Based on the selected Annex of MDR (EU) 2017/745, you must supply with the Application the following documents and samples (see also the submission checklists at the end of this form):

**Annex IX CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION**

**Chapter I QUALITY MANAGEMENT SYSTEM**

2. Quality management system assessment

2.1. The manufacturer shall lodge an application for assessment of its quality management system with a notified body. The application shall include:

* the name of the **manufacturer** and address of its registered place of business and **any additional manufacturing site covered by the quality management system**, and, if the manufacturer's application is lodged by its authorised representative, the name of the authorised representative and the address of the authorised representative's registered place of business,
* all relevant information on the device or group of devices covered by the quality management system,
* a written declaration that no application has been lodged with any other notified body for the same device- related quality management system, or information about any previous application for the same device- related quality management system,
* a draft of an EU declaration of conformity in accordance with Article 19 and Annex IV for the device model covered by the conformity assessment procedure,
* 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 **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,
* 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,
* documentation on the **clinical evaluation plan**, and
* a description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art.

2.2. Implementation of the quality management system shall ensure compliance with this Regulation. **All the elements, requirements and provisions adopted by the manufacturer for its 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.** 5.5.2017 L 117/146 Official Journal of the European Union EN Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular:

(a) the manufacturer's **quality objectives**;

(b) **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

- 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) 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:

* 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 clinical evaluation**, pursuant to Article 61 and Annex XIV, including **post-market clinical 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**; and

(d) **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; and

(e) 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.

In addition, the manufacturer shall grant the notified body **access to the technical documentation** referred to in Annexes II and III.

3.4 The manufacturer in question shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered. [...].

**Annex IX CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION**

**Chapter II ASSESSMENT OF THE TECHNICAL DOCUMENTATION**

4. Assessment of the technical documentation **applicable** to class III devices and to the **class IIb devices** referred to in the second subparagraph of Article 52(4)

4.1. **In addition to the obligations laid down in Section 2**, the manufacturer shall lodge with the notified body an application for assessment of the technical documentation relating to the device which it plans to place on the market or put into service and which is covered by the quality management system referred to in Section 2.

4.2. The **application** **shall describe the** **design, manufacture and performance** of the device in question. It shall **include the technical documentation** as referred to in Annexes II and III.

[…]

4.10. Changes to the approved device shall require approval from the notified body which issued the EU technical documentation assessment certificate **where** **such** **changes could affect the safety and performance of the device** or the **conditions prescribed for use** of the device. Where the manufacturer **plans to introduce** any of the above- mentioned **changes** it shall **inform the notified body** which issued the EU technical documentation assessment certificate thereof. […].

**Annex X CONFORMITY ASSESSMENT BASED ON TYPE-EXAMINATION** (TO BE COUPLED WITH PRODUCT CONFORMITY VERIFICATION PART A or PART B)

1. EU type-examination is the procedure whereby a notified body ascertains and certifies that a **device**, including its **technical documentation** and **relevant life cycle processes** and a corresponding **representative** **sample of the device production** envisaged, fulfils the relevant provisions of this Regulation.

2. Application

The manufacturer shall lodge an application for assessment with a notified body. The **application shall include**:

- the **name of the manufacturer and address** of the registered place of business of the manufacturer **and**, if the application is lodged by the authorised representative, the name of **the authorised representative and the address** of its registered place of business,

- the **technical documentation** referred to in Annexes II and III. The applicant shall make a **representative sample of the device** production envisaged (‘type’) available to the notified body. The notified body may request **other samples as necessary**, and

- a **written declaration** that **no application** has been lodged with any **other notified body** for the same type, **or information about any previous application** for the same type **that was refused** by another notified body **or was withdrawn** by the manufacturer or its authorised representative before that other notified body made its final assessment.

3. Assessment

The notified body shall:

[…]

(f) […] Where the device has to be **connected to another device** or devices in order to operate as intended, proof shall be provided that it conforms to the general safety and performance requirements when connected to any such device or deviceshaving **the characteristics specified by the manufacturer**;

(h) **agree** with the applicant on the **place where** the necessary **assessments and tests** are to be **carried out**; and

[…]

5. Changes to the type

5.1. The **applicant shall inform** the notified body which issued the EU type-examination certificate of **any planned change to the approved type** or of its **intended purpose** and **conditions of use**.

