*G1*	*G7*	*G5*	*G0*	*G2*	*G3*
Directive 90/385/EC (AIMDD)	**2 w/o (4)**	**2.4**	**3**	**4**	**5**	**-**
Relevant Type of certificate at TÜV SÜD PS GmbH	*I1*	*I7*	*I5*	*I8*	*I2*	
The manufacturer declares that there are no significant changes in the design and intended purpose of devices.	Yes	Yes	Yes	Yes	Yes	Yes
The manufacturer declares that it has adjusted its quality management system according to the requirements of Article 120(3) MDR concerning significant changes (MDCG 2020-3 endorsed guidance for clarification).	Yes	-	-	-	Yes	Yes
The undersigned undertakes to fulfil the obligation of Article 120 (3) of Regulation (EU) 2017/745 regarding the adjustment of quality management system on post-market surveillance, vigilance, registration of economic operators and of devices.	Yes	-	-	-	Yes	Yes
The undersigned declares that - all appropriate processes relating to post-market surveillance including risk management and clinical data feed into the post-market surveillance plan. - If applicable, the output of all post-market surveillance activities are included and reflected in a PSUR, and that the PSUR update cycle is appropriate and according to its current risk class as defined in Article 86 MDR.	Yes	Yes	Yes	Yes	Yes	Yes

3 Information on IVDR Application

3.1 Overview: Conformity assessment procedures

Conformity Assessment Procedure		Applied for devices of
Annex IX	**Chapter I&III** (Quality Management System)	Class A devices in sterile condition
		Class B devices excluding Self-testing/Near-patient testing Class C devices excluding Self-testing/ Near-patient testing/ Companion Diagnostics
		Class B devices for Self-testing/ Near-patient testing Class C devices for Self-testing/ Near-patient testing/ Companion Diagnostics Class D devices including Self-testing/ Near-patient testing
	Chapter II (Assessment of Technical Documentation)	
Annex XI (Product Quality Assurance)		Class A devices in sterile condition
		Class C and Class D devices
Annex X (Type Examination)		

3.2 Obligations of the manufacturer

The manufacturer undertakes to comply with all the requirements arising from Regulation (EU) 2017/746 on in vitro diagnostic medical devices. The manufacturer is obliged to enable the notified body to act as required under Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

This includes but is not limited to the following obligations:

Obligation *Reference to Regulation (EU) 2017/746 on in vitro diagnostic medical devices*	**Conformity Assessment Route**			
	Annex IX Chapters I and III	**Annex IX Chapter II**	**Annex X**	**Annex XI**
In case the device presents a serious risk, the manufacturer declares to immediately inform, where applicable, the notified body that issued a certificate for the device in accordance with Article 51, in particular, of the non-compliance and of any corrective action taken. *Article 10 (11)*	**Yes**	**Yes**	**Yes**	**Yes**
The manufacturer declares that if in the course of the post-market surveillance a need for preventive or corrective action or both is identified, to implement appropriate measures and to inform, where applicable, TÜV SÜD Product Service GmbH. *Article 78 (4)*	**Yes**	**Yes**	**Yes**	**Yes**
In case of **manufacturing class D devices**, the manufacturer declares to submit PSURs by means of the electronic system referred to in Article 87 to TÜV SÜD Product Service GmbH. *Article 81 (2)*	–	**Yes**	**Yes**	**Yes**

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Obligation *Reference to Regulation (EU) 2017/746 on in vitro diagnostic medical devices*	**Conformity Assessment Route**			
	Annex IX Chapters I and III	**Annex IX Chapter II**	**Annex X**	**Annex XI**
The manufacturer declares to inform TÜV SÜD Product Service GmbH of vigilance reports information (referred to in *Article 87 (1a - e)*): • the reports by manufacturers on serious incidents and field safety corrective actions referred to in *Article 82 (1) and Article 84 (5)*; • the periodic summary reports by manufacturers referred to in *Article 82 (9)*; • the reports by manufacturers on trends referred to in *Article 83*; • the PSURs referred to in *Article 81*; • the field safety notices by manufacturers referred to in *Article 84 (8)*; The information shall be submitted via the electronic system on vigilance and post market surveillance referred to in *Article 87 (9)*. In case the electronic system is not functional, TÜV SÜD Product Service GmbH shall be informed directly and simultaneously to the relevant competent authority of every above-mentioned vigilance information. The reporting shall be done immediately, i.e. without culpable hesitation, but no later than 15 calendar days in case of serious incidents, 10 calendar days in case of death incidents or unanticipated serious deterioration in a person's state of health and 2 calendar days in case of serious public health threat, starting from the date the manufacturer became aware of the serious incident. Every field safety corrective action or field safety notice shall be reported to the notified body immediately and in advance of the field safety corrective action being undertaken. *Article 82 (3-5, 8)* All reporting shall be done using the formal templates and forms which have been made available by the Commission. Every vigilance information or related documents must be submitted to the notified body in English and/or in German.	**Yes**	**Yes**	**Yes**	**Yes**
The manufacturer declares to inform TÜV SÜD Product Service GmbH of any plans for significant changes to the quality management system or the device-range covered. *Annex IX 2.4 and Annex XI 3.4*	**Yes**	**Yes**	–	**Yes**
The manufacturer declares to inform TÜV SÜD Product Service GmbH of any planned change to the approved type or its intended purpose and conditions of use. *Annex X 5.1*	–	–	**Yes**	–
The manufacturer declares to inform TÜV SÜD Product Service GmbH of plans to introduce changes to the approved device which could affect the safety and performance of the device, or the conditions prescribed for use of the device. *Annex IX (4.11) 1st paragraph* The manufacturer of class D device declares to inform TÜV SÜD Product Service GmbH of plans to introduce changes to the approved device which could affect compliance with the CS or with other solutions chosen by the manufacturer. *Annex IX 4.11 2nd paragraph*	–	**Yes**	–	–

