Gap analysis ISO13485:2016 vs MDR ver 2024-03-11

Introduction

Standard EN ISO 13485:2016 is a harmonized standard to MDR. It means that Annex ZA of the standard specifies how the key requirements of the MDR are complied with by applying the EN ISO 13485:2016 standard.

On the surface the quality management system requirements of MDR (EU) 2017/745 look easy. Article 10 states: “The quality management system shall address at least the following aspects:..” followed by a list of items that the QMS must implement. Unfortunately, the situation is much more complicated. By complying with EN ISO 13485:2016 it is possible cover the Article 10 requirements only partially. To add to the pain, there are tens of additional aspects that the QMS shall implement, scattered within the MDR.

To make compliance easier, we have compiled below a list of the MDR requirements that are not covered by complying with the EN ISO 13485:2016 standard. Each item has a reference where the requirement is from.

Disclaimer: Please use the list with a pinch of salt. We have tried to make the list accurate but cannot guarantee that every requirement has been covered or every detail is 100% correct.

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments
4. Quality System requirements				
4.1	**DoC process / 5.1 Authority to sign DoC** Procedure and/or template for generation and issue of declaration of conformity in compliance with MDR Art.19, including who has the authority to sign it. If the intended purpose is provided as a shortened summary, there is reference to the full intended purpose. A process ensuring that it is available in languages required by the Member State(s) in which the device is made available.	Article 10(6)/ Annex IX, 2.1/annex IV Article 19		EU national language requirements are provided at https://health.ec.europa.eu/document/download/aa9760e3-c864-4173-8b16-d790dac66d74_en?filename=md_sector_lang-req-table-mdr.pdf

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments

4.2	**EU Authorized Representative**
	
	Authorized representative (where the manufacturer does not have a registered place of business in a Member State):
	
	• The contract shall be compliant with Article 11 (Checked at application review and TD assessment), audit to verify that the accepted one is the current as registered at Eudamed.
	• The sole representative shall be appointed. (For certifications, the draft mandate for the designation of an authorized representative and a letter of intention from the authorized representative to accept the mandate) is adequate – however the Certification cannot be issued before there is a contract in place.
	• Agreement shall cover entire certification scope.
	• The manufacturer shall ensure that the authorized representative has the necessary documentation (Full technical documentation (Annex II and III) etc.) permanently available.
	• There shall be Evidence that the EU REP agreement is fulfilled:
	  ○ Evidence from the EU REP – or-
	  ○ Evidence of fee´s paid and that the obligations for the manufacturer, as given in the agreement are fulfilled
		Annex IX, 2.2 (b) 4th bullet
		
		Article 10(8), 3rd bullet
		
		Art. 11		

4.3	**Manufacturer's website** If the manufacturer has a website, information that appear on the device itself, on the packaging or in the instructions for use, shall ALSO be made available and kept up to date on the website. *Note: Any information needed to identify the device and its manufacturer, and by any relevant safety and performance information, SHALL accompany the device.*	Annex I (GSPR) 23.1		
	For devices without an IFU: • For Single use devices, information on the risks in relation to re-sterilization must be available on request (And fulfill language requirements). • Information related to safe disposal must be available upon request (And fulfill language requirements).	Annex I (GSPR) 23.4p & 23.4v		