5.2. **Changes** to the approved device including limitations of its intended purpose and conditions of use shall **require approval from the notified body** which issued the EU type-examination certificate where such changes may affect conformity with the general safety and performance requirements or with the conditions prescribed for use of the product. The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU type-examination report. The approval of any change to the approved type shall take the form of a supplement to the EU type-examination certificate.

5.3. **Changes** to the intended purpose and conditions of use of the approved device, with the exception of limitations of the intended purpose and conditions of use, shall **necessitate** a **new application for a conformity assessment**.

**ANNEX XI****CONFORMITY ASSESSMENT BASED ON PRODUCT CONFORMITY VERIFICATION**

**PART A** **PRODUCTION QUALITY ASSURANCE** (coupled with Annex X OR with Annexes II and III)

1. The objective of the conformity assessment based on product conformity verification is to ensure that devices conform to the type for which an **EU type-examination certificate** has been **issued**, and that they meet the provisions of this Regulation which apply to them.

2. Where an EU type-examination certificate has been issued in accordance with Annex X, the manufacturer may […] **apply the procedure set out in Part A (production quality assurance)** […] of this Annex.

3. By way of derogation from Sections 1 and 2 above, the procedures in this Annex coupled with the **drawing up of technical documentation as set out in Annexes II and III** may also be applied by **manufacturers of class IIa** devices.

[…]

4. The manufacturer shall ensure that the quality management system approved for the manufacture of the devices concerned is implemented, shall **carry out a final verification**, as specified in Section 6, and shall be subject to the surveillance referred to in Section 7.

5. When the manufacturer fulfils the obligations laid down in Section 4, it shall draw up and keep an EU declaration of conformity in accordance with Article 19 and Annex IV for the device covered by the conformity assessment procedure. By **issuing an EU declaration of conformity**, the manufacturer shall be deemed to ensure and to declare that the device concerned **conforms to the type** described in the EU type-examination certificate and **meets the requirements** of this Regulation which apply to the device.

6. Quality management system

6.1. The manufacturer shall lodge an application for assessment of its quality management system with a notified body. The application shall include:

* **all elements listed in Section 2.1** of Annex IX,
* the **technical documentation referred to in Annexes II and III** for the types approved, and
* **a copy of the EU type-examination certificates** referred to in Section 4 of Annex X; if the EU type- examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and its updates and the certificates issued shall also be included in the application.

6.2. Implementation of the quality management system shall be such as to ensure that there is compliance with the type described in the EU type-examination certificate and with the provisions of this Regulation which apply to the devices at each stage. All the elements, requirements and provisions adopted by the manufacturer for its 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.

That documentation shall, in particular, include an **adequate description of all elements listed in points (a), (b), (d) and (e) of Section 2.2 of Annex IX**.

[…]

8. Batch verification **in the case of devices incorporating, as an integral part, a medicinal substance** which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(8).

Upon completing the manufacture of each batch of devices that incorporate, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of Article 1(8), **the manufacturer shall inform the notified body of the release of the batch of devices** and send it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a Member State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

**ANNEX XI****CONFORMITY ASSESSMENT BASED ON PRODUCT CONFORMITY VERIFICATION**

**PART B** **PRODUCT VERIFICATION** (coupled with Annex X OR with Annexes II and III)

1. The objective of the conformity assessment based on product conformity verification is to ensure that devices conform to the type for which an **EU type-examination certificate** has been **issued**, and that they meet the provisions of this Regulation which apply to them.

2. Where an EU type-examination certificate has been issued in accordance with Annex X, the manufacturer may […] **apply** […] the **procedure set out in Part B (product verification)** of this Annex.

3. By way of derogation from Sections 1 and 2 above, the procedures in this Annex coupled with the **drawing up of technical documentation as set out in Annexes II and III** may also be applied by **manufacturers of class IIa** devices.