Obligation *Reference to Regulation (EU) 2017/746 on in vitro diagnostic medical devices*	**Conformity Assessment Route**			
	Annex IX Chapters I and III	**Annex IX Chapter II**	**Annex X**	**Annex XI**
The manufacturer of **class B, C and D devices for self-testing and near-patient testing** declares to inform TÜV SÜD Product Service GmbH of plans to introduce changes to the approved device which could affect the safety and performance of the device, or the conditions prescribed for use of the device. *Annex IX 5.1(f)*	-	**Yes** (if 5.1 is applicable)		
The manufacturer declares to inform TÜV SÜD Product Service GmbH of any planned changes affecting the performance and/or the intended use and/or the suitability of the **companion diagnostics device** in relation to the medicinal product concerned. *Annex IX 5.2(f)*	–	**Yes** (if 5.2 is applicable)	–	–
The manufacturer declares to inform TÜV SÜD Product Service GmbH of the **relevant reports of the batch release of class D devices (conclusion of the controls and tests)**. *Annex IX 4.12 and Annex XI 5.1*	–	**Yes** (if class D device)	–	**Yes**
The manufacturer declares to make the samples of manufactured batches of class D devices available to the notified body in accordance with pre-agreed conditions and detailed arrangements which shall include that the notified body or the manufacturer shall send samples of the manufactured batches of devices to the EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate tests. *Annex IX 4.12 and Annex XI 5.1*	–	**Yes** (if class D device)	–	**Yes**
The manufacturer declares to give authorisation to the notified body to carry out all the necessary audits, including on-site audits, and supply it with all relevant information listed in Annex IX 3.2 for surveillance assessment. *Annex IX 3.2 and Annex XI 4*	**Yes**	**-**	-	**Yes**

3.3 Obligations of the Authorised Representative

This section is applicable if the manufacturer is not established in a member state of the European Union. The mandate of the authorised representative (see Article 11) shall enable the authorised representative to comply with all the requirements related to authorised representatives arising from Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

This includes but is not limited to the following obligation related to information submission to TÜV SÜD Product Service GmbH:

Obligation *Reference to Regulation (EU) 2017/746 on in vitro diagnostic medical devices*	**Conformity Assessment Route**			
	Annex IX Chapters I and III	**Annex IX Chapter II**	**Annex X**	**Annex XI**
An authorised representative who terminates its mandate on the ground referred to in point (h) of paragraph 3 shall immediately inform, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor. *Article 11 (6)*	**Yes**	**Yes**	**Yes**	**Yes**

3.4 Rights and duties of the Notified Bodies

3.4.1 General

TÜV SÜD Product Service GmbH may suspend, restrict, or withdraw certificates issued (Regulation (EU) 2017/746 on in vitro diagnostic medical devices, Annex VII (4.3)) under the circumstances described in the Testing and Certification Regulations of the TÜV SÜD Group.

TÜV SÜD Product Service GmbH may impose restrictions to the intended purpose of a device to certain groups of patients or require manufacturers to undertake specific PMPF studies pursuant to Part B of Annex XIII (Regulation (EU) 2017/746 on in vitro diagnostic medical devices, Article 51 (3)).

3.4.2 Information obligation towards third parties

The manufacturer accepts that TÜV SÜD Product Service GmbH…

- consults a competent authority designated by the Member States in accordance with Directive 2001/83/EC of the European Parliament and of the Council or the EMA, as applicable, in accordance with the procedure set out in Section 5.2 of Annex IX (in case of companion diagnostics devices).

  Article 48 (3)

- requests one of the EU reference laboratories to verify by laboratory testing the performance claimed by the manufacturer and the compliance of the device with the applicable CS, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, once one or more EU reference laboratories have been designated in accordance with Article 100 (in case of class D devices).

  Article 48 (5), Annex IX 4.9 and Annex X 3 (j)

- consults the relevant experts referred to in Article 106 of Regulation (EU) 2017/745 following the procedure laid down in Article 48(6) of Regulation (EU) 2017/746 on the performance evaluation report of the manufacturer (in case of class D devices where no CS are available and where it is also the first certification for that type of device).

  Article 48 (6)

- may exchange information (with the Commission and/or Member States), may disseminate warnings and may provide information under criminal law.