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments
4.4*	**SRN** Requirements in relation to the Single Registration Number • Registration in EUDAMED • Update of the data (Section 1 of Part A of Annex VI) within 1 week of change • Within 1 year from first entry, and thereafter every year the accuracy of the data (Section 1 of Part A of Annex VI) shall be verified *The enforcement of these requirements is currently determined in the country of the member state where the manufacturer (or the EU rep) is residing. The manufacturer shall know current requirements.*	Article 31		
4.5a	**UDI for devices (to be) certified under MDR** Procedure and information related to UDI 1. Selection of Issuing entity for UDI codes 2. Structure of the UDI System (Basic UDI-DI defined and UDI-DI grouping in the Basic UDI-DI) 3. Definition of UDI-PI for product types 4. Having Basic UDI-DI and UDI-DI assigned (Article 27(3)) for all devices covered by certification. 5. Entering Company and device data/information into the UDI database (before placing devices on the market) as per article 29 section 1. Data as described in Part B of Annex VI. The UDI Database is currently. The requirements in relation to EUDAMED, which includes the UDI database, is currently not available. 6. Process for changes shall include evaluation if new Basic UDI or UDI DI shall be requested (Part C of Annex VI) and any subsequent update of UDI databases etc. 7. Implementation of UDI (UDI-DI and PI) in labelling and direct marking as per the deadlines given in the MDR. Placing UDI on the labels of devices: Class IIa and IIb devices: 26.05.2023 Class III and implantable: 26.05.2021 Class I devices: 26.05.2025 Direct marking of reusable devices: Class IIa and IIb devices: 26.05.2025 Class III and implantable: 26.05.2023 Class I devices: 26.05.2027	Article 10(7) Article 29,30, 31		

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments
4.5b*	**UDI for MDD devices after May 26, 2021** The requirements for UDI, for legacy devices (i.e. MDD devices, differs from those for MDD devices) Manufacturers must register the devices in the UDI database if 18 months after the date of application of the MDR or IVDR (or 24 months after the date of publication of the notice referred to in Article 34(3) if EUDAMED is not fully functional before the date of application of the MDR) if equivalent device is not MDR/IVDR certified. For class I (Non-Sterile/measurement) special timelines apply. EUDAMED, which includes the UDI database, is currently not ready and the requirement shall not be enforced. For legacy devices basic UDI-DI and UDI-DI assignment is optional. Procedures and requirements related to UDI <u>that applies at the time given above, for legacy devices:</u> 1. Selection of Issuing entity for UDI codes - is not required for legacy devices 2. Structure of the UDI System (Basic UDI-DI defined and UDI-DI grouping in the Basic UDI-DI) - is required for legacy devices 3. Definition of UDI-PI for product types – Is not required for legacy devices 4. Having Basic UDI-DI and UDI-DI assigned (Article 27(3)), or alternatives assigned in EUDAMED, for all devices covered by certification – is required for legacy devices 5. Entering Company and device data/information into the UDI database as per article 29 section 1. Data as described in Part B of Annex VI. The UDI Database is currently. Is required for legacy devices. 6. Process for changes shall include evaluation if new Basic UDI or UDI-DI shall be requested (Part C of Annex VI) and any subsequent update of UDI databases etc. – is required for legacy devices. 7. Implementation of UDI (UDI-DI and PI) in labelling and direct marking - Not required for legacy devices.	Article 120(3), 123. MDCG 2019-5 (April 2019)		

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments
4.6	**Retention of documents and records** The quality system shall specify a retention time of minimum 10 years (15 Years for Implants) after the last product has been placed on the market for: • the EU declaration of conformity • EU certificates of conformity • the documentation on the manufacturer's quality management system • 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 • Technical documentation (Annex II and III) • Applications to the NB (incl. technical documentation etc.), decisions, certificates and reports from the notified body including those arising from unannounced audits. This shall include any follow up activities • Notifications of changes to the Notified body and the actions and reports arising as a result of this.	Article 10(8) Annex IX Chapter III		
4.7	**Identification and evaluation of new standards and regulations** System to ensure that changes in harmonized standards, CS and implementing/delegated acts are identified and evaluated to ensure that they are adequately considered in a timely manner.	Article 10(9)		
4.8	**Procedure for translation of labeling and Declaration of Conformity** Translation and identification of language requirements: • Process for identification of the language requirements in the member states where the device is to be placed on the market • Information provided (IFU etc. Section 23 of Annex I) in an official Union language(s) determined by the Member State • This requirement also applies to Implant cards (Article 18). • DOC translated into an official Union language or languages required by the Member State(s) in which the device is made available.	Article 10(11) 18 19(1)		EU national language requirements provided at https://health.ec.europa.eu/document/download/aa9760e3-c864-4173-8b16-d790dac66d74_en?filename=md_sector_lang-req-table-mdr.pdf
4.9	**Requirement for pre-notification to Notified body** Procedure for reporting planned changes to the system and/or devices notified body shall be implemented. The use of Notification form in relation to change is required.	Annex XI, 9 Annex IX, 2.4 ; 4.10		