[…]

11. Product verification shall be understood to be the procedure whereby after examination of every manufactured device, the manufacturer, by **issuing an EU declaration of conformity** in accordance with Article 19 and Annex IV, **shall be** **deemed to ensure and to declare** that the devices which have been subject to the procedure set out in Sections 14 and 15 **conform to the type** described in the EU type-examination certificate and meet the requirements of this Regulation which apply to them.

12. The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces devices which conform to the type described in the EU type-examination certificate and to the requirements of the Regulation which apply to them. Prior to the start of manufacture, the manufacturer shall **prepare documents defining the manufacturing process**, in particular as regards sterilisation where necessary, together with all routine, pre-established procedures to be implemented to ensure homogeneous production and, where appropriate, conformity of the devices with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them. In addition, **for devices placed on the market in a sterile condition**, and **only** for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer shall **apply the provisions of Sections 6 and 7**.

13. The manufacturer shall undertake to institute and keep **up to date a post-market surveillance plan**, including a **PMCF plan**, and the **procedures** ensuring compliance with the obligations of the manufacturer resulting from the provisions **on** **vigilance** and **post-market surveillance system** set out in Chapter VII.

14. The notified body shall carry out the appropriate examinations and tests […] as specified in Section 15.

[…]

15. Verification by examination and testing of every product

15.1. **Every device shall be examined** individually and the appropriate physical or laboratory tests as defined in the relevant standard or standards referred to in Article 8, or equivalent tests and assessments, shall be carried out in order to verify, where appropriate, the conformity of the devices with the type described in the EU type- examination certificate and with the requirements of this Regulation which apply to them.

15.2. The notified body shall affix, or have affixed, its identification number to each approved device and shall draw up an EU product verification certificate relating to the tests and assessments carried out.

16. Batch verification in the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(8). Upon completing the manufacture of each batch of devices that incorporate, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of Article 1(8), the **manufacturer shall inform the notified body of the release of the batch of devices** and **send it the official certificate** concerning the release of the batch of human blood or plasma derivative used in the device, issued by a Member State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

18. Application to class IIa devices

18.1. By way of derogation from Section 11, by virtue of the EU declaration of conformity the manufacturer shall be deemed to ensure and to declare that the class IIa devices in question are manufactured in conformity with the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them.

18.2. The verification conducted by the notified body in accordance with Section 14 is intended to confirm the conformity of the class IIa devices in question **with the technical documentation referred to in Annexes II and III** and with the requirements of this Regulation which apply to them.

18.3. If the verification referred to in Section 18.2 confirms that the class IIa devices in question conform to the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them, the notified body shall issue a certificate pursuant to this Part of this Annex.

# Checklists for application submissions

Please include the information on this page to your application and use other FPMDREG1014AX checklists for the identification of the elements of the submitted Technical Documentation.

Annex IX applications

|  |  |  |  |
| --- | --- | --- | --- |
| in | application submission contents | | describe where to be found |
|  | a filled in MED (EU) 2017/745 Certification Application | | FPMDREG1014 - MDR EC Application |
|  | the name of the manufacturer and address of its registered place of business and any additional manufacturing site covered by the quality management system | |  |
|  | Single Registration Number of the manufacturer, available in EUDAMED | | FPMDREG1014 - MDR EC Application |
|  | If the manufacturer is located outside EU: Agreement with the authorized representative (EU REP) addressing responsibilities and authorities of each party. | |  |
|  | a written declaration that no application has been lodged with any other notified body, or information about any previous applications | |  |
|  | a draft of an EU declaration of conformity | |  |
|  | the documentation on the manufacturer's quality management system | |  |
|  | a documented description of the QMS procedures | |  |
|  | a description of the procedures in place to ensure that the QMS remains adequate and effective, and the undertaking by the manufacturer to apply those procedures | |  |
|  | the documentation on the post-market surveillance system, PMCF plan and vigilance | |  |
|  | a description of the procedures in place to keep up to date the post-market surveillance system, the PMCF plan, and to ensure compliance with vigilance and the undertaking by the manufacturer to apply those procedures | |  |
|  | A copy of the current internal audit schedule, the last internal audit report and the minutes of the last management review to demonstrate that your internal audit and management review processes are functioning, | |  |
|  | description of the design, manufacture and performance of the device(s) in question | |  |
|  |  | the technical documentation (TD) as referred to in Annexes II and III or, | In addition to the TD,  please include filled in  FPMDREG1014A2 - MDR EC Application Attachment 2 - SGS Fimko GSPR Checklist  FPMDREG1014A3 - MDR EC Application Attachment 3 - SGS Fimko CER Checklist  FPMDREG1014A4 - MDR EC Application Attachment 4 - SGS Fimko TD Checklist  and/or  other equivalent listings to help identify the contents and purpose of the documents in the TD |
|  | based on Regulation (EU) 2023/607 the manufacturer plans to complete the TD only after the MDR certification agreement is signed and at this stage provides only the schedule to complete the TD later. | FPMDREG1014 - MDR EC Application with  planned schedules  The document level schedules may also be detailed using the Application Attachment checklists |
|  | If the MDR application is submitted to extend the validity of the MDD certificate(s), a written declaration for legacy devices as a justification of the extension. | | FPPMDREG1014A7 – MDR EC Application Attachment 7 – MDR Manufacturer Declaration for Legacy Devices |
|  | If the medical device consists of or incorporates software AND  stores critical information OR the software or data can be altered | | in addition to the SW process and TD documents  please also fill in the  FPMDREG1014A5 - MDR EC Application  Attachment 5 - SGS Fimko Cybersecurity Checklist  and if applicable  Attachment 6 – SGS Fimko AI/ML Checklist |