  Article 102 (3)

- submits data to as well as gets data from the European database on medical devices following the requirements of Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

  Articles 26 (2); 28 (3); 29 (1); 49; 52; 87 (2); Annex VI, Part A 2.2; Annex VII 4.3

- makes available and submits upon request all relevant documentation, including the manufacturer´s documentation to the authority responsible for notified bodies.

  Article 32 (2)

- makes available and submits upon request assessments of the manufacturer´s technical documentation, in particular the performance evaluation documentation, to the authority responsible for notified bodies.

  Article 41 (1)

TÜV SÜD Product Service GmbH…

- informs the manufacturers concerned at the latest within 10 days, if the designation of TÜV SÜD Product Service GmbH has been suspended, restricted, or fully or partially withdrawn.

  Article 42 (5)

- informs the manufacturers concerned as soon as possible and in the case of a planned cessation one year before ceasing its conformity assessment activities.

Article 42 (3)

- ensures publicly availability of information according to the requirements of Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

  Articles 33 (3) and 46; Annex VII 1.2.5 and 4.2

- ensures to inform of the requirements related to subcontractors and/or external experts involved in conformity assessment activities.

  Annex VII 3.4.2

- informs as outlined in the Testing and Certification Regulations of the TÜV SÜD Group.

3.5 Documentation to be submitted with this application

The following sections define the minimum content of documentation required for the respective conformity assessment procedure, the timepoint of documentation submission and the respective reference to Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR reference).

Accessibility requirements

The manufacturer must submit any documentation being part of the respective conformity assessment either in English and/or in German. A 'read only' access to the documentation only via manufacturers electronic data platform (e.g. IT-systems, cloud) is not permitted.

If necessary, further documents apart from the ones listed within these sections may be requested during the assessment.

Time limits of submission

The following two points in time exist for the submission of documentation:

1. "Lodge of Application", i.e. documentation to be submitted together with this application
2. "Assessment of the quality management system", i.e. documentation to be submitted to enable the assessment of the quality management system during an audit and/or during technical documentation assessment

Provisions of providing the technical documentation

In case the conformity assessment procedure applied for is linked to assessment of technical documentation for devices selected on a representative basis, the manufacturer is obliged to provide the technical documentation as referred to in Annexes II and III of Regulation (EU) 2017/746 on in vitro diagnostic medical devices without undue delay.

3.5.1 Annex IX – Quality management system and assessment of technical documentation

Timepoint 1: Lodge of application

Documentation to be submitted until Lodge of Application	***IVDR reference***
Draft of an EU declaration of conformity in accordance with Article 17 and Annex IV for the device model covered by the conformity assessment procedure	*Annex IX Ch. I Sec. 2.1. indent 4*
The documentation on the manufacturer's quality management system	*Annex IX Ch. I Sec. 2.1.indent 5*
A documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under this Regulation and the undertaking by the manufacturer in question to apply those procedures	*Annex IX Ch. I Sec. 2.1. indent 6*
A description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures	*Annex IX Ch. I Sec. 2.1. indent 7*

General Information on MDR/IVDR Application

Documentation to be submitted until Lodge of Application	*IVDR reference*
The documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMPF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87	*Annex IX Ch. I Sec. 2.1. indent 8*
A description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMPF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87, as well as the undertaking by the manufacturer to apply those procedures	*Annex IX Ch. I Sec. 2.1. indent 9*
Documentation on the performance evaluation plan	*Annex IX Ch. I Sec. 2.1.indent 10*
A description of the procedures in place to keep up to date the performance evaluation plan, taking into account the state of the art	*Annex IX Ch. I Sec. 2.1.indent 11*
For assessment of the technical documentation of class B, C and D devices and batch verification applicable to class D devices:	*Annex IX Ch. II Sec. 4.1,Sec. 4.2*
↳ Description of the design, manufacture and performance of the device in question	
↳ Technical documentation as referred to in Annexes II and III (including the clinical evidence presented in the performance evaluation report)	
For assessment of the technical documentation of class B, C and D devices for self-testing and near-patient testing	*Annex IX Ch. II Sec. 4.1,Sec. 4.2, Sec. 5.1*
↳ Description of the design characteristics and performance(s)	
↳ Technical documentation as referred to in Annexes II and III (including the clinical evidence presented in the performance evaluation report)	
↳ Test reports, including results of studies carried out with intended users	
↳ Where practicable, an example of the device; if required, the device shall be returned on completion of the technical documentation assessment	
↳ Data showing the suitability of the device in view of its intended purpose for self-testing or near patient- testing	
↳ Information to be provided with the device on its label and its instructions for use	
For assessment of the technical documentation of companion diagnostics	*Annex IX Ch. II Sec. 4.1,Sec. 4.2, Sec. 5.2*
↳ Description of the design characteristics, manufacture and performance(s)	
↳ Technical documentation as referred to in Annexes II and III (including the clinical evidence presented in the performance evaluation report)	

Timepoint 2: Assessment of Quality management system

Documentation to be submitted until assessment of Quality Management System	*IVDR reference*
The quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures such as quality programmes, quality plans and quality records, including **(items A to E listed below)**	*Annex IX Ch. I Sec. 2.2*
A) Adequate description of the manufacturer's quality objectives	*Annex IX Ch. I Sec. 2.2 a)*