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments

	The procedure shall include criteria of what to report in relation to the following:
	
	• Changes to the organization, to sites, to activities at the sites
	• Significant change to the system (including change of Key suppliers or subcontractors, or the control of the current)
	• Significant changes to the organization or key personnel
	• Site(s)
	• Change of EU representative and
	• Significant changes to the quality system or processes – e.g. a new design procedure, an automation of a critical process
	•
	• Change of the device range covered
	  ○ IIa & IIb: A new/changed device leading to new code(s) being relevant (MDN, MDA, MDT, MDS)
	  ○ IIb: The new/changed device falls within a new GMDN code
	  ○ Changed intended use of or claims made for the device
	  ○ New device to be covered by Certification
	• Class III devices: **All** changes shall be approved by the Notified Body before implementation including design, raw materials/components, sourcing, manufacturing.
	• Changes to Basic UDI, UDI-DI and Single registration number (see MDCG2018-01 on UDI changes)			

4.10	**SSCP – Implantable and Class III devices only** Implantable devices and Class III devices - The manufacturer shall have a process in place for establishment of summary of safety and clinical performance in compliance with article 32. The frequency shall minimum be annually and require submission to the notified body	Article 32 & 61(11)		
4.11	**Systems and procedure packs**. Requirements for NB involvement in case of procedure packs being sterilized and where one or more of the devices is not already CE marked or is used outside its intended use.	Article 22		

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments
4.12	**Change management/QMS changes** Process for change of processes, procedures, work instructions etc. shall include • Evaluation of impact of MDR compliance, including risk management, clinical data (including need for clinical investigations) and general safety and performance requirements. • Evaluation of the need for reporting the change to the Notified body per defined criteria's (NB. Some changes required notified body accept before implementation and some not- Procedures shall be in place – see 4.8). • Impact in relation to UDI-DI, Basic UDI-DI	Annex IX, 2.2(c)/2.4		
4.13	**Reserved**			
4.14	**Product list** The manufacturer shall maintain a list of devices which has been CE marked with Notified body Number 0598. This may be the DOC´s	Annex XII,5		
4.15	**Technical Documentation** Technical documentation shall be established, maintained, and follow annex II and III The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organized, readily searchable and unambiguous manner and shall include in particular the elements listed in annex II and III Identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed. • The compliance with the General safety and performance requirements shall be established • Risk management system shall be established, documented, implemented and maintained as described in Section 3 of Annex I. • fulfilling the applicable specific requirements regarding design and construction, including appropriate pre-clinical evaluation, in particular the requirements of Chapter II of Annex I, • Procedure for fulfilling the requirements for information to be supplier with the device and in particular those referred in Chapter III of Annex I (All labelling)	Annex II		

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments
5. Management				
5.1	**Authority to sign DOC** Identification of person(s) with authority to sign the declaration of conformity	Derived from Annex IX,2.2(b), 1st bullet		
5.2	**PRRC** Person(s) responsible for regulatory compliance shall be identified (Art 15) and registered at Eudamed. Responsibilities (Article 15 section 3 & 4) shall be defined in the QMS (specific for each person in case that more than one is appointed) “Organizational independence” and “free form disadvantages” shall be ensured (art.16 section 5. Resume shall be evaluated to verify adequate competences (as per the MDR)	Based on Annex IX,2.2 (b) 1st bullet		
5.3	**QMS monitoring:** 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 shall be established. The data should include data on Incidents, recalls, audits and be part of management review	Annex IX, 2.2 ,(b), 2nd bullet		
5.4	**Quality policy and/or Quality management system:** Manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner, that is proportionate to the risk class and the type of device. The quality system shall maintain its effectiveness throughout the life cycle of the devices concerned. The quality system shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation	Article 10(9) Annex IX,1 Article 10(9)		