Annex X applications

|  |  |  |
| --- | --- | --- |
| in | application submission contents | describe where to be found |
|  | a filled in MED (EU) 2017/745 Certification Application | FPMDREG1014 - MDR EC Application |
|  | the name of the manufacturer and address of its registered place of business and the name of the authorised representative and the address of its registered place of business |  |
|  | a written declaration that no application has been lodged with any other notified body, or information about any previous applications |  |
|  | the technical documentation as referred to in Annexes II and III | In addition to the TD,  please include filled in  FPMDREG1014A2 - MDR EC Application Attachment 2 - SGS Fimko GSPR Checklist  FPMDREG1014A3 - MDR EC Application Attachment 3 - SGS Fimko CER Checklist  FPMDREG1014A4 - MDR EC Application Attachment 4 - SGS Fimko TD Checklist  Attachment 5 – SGS Fimko Cybersecurity Checklist  Attachment 6 – SGS Fimko AI/ML Checklist  and/or  other equivalent listings to help identify the contents and purpose of the documents in the TD |
|  | If the medical device consists of or incorporates software AND  stores critical information OR the software or data can be altered | in addition to the SW process and TD documents  please also fill in the  FPMDREG1014A5 - MDR EC Application  Attachment 5 - SGS Fimko Cybersecurity Checklist  and if applicable  Attachment 6 – SGS Fimko AI/ML Checklist |
|  | representative sample of the device production envisaged (‘type’) |  |

Annex XI applications

|  |  |  |
| --- | --- | --- |
| in | application submission contents | describe where to be found |
|  | all Annex IX elements |  |
|  | a written declaration that no application has been lodged with any other notified body, or information about any previous applications |  |
|  | the technical documentation as referred to in Annexes II and III for the types approved | In addition to the TD,  please include filled in  FPMDREG1014A2 - MDR EC Application Attachment 2 - SGS Fimko GSPR Checklist  FPMDREG1014A3 - MDR EC Application Attachment 3 - SGS Fimko CER Checklist  FPMDREG1014A4 - MDR EC Application Attachment 4 - SGS Fimko TD Checklist  Attachment 5 – SGS Fimko Cybersecurity Checklist  Attachment 6 – SGS Fimko AI/ML Checklist  and/or  other equivalent listings to help identify the contents and purpose of the documents in the TD |
|  | If the medical device consists of or incorporates software AND  stores critical information OR the software or data can be altered | in addition to the SW process and TD documents  please also fill in the  FPMDREG1014A5 - MDR EC Application  Attachment 5 - SGS Fimko Cybersecurity Checklist  and if applicable  Attachment 6 – SGS Fimko AI/ML Checklist |
|  | copy of the EU type-examination certificates or if NB 0598 issued it, a reference to the technical documentation and its updates and the certificates issued |  |

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