General Information on MDR/IVDR Application

Documentation to be submitted until assessment of Quality Management System	*IVDR reference*
B) Adequate description of, the organisation of the business and in particular	*Annex IX Ch. I Sec. 2.2 b)*
↳ The organisational structures with the assignment of staff responsibilities in relation to critical procedures, the responsibilities of the managerial staff and their organisational authority	
↳ The methods of monitoring whether the operation of the quality management system is efficient and in particular the ability of that system to achieve the desired design and device quality, including control of devices which fail to conform	
↳ Where the design, manufacture and/or final verification and testing of the devices, or parts of any of those processes, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party, and	
↳ Where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention from the authorised representative to accept the mandate	
C) Adequate description of the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices and the corresponding documentation as well as the data and records arising from those procedures and techniques. Those procedures and techniques shall specifically cover:	*Annex IX Ch. I Sec. 2.2 c)*
↳ The strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence, choice of and compliance with conformity assessment procedures	
↳ Identification of applicable general safety and performance requirements and solutions to fulfil those requirements, taking applicable CS and, where opted for, harmonised standards or other adequate solutions into account	
↳ Risk management as referred to in Section 3 of Annex I,	
↳ The performance evaluation, pursuant to Article 56 and Annex XIII, including post-market performance follow-up	
↳ Solutions for fulfilling the applicable specific requirements regarding design and construction, including appropriate pre-clinical evaluation, in particular the requirements of Chapter II of Annex I,	
↳ Solutions for fulfilling the applicable specific requirements regarding the information to be supplied with the device, in particular the requirements of Chapter III of Annex I,	
↳ The device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture, and	
↳ Management of design or quality management system changes	
D) Adequate description of the verification and quality assurance techniques at the manufacturing stage and in particular the processes and procedures which are to be used, particularly as regards sterilisation and the relevant documents	*Annex IXCh. I Sec. 2.2 d)*
E) Adequate description of the appropriate tests and trials which are to be carried out before, during and after manufacture, the frequency with which they are to take place, and the test equipment to be used; it shall be possible to trace back adequately the calibration of that test equipment	*Annex IX Ch. I Sec. 2.2 e)*
Access to the Technical documentation referred to in Annexes II and III	*Annex IX Ch. I Sec. 2.2 2nd subparagraph*

Documentation to be submitted until assessment of Quality Management System	*IVDR reference*
Surveillance assessment applicable to class C and class D devices:	*Annex IX Ch. I Sec. 3.2*
↳ Documentation on the quality management system	
↳ Documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the PMPF plan, for a representative sample of devices, and of the provisions on vigilance set out in Articles 82 to 87	
↳ Data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests and the solutions adopted regarding the risk-management as referred to in Sect. 4 of Annex I	
↳ Data stipulated in the part of the quality management system relating to manufacture, such as quality control reports and test data, calibration data, and records on the qualifications of the personnel concerned	

3.5.2 Annex X – Type-Examination

Timepoint 1: Lodge of application

Documentation to be submitted until Lodge of Application	*IVDR reference*
The technical documentation referred to in Annexes II and III (including the clinical evidence presented in the performance evaluation report)	*Annex X Sec. 2 indent 2*
A representative sample of the device production envisaged ('type') including information about the representative sample made available to TÜV SÜD Product Service GmbH (Please note: TÜV SÜD Product Service GmbH may request additional samples as necessary and thus also additional information about them)	*Annex X Sec. 2 indent 2*
Additionally, in the case of devices for self-testing or near-patient testing:	
↳ test reports, including results of studies carried out with intended users, and data showing the handling suitability/suitability of the device in relation to its intended purpose for self-testing or near patient-testing	*Annex X Sec. 2 indent 3*
↳ the information to be provided with the device on its label and its instructions for use	*Annex X Sec. 2 indent 6*

Timepoint 2: Assessment of Quality Management System

Documentation to be submitted until assessment of Quality Management System	*IVDR reference*
In case of companion diagnostics: - Draft of the summary of safety and performance - Draft instructions for use	*Annex X Sec. 3 (k)*

3.5.3 Annex XI – Production quality assurance

Timepoint 1: Lodge of application

Documentation/Products to be submitted until Lodge of Application	*IVDR reference*
Draft of an EU declaration of conformity in accordance with Article 17 and Annex IV for the device model covered by the conformity assessment procedure	*Annex XI Sec. 3.1*
The documentation on the manufacturer's quality management system	
A documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under this Regulation and the undertaking by the manufacturer in question to apply those procedures	
A description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures	
The documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMPF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87	
A description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMPF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87, as well as the undertaking by the manufacturer to apply those procedures	
Documentation on the performance evaluation plan	
A description of the procedures in place to keep up to date the performance evaluation plan, taking into account the state of the art	
The technical documentation referred to in Annexes II and III for the types approved (including the clinical evidence presented in the performance evaluation report)	