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments
6. Resource management				
6.1	**PRRC** Person(s) responsible for regulatory compliance shall fulfill the educational and experience requirements given in Art.15 section 1 (and section 6 for EU reps.)	Based on Annex IX, section 2.2(b) 1st bullet		
6.2	**Dedicated personnel whose responsibilities include MDR** shall have the competences needed. This includes persons being involved in Clinical Investigation, Persons involved in clinical evaluation, Clinical evaluations, PMS plans and systems, PSUR, persons involved in risk management, QA and RA personnel, Internal auditors and persons responsible for UDI processes and implementation.	Art.10(9d)		
7. Planning of product realization				
7.1.1	**Risk management** Risk management system shall be established, documented, implemented and maintained as described in Section 3 of Annex I.	Annex IX,2.2(c), 3rd bullet Article 10(2)		
7.2 Customer-related processes				
7.2.1	**Distributor and importer contracts** In case of Distributor's and/or importers Contracts shall be established and include the requirements of Article 13 respective 14- e.g.: • Traceability • Reporting complaints, post market feedback, incidents etc. to the manufacturer – including time frames • Participation in FSCA • Keeping registers for complaints etc. The Distributor's or external sales org. shall be familiar with reporting requirements	Related to e.g.: Article 13 (importers) Article 13 (Distributors) Article 25		

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments
7.2.2	**Control of misuse of Certifications and avoiding misbranding** Systems and processes shall ensure that: • The manufacturer does not use quality management system or device approvals in a misleading manner • Misbranding in relation to customer communication (Web, Social medias, Brochures, FAQ, accompanying documents) is not made	Article 10 Article 7 Annex VII, 4.10		
7.2.3	**Language requirements** For the Information required in section 23 of the GSPR (Labels, Instructions for use including text on electronic devices and in Software) shall fulfill the requirements for language set out by the Member State in which the device is made available to the user or patient.	Article 10(11)		
7.3 Design and development				
7.3.1	Procedure for "**Strategy for regulatory compliance"**, including: • processes for identification of relevant legal requirements, • qualification (as regards to device), • classification, • handling of equivalence, • choice of and compliance with conformity assessment procedures	Annex IX,2.2(c) 1st bullet		
7.3.2	**GSPR** Procedure ensuring identification of applicable general safety and performance requirements and identification of solutions to fulfil those requirements - taking applicable CS and, where opted for, harmonized standards or other adequate solutions into account	Annex IX,2.2(c) 2nd bullet		

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments
7.3.3	**Establishment of technical documentation** Technical documentation shall be established, maintained and be in compliance with Annex II and III The technical documentation (TD) and, if applicable, the summary thereof is to be drawn up by the manufacturer. The TD shall be presented in a clear, organized, readily searchable and unambiguous manner and shall include in particular the elements listed in annex II and III Identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.	Article 10(5) Annex II & III		
7.3.4	**Verification and validation documenting GSPR compliance** The design verification/validation and design output shall document compliance to the general safety and performance requirements	Annex I		
7.3.5	**Clinical evaluation** Procedure and system for the clinical evaluation - planning, conduction and documenting in accordance with national requirements, article 61 and Part A of Annex XIV, including taking into account the state of the art including post-market clinical follow-up.	Annex IX,2.2(c), 4th bullet Article 10(3) Annex IX,2.1		
7.3.6	**PMCF** Procedure and system post-market clinical follow-up (PMCF) in accordance with article 61 and Part B of Annex XI - or a justification why a PMCF is not applicable. ***See section "Check items for Post Market Clinical Follow up."*** *See 8.4*	Annex IX,2.2(c), 4th bullet Article 10(3)		

