Implementation of Medical Devices EU-Regulation – Focus on Manufacturers' obligations
Source: British Medicines and Healthcare Products Regulatory Agency (MHRA)

Task	Source of requirement	Who	Date of application
General systems and process requirements			
Consider taking out **liability insurance**	Article 10(16)	Manufacturer	
Establish and document a **system for risk management** (Annex I, Section 3)	Article 10(2)	Manufacturer	
[Proportionate to risk class, except for investigational devices] establish, document, implement, maintain, keep up to date and continually improve a **Quality Management System** (detailed requirements concerning scope in text)	Article 10(9)	Manufacturer	
[Proportionate to risk class and appropriate to type of device] Plan, establish, document, implement, maintain and update a **post-market surveillance system** based on a post-market surveillance plan included in technical documentation (except for custom-made devices), as integral part of quality management system	Article 10(9i), Article 83(1)	Manufacturer	
Establish a **system for reporting incidents and field safety corrective actions** as described in Articles 87 and 88.	Article 10(13)	Manufacturer	
Make provisions to keep copy of technical documentation (if applicable, including STED), declaration of conformity and (if applicable) certificate available for CA for at least 10 (15 in the case of implantable devices) years after last device placed on market	Article 10(8)	Manufacturer	
Distribution chain			
Identify distributors and importers and establish responsibilities		Manufacturer	*See separate sheets for responsibilities*
Make provisions to ensure ability to identify their suppliers of devices and any economic operator/health institution to whom they have supplied devices to CA for 10 yrs (15 years for implantables) after the last device placed on market	Article 25(2)	Economic operators	
Cooperate with distributors and importers to achieve appropriate level of traceability	Article 25(1)	Economic operators	
Authorised representative			*See separate sheet for responsibilities*
Designate authorised representative and agree mandate	Article 11(1, 2)	Manufacturer not established in Union	
Ensure that authorised representative has permanent access to all documentation required to fulfil tasks (Article 11(3))	Article 10(8)	Manufacturer not established in Union	
[When changing authorised representative] Define modalities in agreement between manufacturer and (where practicable) both outgoing and incoming AR	Article 12	Manufacturer not established in Union	

Person responsible for regulatory compliance			
Appoint within their organisation a person responsible for regulatory compliance with demonstrated expertise	Article 15(1)	Medium/large manufacturer	
Ensure permanent, continuous access to person responsible for regulatory compliance within/outside organisation	Article 15(2)	Micro manufacturer/SME	
Conformity assessment and CE marking			
Determine risk classification of devices according to new MDR classification rules	Annex VIII	Manufacturer	
Technical documentation			
[Except for custom-made devices] Draw up and keep up to date technical documentation (Annexes II and III)	Article 10(4)	Manufacturer	
[For custom-made devices] Draw up, keep up to date and keep available to CA documentation in line with Annex XIII, Section 2	Article 10(5)	Manufacturer of custom-made device	
[For class II and implantable devices, except custom-made or investigational devices] Draw up summary of safety and clinical performance (STED); submit draft of summary as part of doc submitted to NB (Article 52); provide link to summary report on Eudamed on label or IFU	Article 32(1)	Manufacturers of class III and implantable devices	*Applies from 6 months after publication of notice of full functionality of UDI system/Eudamed, but no earlier than date of application*
[Except for custom-made devices] Establish a post-market surveillance plan (Annex III, Section 1.1) as part of technical doc	Article 84	Manufacturer	
Ensure that technical file structure for existing, marketed devices is in line with MDR requirements	Annex II	Manufacturer	
Interaction with Notified Body			
Verify that (existing) Notified Body is designated under MDR/for relevant category of devices or establish relationship with new NB		Manufacturer of devices requiring NB involvement in conformity assessment	*Notified Bodies designated under Directives may operate/issue certificates until Date of Application of MDR*
Discuss management of transition for devices certified under Directives with Notified Body		Manufacturer of existing devices requiring NB involvement in conformity assessment	*See above*
[Where conformity assessment requires involvement of NB] May apply to NB of choice notified for relevant activities, procedures, devices	Article 53(1)	Manufacturer	
Declare where they have withdrawn application with another NB prior to decision, and/or provide information on any previous applications for same device type refused by another NB	Article 53(3)	Manufacturer having made previous application for same device type	