Timepoint 2: Assessment of quality management system

Documentation to be submitted until assessment of quality management system	*IVDR reference*
The quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures such as quality programmes, quality plans and quality records, including	*Annex XI Sec. 3.2*
↳ Adequate description of the manufacturer's quality objectives	
↳ Adequate description of, the organisation of the business and in particular	
↳ The organisational structures with the assignment of staff responsibilities in relation to critical procedures, the responsibilities of the managerial staff and their organisational authority	
↳ The methods of monitoring whether the operation of the quality management system is efficient and in particular the ability of that system to achieve the desired design and device quality, including control of devices which fail to conform	
↳ Where the design, manufacture and/or final verification and testing of the devices, or parts of any of those processes, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party, and	

Documentation to be submitted until assessment of quality management system	*IVDR reference*
↳ Where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention from the authorised representative to accept the mandate	
↳ Adequate description of the verification and quality assurance techniques at the manufacturing stage and in particular the processes and procedures which are to be used, particularly as regards sterilisation and the relevant documents	
↳ Adequate description of the appropriate tests and trials which are to be carried out before, during and after manufacture, the frequency with which they are to take place, and the test equipment to be used; it shall be possible to trace back adequately the calibration of that test equipment	
Surveillance assessment applicable to class C and class D devices:	*Annex XI Sec. 4*
↳ Documentation on the quality management system	
↳ Documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the PMPF plan, for a representative sample of devices, and of the provisions on vigilance set out in Articles 82 to 87	
↳ Data stipulated in the part of the quality management system relating to manufacture, such as quality control reports and test data, calibration data, and records on the qualifications of the personnel concerned	

3.6 Obligations under IVDR Article 110(3) (Directives 98/79/EC (IVDD))

The undersigned further undertakes to comply with all other requirements following from the In vitro Devices Directives (EC Directives) and their transposition into the national law of the EU Member States.

Obligation	**Conformity assessment according to Annex**					
Directive 98/79/EC (IVDD)	**IV.3**	**VII**	**IV.4**	**III.6**	**V**	**VI**
Relevant Type of certificate at TÜV SÜD PS GmbH	*V1*	*V2*	*V7*	*V9*	*V5*	*V8*
The manufacturer declares that there are no significant changes in the design and intended purpose of devices.	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
The manufacturer declares that it has adjusted its quality management system according to the requirements of Article 110(3) IVDR concerning significant changes (MDCG 2022-6 endorsed guidance for clarification).	**Yes**	**Yes**	**-**	**-**	**-**	**-**
The undersigned undertakes to fulfil the obligation of Article 110(3) of Regulation (EU) 2017/746 regarding the adjustment of quality management system on post-market surveillance, vigilance, registration of economic operators and of devices.	**Yes**	**Yes**	**-**	**-**	**-**	**-**
The undersigned declares that all appropriate processes relating to post-market surveillance including risk management and performance data feed into the post-market surveillance plan.	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**

4 Reporting changes to the Notified Body

4.1 Reporting significant changes under MDR

The Medical Devices Regulation requires certain changes of the device or of the quality system to be notified to the Notified Body. For the definition of significant changes, please refer to NBOG-BPG 2014-3.

Disclaimer: It is the sole responsibility of the manufacturer to adequately categorize the change accordingly. In case of doubt whether a given change is significant, manufacturers should ask their notified body.

The following chapters define three types of changes and provide guidance to which change can be categorized as which change type. The list of criteria for change types is not exhaustive.

4.1.1 Definition of change type

The changes are defined either as significant, non-significant and non-reportable.

Significant /Administrative changes:

All significant changes and certain administrative changes associated with conformity assessment procedures are considered as **reportable changes to notified body**. Reporting of significant changes must occur prior to implementation of a significant change to allow Notified body to assess the change.

Where the manufacturer plans to introduce any of the significant changes to approved QMS, device range covered or approved device/ type, it shall inform the notified body which issued the corresponding certificate of conformity assessment procedure thereof. The notified body assesses the planned changes and decides whether the planned changes require a new conformity assessment in accordance with MDR Article 52 or whether they could be addressed by means of an amendment or a supplement to existing certificate of conformity. In the latter case, the notified body assess the significant changes, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the certificate of conformity. Once the significant changes are approved by notified body, they can be implemented by the manufacturer.

Non-significant changes:

Non-significant changes associated with approved QMS do not require submission of change notification, but it **shall be communicated per E-mail** to responsible person for conformity assessment at notified body and / or provide information on non-significant changes in update information form requested by notified body in course of audit planning during surveillance activities.

Non-reportable changes:

Minor changes associated with approved QMS, device range covered or approved device/type are considered as non-reportable and do not require the submission or notification to Notified body. These types of changes and the manufacturer's justification for not reporting the change are to be documented and controlled in the manufacturer's quality management system.

4.1.2 Criteria for significant and administrative changes

Changes to the approved device

Planned changes to the approved device **might require a new conformity assessment** in accordance with MDR Article 52. The following are considered as significant changes to the device:

- Extension of the intended purpose, such as:
  - additional or new indications;
  - additional or new clinical conditions.
- New user or patient population, such as:
  - additional or new target population;

- additional or new user (e.g. change from professional use to layman use).