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments
7.3.7	**Pre-clinical evaluations and procedures** Procedures and techniques for pre-clinical evaluations and in particular to the requirements of chapter II of annex I – i.e., procedures in relation to: • Toxicity and flammability, Biocompatibility/Compatibility with tissue incl. where relevant, absorption, distribution, metabolism and excretion (10.1) • Mechanical properties (strength, fracture resistance etc.), Surface properties (10.1) • Compatibility with used materials, gases and substances (10.3) • Biocompatibility – Substances: CMR, Endocrine disruptors, phthalates, Nano, ingress into the device) 10.4-10.6) • Infection and microbial contamination (cut/pricks, contamination, packaging, Cleanliness, facility reprocessing, sterility integrity, packaging validation(sealing), medicinal product, absorbed by or locally dispersed) (11 & 12) • Combination of devices and interaction with environment (13.) • Microbiology • Transport and storage • Radiation intended (ionizing and non-ionizing) • Software, IT security, data protection • Electrical safety and EMC tests • Functional tests • Mechanical and thermal tests *This is not a full list – see annex I chapter II for identification of relevant disciplines*	Annex IX, 2.2 (c) 5th bullet		
7.3.8	**Procedure for fulfilling labeling requirements** Procedure for fulfilling the requirements for information to be supplied with the device and in particular those referred in Chapter III of Annex I (All labelling) The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.	Annex IX,2.2(c) 6th bullet Article 10(11)		
7.3.9	**Information intended for the patient and implant card – relevant to implantable devices only** See Article 18 for requirements. Applies to all implants excl. sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors (= Well Established Technology, WET).	Article 18		

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments
7.3.10 * Bullet 3 only	The **design change process** shall include the following: 1. Evaluation of impact of MDR compliance, including Risk management, clinical data (including need for clinical investigations) and general safety and performance requirements. 2. Evaluation of the need for reporting the change to the Notified body per defined criteria's (NB. Some changes required notified body accept before implementation and some not- Procedures shall be in place – see 4.8). 3. Impact in relation to UDI and any subsequent updates of UDI database (The requirements in relation to EUDAMED, which includes the UDI database, is currently not available.)	Annex IX, 2.2(c)/2.4		
7.4 Purchasing				
7.4.1	**Control of suppliers and subcontractors** 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, 2.2(b) 3rd bullet		
7.4.2	**Contractual requirements and requirements for Notified body of Control of suppliers and subcontractors** For these crucial suppliers/critical subcontractors, where evidence of compliance is not generated at the manufacturer, the contracts shall include the below unless irrelevant. Further requirements may apply: 1. Unambiguously identification of services covered and quality system requirements for the supplier/s 2. That SGS Fimko Ltd has right to audit the supplier, including unannounced audits. The right shall cover the entire supply chain (incl. unannounced) until evidence of compliance can be identified. 3. That SGS Fimko Ltd has the right to request tests conducted or to take sample for tests as part of the audit, including the unannounced audits. 4. That the manufacturer has right to audit the supplier 5. Requirements in relation to change control & waivers (aka Dispensations, on-time-changes etc.) shall include (i.e., who can authorize and accept). Any changes/waivers that potentially impacts compliance with MDR shall be accepted by the manufacturer. 6. Any change to documents being part of the technical documentation (which is all that in any way can "impact" the device) shall require approval by the Manufacturer. 7. Obligations, responsibilities and duties of the supplier/subcontractor (related to QS requirements, Standards, processes) 8. Any relevant specific requirements e.g., Traceability of raw materials, raw material authentication/verification, handling of materials/devices.	"checklist" Based on e.g. NBOG 2010-1 and NB bullet 1 is an absolute requirement for key suppliers/subcontractors		

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments
	9. Certifications of the supplier/subcontractor and notification to manufacturer if cancelled/withdrawn/suspended 10. Requirement for COC/COA 11. Corporation in case of CAPA, Complaints, recalls and Incidents SGS Fimko Ltd shall evaluate the need for audit critical supplier and subcontractors The need for supplier audit by SGS Fimko Ltd is determined by evaluation of the controls in place between the manufacturer and the supplier. The following items are evaluated to make a conclusion 1.The complexity and significance of the outsourced process 2. Product risks and risk mitigations related to the outsourced process 3.The control of the outsourced process by the manufacturer 4.The certification(s) of the supplier, accreditation status of the Conformity Assessment Body and validity of certificates. 5. Other relevant parameters that are relevant to the process (e.g., Special processes) 6. The availability of objective evidence of compliance at the manufacturer, for the processes at the subcontractor (or material compliance for a supplier) Supplier audits shall be conducted when: • Evidence of compliance with the requirements cannot be obtained at the legal manufacturer • The activity outsourced affects the risk and/or performance of the device or the compliance with the requirements. A copy of the contract between the company and the supplier is required. **Note: The evaluation of SGS Fimko Ltd's need for auditing critical suppliers/subcontractors shall be done for all critical suppliers/subcontractors.** **For all critical subcontractors and crucial suppliers where the need to do supplier audits is needed a copy of the contract between the company and the supplier/subcontractor shall be**			