[When terminating contract with NB to enter into new contract regarding same devices] Define modalities in agreement with incoming and where practicable outgoing NB	Article 58(1)	Manufacturer voluntarily changing NB	
Conformity assessment and CE marking			
Undertake conformity assessment in line with requirements for risk class (Article 52, Annexes IX-XIII) prior to placing devices onto market and prior to putting into service devices not placed on market [except in-house]	Article 52(1, 2)	Manufacturer	
[For class III devices, except custom-made or investigational devices] Shall be subject to conformity assessment based on quality management system assurance and assessment of technical documentation (Annex IX) or conformity assessment based on type examination (Annex X) combined with product conformity verification (Annex XI)	Article 52(3)	Manufacturer of class III device	
[For class III implantable devices] NB shall follow procedure regarding clinical evaluation consultation in Section 5.1 of Chapter II of Annex IX, as applicable; except in cases stated	Annex 52(3)	Manufacturers of class III implantable devices	
[For devices incorporating medicinal substances] NB shall follow consultation procedure in Section 5.2 of Chapter II of Annex IX, as applicable	Article 52(9)	Manufacturer of device incorporating medicinal substance	
[For devices incorporating non-viable cells or tissues of animal or human origin] NB shall follow consultation procedure in Section 5.3 of Annex IX, as applicable	Article 52(10)	Manufacturer of device incorporating non-viable cells or tissues of human origin	
[For devices composed of substances that are absorbed by/locally dispersed in the body] Quality and safety of device shall be verified (where applicable, in aspects not covered by MDR) in accordance with Annex I of Directive 2001/83/EC; [for devices/products of metabolism that are absorbed in order to achieve their intended purpose] Notified Body shall consult medicinal products competent authorities/EMA on compliance with Directive 2001/83/EC	Annex IX Section 5.4	Manufacturer of device composed of substances that are absorbed by/locally dispersed in the body	
[For class IIb devices, except custom-made or investigational] Conformity assessment based on quality management system (Annex IX, except Chapter II), with assessment of technical documentation of at least one representative device per generic device group; for class IIb implantable devices, assessment of technical documentation (Section 5 of Chapter II of Annex VIII) applies; OR type examination (Annex IX) combined with product conformity verification (Annex X)	Article 52(4)	Manufacturer of class IIb devices	
[For class IIa devices, except custom-made or investigational devices] Conformity assessment based on quality management system (Annex IX except Chapter II), with assessment of technical documentation of at least one representative device for each category of devices; OR Draw up technical documentation (Annexes II and III) coupled with conformity assessment based on product conformity verification (Annex XI, Section 10 or 18)	Article 52(6)	Manufacturer of Class IIa devices	

[For class I devices, except custom-made or investigational] Declare conformity of products by issuing EU declaration of conformity (Article 19) after drawing up technical documentation (Annexes II and III); [for devices placed on market in sterile condition or with measuring function] Apply procedures in Annex IX (except Chapter II) or Part A in Annex XI, with involvement of NB limited to relevant elements	Article 52(7)	Manufacturer of class I devices	
[For custom-made devices] Follow procedure in Annex XIII and draw up statement in Section I of Annex XIII before placing device on market	Article 52(8)	Manufacturer of custom-made devices	
[For class III custom-made implantable devices] Conformity assessment procedure based on quality management system (Annex IX except Chapter II, or Part A of Annex XI)	Article 52(8)	Manufacturer of class III custom-made devices	
Declaration of Conformity			
[Following completion of appropriate conformity assessment procedure, except for custom-made or investigational devices] Draw up single EU declaration of conformity (Article 19, Annex IV; translated into official language required by MS where device is made available) and affix CE mark (Article 10)	Article 10(6)	Manufacturer	
[By drawing up EU declaration of conformity] Assume responsibility for compliance with requirements of MDR and all other Union legislation applicable to device	Article 19(3)	Manufacturer	
Labelling and user information requirements			
Check labelling on existing marketed devices against new requirements	Annex I, Chapter III	Manufacturer	
Ensure that device is supplied with required information (Annex I, Section 23) in official EU language, with label being easily legible, comprehensible and indelible	Article 10(11)	Manufacturer	
[For implantable devices, except those placed on list of devices exempt from requirement by Cion] Provide appropriate information for patients receiving implant, including UDI, by any means allowing rapid access to info and readily understood by layperson	Article 18	Manufacturer of implantable devices	
[For custom-made devices] Make available to patient/user identified by name, acronym or numerical code the statement in Section 1 of Annex XIII	Article 21(2)	Manufacturer of custom-made devices	
Provisions concerning specific device types/activities			
Investigational devices			
Shall be subject to requirements in Articles 62 to 81	Article 52(13)		
[When supplied to investigator for clinical investigation] Must comply with conditions in Articles 62 to 82 and Annex XV	Article 21(1)		