- New way of clinical application, such as:
  - additional or new applications (different stage or severity of disease);
  - additional or new anatomical site;
  - new delivery pathway or deployment method.
- Changes to the built-in control mechanism,
- Changes to the device's operating principle,
- Changes to the change of the source of energy, or
- Changes to the alarms systems.

Regulatory reference:
EU Technical Documentation Assessment – MDR Annex IX Ch. II 4.10
EU Type Examination – MDR Annex X 5.2

Administrative changes

Administrative changes need to be reported to the Notified Body via a change notification. The following are considered as administrative changes:

- Editorial change on certificate related content.
- Change of manufacturer's data e.g. ownership, legal entity status, name and/or address.
- Change of authorized representative data e.g. name and/or address, SRN.

Changes to approved quality management system

Changes to an approved quality management system need to be reported to the Notified Body via a change notification. The following are considered as significant changes to the approved quality management system:

- Change of approved quality management activities e.g. design, manufacturing, installation, servicing, distribution…etc.
- Change of manufacturing technology.
- Change of sterilization procedure.
- Change of critical supplier.
- Changes to site e.g. relocation, addition of new site or closure of site.
- Transfer of process(es) to other sites.
- Change to manufacturing quality control procedures, such as the methods, tests or procedures used to control the quality of the materials or the product.
- Other significant changes affecting the quality management system e.g. organizational changes.

Regulatory reference:
EU Quality Management System – MDR Annex IX Ch. I 2.4
EU Production Quality Assurance – MDR Annex IX 6.4

Changes to approved quality management system regarding device-range / product-range covered

Changes to an approved quality management system which relate to the device-range / product range need to be reported to the Notified Body via a change notification. The following are considered as significant changes regarding device-range / product-range:

- Addition of group of devices e.g. new device categories for class IIa or generic device group for class IIb medical device to be certified.
- Addition of Class III medical devices.
- Addition of implantable devices e.g. new device assessed on representative basis, but requires SSCP to be submitted in EUDAMED.

- Removal of group of devices (e.g. device categories for class IIa or generic device group for class IIb) or devices (e.g. class III).
- Addition of devices affecting parameters listed on the certificate (e.g. EMDN code).

Regulatory reference:
EU Quality Management System – MDR Annex IX Ch. I 2.4
EU Production Quality Assurance – MDR Annex IX 6.4

Changes to the approved design of a device

The following are considered as significant design changes to the device:

- Changes affecting conformity with general safety and performance requirements.
- Change affecting intended purpose e.g. additional/amended indications and limitations, change(s) influencing the clinical data.
- Change affecting product specifications and/or design e.g. change in safety-related functions / performance data / materials / shelf-life / parameters listed on the certificate / device identification.
- Changes that may adversely affect the safety or performance and negatively affect the risk/benefit ratio of the device.
- Changes to the materials supplied with the MD e.g. accessories.
- Changes of critical suppliers.
- Change of labelling / instruction for use (IFU).
- Addition or removal of product variants.

Regulatory reference:
EU Technical documentation assessment - MDR Annex IX Ch. II 4.10
EU Type Examination - MDR Annex X 5.

Changes to medical device software

The following are considered as significant changes to medical device software:

- a software change, which impacts the control of the device, that may alter the diagnosis or therapy delivered to the patient.
- an alteration in software that modifies an algorithm impacting the diagnosis or the therapy delivered.
- a software change that impacts the way data is read or interpreted by the user, such that the treatment or diagnosis of the patient may be altered when compared to the previous version of the software.
- a software change that replaces previously required user input to a closed loop decision;
- addition of a new feature to the software that may change the diagnosis or the therapy delivered to the patient.
- introduction to or removal of a new alarm function from the software such that a response to the new configuration may change the treatment of the patient in comparison to the previous version of the software.
- a software change that incorporates a significant change to the operating system on which the software runs.

Regulatory reference:
EU Technical Documentation Assessment - MDR Annex IX Ch. II 4.10
EU Type Examination - MDR Annex X 5

Changes affecting special procedures

The following are considered as significant changes affecting special procedures:

- Change to an ancillary substance incorporated in a device.

- Change to non-viable tissues or cells of human origin or their derivatives incorporated in a device, in particular relating to their donation, testing or procurement.
- Changes to materials of animal origin: changes of the geographical source of animals, the raw materials of animal origin, and the processes for selection, collection, handling, control and in-activation/elimination that may modify viral safety.

Regulatory reference:
EU TDA - MDR Annex IX Ch. II 5.2 (f), 5.3.1 (d), 5.3.2
EU Type Examination – MDR Annex X 6.

4.1.3 Criteria for non-significant changes

Non-significant changes **shall be communicated via notice per E-mail or information on request**. The following are considered as non-significant changes:

- Changes to managerial personnel e.g. management representative, PRRC, QMR, QMB…etc.
- Addition of new class IIa non-implantable devices to existing device categories and Class IIb non-implantable devices without addition of new MDT or certain IVS code (certain MDS codes such as MDS 1001, MDS 1002, MDS 1003, MDS 1005 (sterilization technology), MDS 1007, MDS 1008, MDS 1009, MDS 1010, MDS 1012).
- Change of number of employees since the last audit.
- Updated SSCP for class IIa and IIb device or any SSCP translations, which requires upload in EUDAMED though notified body.