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments
	requested. If suppliers further down the supply chain are critical the contracts between the parties in the supply chain shall be requested. Note: the subcontracting contract shall contain the statements that allows the NB (SGS Fimko Ltd) to perform an unannounced audit at the subcontractor's premises. *Note: **If the distributors/ sales agents** etc. provide critical services that are critical for compliance they should be subject to supplier control. Depending on the control in place, the processes outsourced and the evidence of compliance available at the manufacturer the distributor may be subject to supplier audit by the mfg. or Notified Body* *The services can include translation of documentation, Addition of accompanying documents (in the right language) to devices before shipment etc.*			
7.4.3	**In-process quality control requirements** Verification that the controls, verifications/validations and processes are as described in technical documentation including (but not limited to) the risk analysis and the GSPR	Annex IX,2.2(d&e)		
7.4.4	**Class III Tests by Notified Body – Class III devices only** In the case of class III devices, the surveillance assessment shall also include a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.	Annex IX,3.5		
7.5 Production and service provision				
7.5.1	**Test plans** Procedures for 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 sterilization and the relevant document	Annex IX, 2.2(d)		
7.5.2	**Quality control test procedures (in-process control, final testing, etc.)** Procedure for 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, 2.2(e)		

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments
7.5.3	**Special req. for devices containing medicinal product derived from human blood or plasma.** In 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 as referred to in Article 1(8) procedural requirements for informing the notified body of the release of the batch of devices with the documentation required (Annex IX section 6 & annex XI section 8)	Annex IX,6. Annex XI,8		
7.5.4	**Tests and validations are as described in technical documentation** Verification that the processes and the validations/verifications are as described in technical documentation including (but not limited to) the risk analysis and the GSPR	Annex IX,2.2(c) & 3.4		
7.5.5	**UDI printing** Processes for UDI printing and control shall be validated. Printing equipment shall be maintained.			
8. Measurement, analysis and improvement				
8-1*	**Post-market surveillance System and plans** For each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. (Art 38) The system be designed to fulfill the Post market surveillance fulfilling article 84 and Annex III, section 1.1. • Input to the process is defined in section 1.1(a) of annex III • Coverage is defined in section 1.1(b) of annex III • The use of the data is described in Article 83 and Criteria for reporting CAPA, initiated based on the analysis, to CA and NB shall be specified The system shall be fully integrated in the quality system of the Manufacturer ***See section "Check items - Post market system and plans."***	Art. 83, 84 and Annex III Art. 10(9i) & 10(10) Annex VII, 4.10		

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments
8.2 *Excl PSUR	**PMS reports and/or PSUR** Procedure shall be established for Post-market surveillance report (class Im, Is, Ir- class I is not within our scope) and Periodical safety update reports (PSUR)(Class IIa and higher), covering each device, group of devices and/or category of devices. • Report contents shall be defined • Frequency of update shall be specified (depending on Class) • Process for uploading the PSUR to "Electronic system on vigilance and on post-market surveillance" and notification of the upload to SGS Fimko Ltd directly – while Eudamed vigilance module is not available, the PSUR must be supplied to SGS Fimko Ltd directly. ***See section "Check items - Periodical safety update report (PSUR)."***	Part of Annex III. Art. 85 and 86		
8.3*	Procedures for **vigilance** shall be established including • Definitions • Timelines for reporting of incidents and FSCA- including exceptions • process for interaction with CA and NB – including uploading data to "Electronic system on vigilance and on post-market surveillance" • Periodic summary reporting requirements, as relevant. • Reporting of trends being statistically significant • Analyses of incidents • Initial and final Incident concept • Evaluating and coordination CA • FSCA contents • **Reporting directly to Notified Body** Manufacturers who consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the device in question and, where applicable, the authorized representative and importers accordingly. Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available and, 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.	Annex IX, 2.1, 8th"-" Art 87,88,89 Art. 10(9k) & 12		