Shall not bear CE marking, except devices referred to in Article 74 [CE-marked devices subject to PMCF or investigations for new purpose]	Article 21(1)		
May only be used for clinical investigation where they comply with applicable general safety and performance requirements apart from aspects covered by clinical investigation, with regard to which every precaution has been taken to protect health and safety of subjects	Article 62(4)		
Ensure that statement referred to in point 4.1 of Chapter II of Annex XV is issued	Article 15(3)	Person responsible for regulatory compliance	
Custom-made devices			
Must comply with Article 52(8) and Annex XIII	Article 21(1)		
Shall be accompanied by statement referred to in Section 1 of Annex XIII, which shall be made available to patient/user identified by name, acronym or numerical code	Article 21(2)		
May be required by MS submit list of all custom-made devices made available on territory to competent authority	Article 21(2)	Manufacturer of custom-made devices	
Systems and procedure packs			
[When combining any combination of CE-marked MD, IVD, or other product conforming with applicable legislation as systems or procedure pack, in accordance with intended purpose, for placement on market] Provide statement declaring verification of mutual compatibility of those products; provision of necessary instructions; that combined with appropriate internal monitoring and verification. Shall keep statement available for CA for 10 years (15 for implantable devices) after last device placed on market.	Article 22(1, 2, 5)	Person creating systems and procedure pack for placement on market	
[For sterilised combination packs] Follow either procedure in Annex IX or Part A of Annex XI, limited to aspects of procedure relating to sterility; provide declaration that sterilisation carried out in accordance with manufacturer's instructions	Article 22(3)	Person sterilising systems and procedure pack for placement on market	
Systems and procedure pack shall count as device in its own right subject to relevant conformity assessment requirements if includes non-CE marked products, not in line with intended purpose, or sterilisation not in accordance with manufacturer's instructions	Article 22(4)		
Systems and procedure packs shall not bear additional CE marking, but shall bear name, trade mark/name and contact details of combining person; shall be accompanied by information (Section 23 of Annex I)	Article 22(5)		
Parts and components			
[When making available article to replace identical or similar integral part to re-establish/maintain normal function of device] Ensure article does not adversely affect safety and performance and keep supporting evidence available to CA	Article 23(1)	Person making available replacement parts	

Item intended to replace part of device that significantly changes its performance or safety is considered a device	Article 23(2)		
Devices without an intended medical purpose			
Adoption of CS concerning Annex XVI products	Article 1(2)	Cion (required)	*Shall be adopted as soon as possible following entry into force and at the latest so they enter into force on date of application*
Empowered to adopt delegated acts to add new groups of products to Annex XVI list	Article 1(5)	Cion	
Devices listed in Annex XVI are in scope and subject to common specifications addressing at least application of risk management and general safety and performance requirements (Annex I) and clinical evaluation	Article 1(2)	Manufacturer of aesthetic products	*Applies from date of entry into force of common specifications or date of application of MDR, whichever is the latest*
Devices incorporating as integral part substances considered medicinal products if used separately			
[If action of medicinal substance is ancillary to that of device] Product shall be assessed and authorised in accordance with MDR	Article 1(8)		
[If action of medicinal substance principal to that of device] Product shall be governed by Directive 2001/83/EC or Regulation (EC) No 726/2004, as applicable	Article 1(8)		
Devices incorporating substances of animal or human origin			
[If transplants, tissues or cells or their derivatives are viable] Not regulated under MDR	Article 1(6f, 6g)		
[If transplants, tissues or cells or their derivatives are non-viable or rendered non-viable] Regulated under MDR	Article 1(6f, 6g)		
Devices incorporating non-viable human or animal tissues legally placed on market or put into service in accordance with Member State rules in force prior to application of MDR may continue to be placed on the market/put into service in Member States concerned	Article 120(10)		
Distance sales			
Device offered by means of information society services shall comply with MDR when placed on market	Article 6(1)	Manufacturers of devices for distance sale	
Device not placed on market but used in context of commercial activity for provision of diagnostic or therapeutic service offered by means of information society services shall comply with MDR	Article 6(2)	Manufacturers of devices to be used for distance services	
Make available copy of EU declaration of conformity on request by competent authority	Article 6(3)	Person offering device via distance sales or using device to provide distance services	