4.1.4 Criteria for non-reportable changes

The following are considered as non-reportable changes:

- Changes that are made to clarify labelling statements or correct errors (typographical errors or numerical errors) without changing the procedure.
- Translating the label and/or Instructions for Use (IFU) from one language to another.
- Addition of languages to labelling.
- Replacing (or complementing) written text by internationally recognized hazard symbols.
- Minor QMS changes such as increased post market surveillance activity or regular updates of controlled QMS procedures (such as control of documents, management review etc.).
- Minor manufacturing changes that would not have an effect on the safety or performance of the finished device.
- Minor software changes that do not impact the safety or performance of the product.
- Additional in-process quality control criteria or test methods for manufacturing.
- Processes to provide equivalent or better assurances of reliability, as determined by the manufacturer but which do not affect safety or performance.

4.2 Reporting changes under MDR Article 120

For guidance on significant design changes and changes to the intended purpose regarding the transitional provision under EU Regulation 2017/745 (MDR) Article 120, please refer to MDCG 2020-3. Significant changes to the design and intended purpose cannot be processed under EU Regulation 2017/745 (MDR) Article 120 and require an application for an EU Regulation 2017/745 (MDR) conformity assessment.

4.3 Reporting significant changes under IVDR

The In-vitro Diagnostic Medical Devices Regulation requires certain changes of the device or of the quality system to be notified to the Notified Body. For the definition of significant changes, please refer to NBOG-BPG 2014-3.

Disclaimer: It is the sole responsibility of the manufacturer to adequately categorize the change accordingly. In case of doubt whether a given change is significant, manufacturers should ask their notified body.

The following chapters define three types of changes and provide guidance to which change can be categorized as which change type. The list of criteria for change types is not exhaustive.

4.3.1 Definition of change type

The changes are defined either as significant, non-significant and non-reportable.

Significant /Administrative changes:

All significant changes and certain administrative changes associated with conformity assessment procedures are considered as **reportable changes to notified body**. Reporting of significant changes must occur prior to implementation of a significant change to allow Notified body to assess the change.

Where the manufacturer plans to introduce any of the significant changes to approved QMS, device range covered or approved Device/Type, it shall inform the notified body which issued the corresponding certificate of conformity assessment procedure thereof. The notified body assesses the planned changes and decides whether the planned changes require a new conformity assessment in accordance with IVDR Article 48 or whether they could be addressed by means of an amendment or a supplement to existing certificate of conformity. In the latter case, the notified body assess the significant changes, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the certificate of conformity. Once the significant changes are approved by notified body, they can be implemented by the manufacturer.

Non-significant changes:

Non-significant changes associated with approved QMS do not require submission of change notification, but it **shall be communicated per E-mail** to responsible person for conformity assessment at notified body and / or provide information on non-significant changes in update information form requested by notified body in course of audit planning during surveillance activities.

Non-reportable changes:

Minor changes associated with approved QMS, device range covered or approved Device/Type are considered as non-reportable and do not require the submission or notification to Notified body. These types of changes and the manufacturer's justification for not reporting the change are to be documented and controlled in the manufacturer's quality management system.

4.3.2 Criteria for significant and administrative changes

Changes to the approved device

Planned changes to the approved device **might require a new conformity assessment** in accordance with IVDR Article 48. The following are considered as significant changes to the device:

- A change to what is detected (i.e. the analyte or measurand).
- Replacement of critical ingredients of the device such as antibodies, antigens, enzymes and nucleic acid primers.
- A change to the specific disorder, condition or risk factor of interest that the IVD is intended to detect, define or differentiate.
- A change in the test result format from qualitative to quantitative or vice versa.
- A change in biological or chemical principle of the test; and/or a change in design of test technology.

Regulatory reference:
EU Technical Documentation Assessment – IVDR Annex IX Ch. II 4.9
EU Type Examination – MDR Annex X 5.2

Administrative changes

Administrative changes need to be reported to the Notified Body via a change notification. The following are considered as administrative changes:

- Editorial change of manufacturer/authorized representative.
- Change of manufacturer's data e.g. Ownership, legal entity status, name and/or address.
- Change of authorized representative data e.g. name and/or address, SRN.

Changes to approved quality management system

Changes to an approved quality management system need to be reported to the Notified Body via a change notification. The following are considered as significant changes to the approved quality management system:

- Change of approved quality management activities e.g. design, manufacturing, installation, servicing, distribution…etc.
- Change of manufacturing technology.
- Change of sterilization procedure.
- Change of critical supplier.
- Changes to site e.g. relocation, addition of new site or closure of site.
- Transfer of process(es) to other sites.
- Change to manufacturing quality control procedures, such as the methods, tests or procedures used to control the quality of the materials or the product.
- Other significant changes affecting the quality management system e.g. organizational changes.