Req. No	Requirement (Keywords- not the full requirements)	Reference:		Comments
8.4	**PMCF** Procedure and system post-market clinical follow-up (PMCF) in accordance with article 61 and Part B of Annex XIV - or a justification why a PMCF is not applicable. *See section "Check items - Post Market Clinical Follow up."* Same as 7.3.6	Annex IX, 2.2,(c), 4th bullet Article 10(3)		

Check items - Post Market Clinical Follow up.

ID	Requirement /check Item	Reference :		
1*	**Post market clinical follow up plan contents:** PMCF shall be performed pursuant to a documented method laid down in a PMCF plan including time points where the results are compiled, and a report issued The PMCF plan shall specify the methods and procedures for proactively collecting and evaluating clinical data with the aim of: (a) confirming the safety and performance of the device throughout its expected lifetime, (b) identifying previously unknown side-effects and monitoring the identified side-effects and contraindications, (c) identifying and analyzing emergent risks on the basis of factual evidence, (d) ensuring the continued acceptability of the benefit-risk ratio referred to in Sections 1 and 9 of Annex I, and (e) Identifying possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct. **Shall include:** (a) the general methods and procedures of the PMCF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data, (b) the specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies, (c) a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b), (d) a reference to the relevant parts of the clinical evaluation report and to the risk management referred to in Section 3 of Annex I (General safety and performance requirements)- including of specifically pointing out and endpoints/risks to be investigated, (e) the specific objectives to be addressed by the PMCF,	Annex XIV, Part B		

	(f) an evaluation of the clinical data relating to equivalent or similar devices, (g) reference to any relevant CS, harmonized standards when used by the manufacturer, and relevant guidance on PMCF, and (h) a detailed and adequately justified time schedule for PMCF activities (e.g. analysis of PMCF data and reporting) to be undertaken by the manufacturer. If no PMCF plan has been established this shall be adequately justified. *Note: Any investigations or protocols for collecting data shall follow the requirements for GCP - See MDR chapter Art 62 to 82 and Annex XV "Clinical investigation"*			

Check items - Post market system and plans*.

ID	Requirement /check Item	Reference :		
1*	Post-market surveillance System and plans For each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. (Art 38) The system be designed to fulfill the Post market surveillance fulfilling article 84 and Annex III, section 1.1. • Input to the process is defined in section 1.1(a) of annex III • Coverage is defined in section 1.1(b) of annex III • The use of the data is described in Article 83 and Criteria for reporting CAPA, initiated based on the analysis, to CA and NB shall be specified The system shall be fully integrated in the quality system of the Manufacturer	Art. 83, 84 and annex III Art. 10(9i) & 10(10)		
2*	For each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer's quality management system referred to in Article 10(9).	Article 83(1) **10(9).**		
3*	The post-market surveillance system shall be suited to actively and systematically gathering, recording and analyzing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.	Article 83(2)		
4*	The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 83 to 86 shall be presented in a clear, organized, readily searchable and unambiguous manner and shall include in particular the elements described in this Annex.	Annex III (top section)		

ID	Requirement /check Item	Reference :		
5*	**INPUT** The manufacturer shall prove in a post-market surveillance plan that it complies with the obligation referred to in Article 83. The post-market surveillance plan shall address the collection and utilization of available information, in particular: (a) information concerning serious incidents, including information from PSURs, and field safety corrective actions, (b) records referring to non-serious incidents and data on any undesirable side-effects, (c) information from trend reporting, (d) relevant specialist or technical literature, databases and/or registers; — information, including feedbacks and complaints, provided by users, distributors and importers, and (e) publicly available information about similar medical devices.	Annex III,1.1(a)		