Regulatory reference:
EU Quality Management System – IVDR Annex IX Ch. I 2.4
EU Production Quality Assurance – IVDR Annex IX 3.4

Changes to approved quality management system regarding device-range / product-range covered

Changes to an approved quality management system which relate to the device-range / product range need to be reported to the Notified Body via a change notification. The following are considered as significant changes regarding device-range / product-range:

- Addition of group of devices e.g. new device categories for class B or generic device group for class C IVD to be certified.
- Addition of devices e.g. new Self-testing, near patient testing, companion diagnostic or class D IVD devices to be certified.
- Addition of new class C devices to existing generic device group e.g. new Class C device assessed on representative basis, but requires SSP to be submitted in EUDAMED.
- Removal of device (s) or group of devices or devices.

Regulatory reference:
EU Quality Management System – IVDR Annex IX Ch. I 2.4
EU Production Quality Assurance – IVDR Annex IX 3.4

Changes to the approved design of a device

The following are considered as significant design changes to the device:

- Changes affecting conformity with general safety and performance requirements.
- Indications and/or contraindications and/or warnings determined by the manufacturer to be appropriate to ensure the clinical performance of the device.
- Change affecting intended purpose e.g. additional/amended indications and limitations, change(s) influencing the clinical/performance data.

- Change affecting product specifications and/or design e.g. change in safety-related functions / performance data / materials/ shelf life / parameters listed on the certificate / device identification.
- Changes to the materials supplied with the IVD e.g. accessories such as lancets or swabs provided within IVD Kit.
- Changes of critical suppliers.
- Change of labelling / instruction for use (IFU).
- Addition or removal of product variants.
- Changes to specification of final QC affecting batch verification of class D devices.
- Any changes that may have an effect on the verification of manufactured batches of class D devices such as changes to manufacturing, raw materials (ingredients, formulation etc), equipment, quality control, transport or storage.
- Any relevant changes to scientific, technical or clinical information which has come to manufacturer´s knowledge, impacting scientific or technical validity of the batch verification testing of class D Device (e.g. new variant strain for microbiological assays or knowledge of new interfering or cross-reacting substances).

Regulatory reference:
EU Technical documentation assessment - IVDR Annex IX Ch. II 4.11
EU Type Examination - IVDR Annex X 5.

Changes to medical device software

The following are considered as significant changes to medical device software:

- A software change that impacts the control of the product, and may alter the reporting result that is used in the diagnosis or other function.
- A software change that modifies an algorithm impacting the test result.
- A software change that impacts the way data are read or interpreted by the user, such that the diagnosis or other function may be altered when compared to the previous version of the software.
- A software change that replaces previously required user input.
- A software change to correct an error that presents a safety risk to the patient.
- Addition of a new feature to the software that may affect the diagnosis or other software driven function.
- A software change that incorporates a significant change to the operating system on which the software runs.

Regulatory reference:
EU Technical Documentation Assessment - IVDR Annex IX Ch. II 4.11
EU Type Examination - IVDR Annex X 5

Changes affecting special procedures

The following are considered as significant changes affecting special procedures:

- For Class D IVD Device - Changes affecting performance claimed by the manufacturer or compliance with the CS or with other solutions chosen by the manufacturer.
- For Companion Diagnostic IVD Device - Changes affecting the performance and/or the intended use and/or the suitability of the device in relation to the medicinal product.

Regulatory reference:
EU TDA - IVDR Annex IX Ch. II 5.1 & 5.2
EU Type Examination – IVDR Annex X 5.4 & 5.5

4.3.3 Criteria for non-significant changes

Non-significant changes **shall be communicated via notice per E-mail or information on request**. The following are considered as non-significant changes:

- Changes to managerial personnel e.g. management representative, PRRC, QMR, QMB…etc.
- Addition of new class B devices to existing device categories.
- Change of number of employees since the last audit.
- Updated SSP for class C device or any SSP translations, which requires upload in EUDAMED though NB.

4.3.4 Criteria for non-reportable changes

The following are considered as non-reportable changes:

- Changes that are made to clarify labelling statements or correct errors (typographical errors or numerical errors) without changing the procedure.
- Translating the label and/or Instructions for Use (IFU) from one language to another.
- Addition of languages to labelling.
- Replacing (or complementing) written text by internationally recognized hazard Symbols.
- Minor QMS changes such as increased post market surveillance activity or regular updates of controlled QMS procedures (such as control of documents, management review etc.).
- Minor manufacturing changes that would not have an effect on the safety or performance of the finished device.
- Minor software changes that do not impact the safety or performance of the product.
- Additional in-process quality control criteria or test methods for manufacturing.
- processes to provide equivalent or better assurances of reliability, as determined by the manufacturer but which do not affect safety or performance.

4.4 Reporting changes under IVDR Article 110

For guidance on significant design changes and changes to the intended purpose regarding the transitional provision under EU Regulation 2017/746 (IVDR) Article 110, please refer to MDCG 2022-6. Significant changes to the design and intended purpose cannot be processed under EU Regulation 2017/746 (IVDR) Article 110 and require an application for an EU Regulation 2017/746 (IVDR) conformity assessment.