ID	Requirement /check Item	Reference :		
6*	**Criteria for collection of data, definitions of thresholds, analyzing** (a) The post-market surveillance plan shall address the collection and utilization of available information, in particular: - information concerning serious incidents, including information from PSURs, and field safety corrective actions, - records referring to non-serious incidents and data on any undesirable side-effects; - information from trend reporting, - relevant specialist or technical literature, databases and/or registers, - information, including feedbacks and complaints, provided by users, distributors and importers, and - publicly available information about similar medical devices. (b) The post-market surveillance plan shall cover at least: - a proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterization of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market, - effective and appropriate methods and processes to assess the collected data, - suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management as referred to in Section 3 of Annex I, - effective and appropriate methods and tools to investigate complaints and analyses market-related experience collected in the field, - methods and protocols to manage the events subject to the trend report as provided for in Article 88, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period, - methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users, - reference to procedures to fulfil the manufacturers obligations laid down in Articles 83, 84 and 86, - systematic procedures to identify and initiate appropriate measures including corrective actions, - effective tools to trace and identify devices for which corrective actions might be necessary; and - a PMPF plan as referred to in Part B of Annex XIV, or a justification as to why a PMPF is not applicable. The quality and categorization of data shall allow for trending and for a compliant PSUR.	Annex III,1.1 Article 83		

ID	Requirement /check Item	Reference :		
7*	**Usage of the analyze** Data gathered by the manufacturer's post-market surveillance system shall in particular be used: (a) to update the benefit-risk determination and to improve the risk management as referred to in Chapter I of Annex I, (b) to update the design and manufacturing information, the instructions for use and the labelling, (c) to update the clinical evaluation, (d) to update the summary of safety and clinical performance referred to in Article 32, (e) for the identification of needs for preventive, corrective or field safety corrective action, (f) for the identification of options to improve the usability, performance and safety of the device, (g) when relevant, to contribute to the post-market surveillance of other devices, and (h) to detect and report trends in accordance with Article 88 “trend reporting”. The technical documentation shall be updated accordingly.	Article 83(3)		
8*	**CAPA** If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body. Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with Article 87.	Article 83(4)		
9*	**PMS based on PMS plan** The post-market surveillance system referred to in Article 83 shall be based on a post-market surveillance plan, the requirements for which are set out in Section 1.1 of Annex III. For devices other than custom-made devices, the post- market surveillance plan shall be part of the technical documentation specified in Annex II.	Article 84		

ID	Requirement /check Item	Reference :		
10*	**For Class I devices manufacturers** Manufacturers of class I devices shall prepare a post-market surveillance report summarizing the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the competent authority upon request.	Article 85		

Check items - Periodical safety update report (PSUR).

ID	Requirement /check Item	Reference :	Include in all audits	Notes
1*	Manufacturers of class IIa, class IIb and class III devices shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices: • summarizing the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 (post market surveillance plan) - together with a • rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned, that PSUR shall set out: (a) the conclusions of the benefit-risk determination; (b) the main findings of the PMCF; and (c) the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device. Manufacturers of class IIb and class III devices shall update the PSUR at least annually. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III. Manufacturers of class IIa devices shall update the PSUR when necessary and at least every two years. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III. For custom-made devices, the PSUR shall be part of the documentation referred to in Section 2 of Annex XIII.	Article 86(1)		
2*	For class III devices or implantable devices, manufacturers shall submit PSURs by means of the electronic system referred to in Article 92 to the notified body involved in the conformity assessment in accordance with Article 52. The notified body shall review the report and add its evaluation to that electronic system with details of any action taken. Such PSURs and the evaluation by the notified body shall be made available to competent authorities through that electronic system.	Article 86(2)		
3*	For devices, other than those referred to in paragraph 2, manufacturers shall make PSURs available to the notified body involved in the conformity assessment and, upon request, to competent authorities.	Article 86(3)		