Requirements relating to UDI			
Note: The application of these requirements is in most cases dependent on the Commission's conducting an audit of the systems and announcing the full functionality of Eudamed via a notice in the Official Journal of the EU (Article 34(3)). Until the Commission has designated the UDI assigning entities, GS1 AISBL, HIBCC and ICCBBA shall be considered as designated UDI assigning entities.			
Note: Under Article 120(8), manufacturer's compliance with Articles 29(4) and 56(5) is recognised as compliance with the relevant registration requirements under the old Directives.			
Comply with obligations related to UDI system and registration obligations (Articles 27, 29 and 31)	Article 10(7)	Manufacturer	
[Except for custom-made device, before placing device on market] Assign to device and (if applicable) all higher levels of packaging UDI created in compliance with rules of designated entity	Article 27(3)	Manufacturer	*Applies from 24 months after publication of notice of full functionality of Eudamed, but no earlier than 18 months after date of application of MDR*
Place UDI carrier on label of device and all higher levels of packaging, not including shipping containers	Article 27(4)	Manufacturer	*Applies one year after date of application for implantable and class III devices; three years after for class IIa and II b devices; five years after for class I devices; two years after date stipulated for relevant risk class for reusable devices that shall bear UDI carrier on device itself*
Use UDI for reporting serious incidents and field safety corrective actions (Article 87) and include in information to be provided to patient receiving implant (Article 18)	Article 27(5)	Manufacturer	
Include Basic UDI DI in EU declaration of conformity	Article 27(6)	Manufacturer	
Keep up-to-date list of all UDI assigned as part of technical documentation (Annex II)	Article 27(7)	Manufacturer	
Store and keep, preferably by electronic means, UDI of devices supplied/supplied with belonging to the categories/groups determined by Cion	Article 27(8)	Manufacturer	
[Except for custom-made or investigational device, before placing on market] Ensure that info in Part B of Annex VI is correctly submitted and transferred to UDI database	Article 29(1)	Manufacturer	
[Except for custom-made device, before placing device on market] Assign Basic UDI-DI as defined in Part C of Annex VI to device, in compliance with rules of designated issuing entities	Article 29(1)	Manufacturer	*Applies from 24 months after publication of notice of full functionality of Eudamed, but no earlier than 18 months after date*

			of application of MDR
[For systems and procedure pack, except custom-made device, before placing on market] Assign Basic UDI-DI (Part C of Annex VI) and submit to UDI alongside linked information (Part B of Annex VI)	Article 29(2)	Person responsible for placing on market system or procedure pack	*Applies from 24 months after publication of notice of full functionality of Eudamed, but no earlier than 18 months after date of application of MDR*
[Except for custom-made or investigational device, when applying conformity assessment procedure according to Article 52(3) and second and third subparagraphs of Article 52(4)] Submit Basic UDI-DI and linked info to UDI database before applying for the assessment	Article 29(3)	Manufacturer	*Applies from 24 months after publication of notice of full functionality of Eudamed, but no earlier than 18 months after date of application of MDR*
[Devices referred to above] Include a reference to the Basic UDI-DI on the certificate issued (Annex XII, Chapter I, Section 4) and confirm in Eudamed that information referred to in Section 2.2 of Part A of Annex VI is correct.	Article 29(3)	Notified Bodies	*Applies from 24 months after publication of notice of full functionality of Eudamed, but no earlier than 18 months after date of application of MDR*
[Except for custom-made device, before placing device on market] Submit, or verify where already provided, the information in Eudamed referred to in Section 2 of Part A of Annex VI (except Section 2.2), and keep updated thereafter	Article 29(4)	Manufacturer	*Applies from 24 months after publication of notice of full functionality of Eudamed, but no earlier than 18 months after date of application of MDR*
[If not registered before, except for custom-made device] Submit information in Annex VI Part A Section 1 to electronic system before placing device on market. [Where conformity assessment procedure requires involvement of NB] Submit information in Annex VI Part A Section 1 before applying to NB	Article 31(1)	Manufacturer	*Applies from 24 months after publication of notice of full functionality of Eudamed, but no earlier than 18 months after date of application of MDR*
[After verifying information submitted for Article 31(1)] Obtain and issue Single Registration Number to the economic operator	Article 31(2)	Competent Authority	*Applies from 24 months after publication of notice of full functionality of Eudamed, but no earlier than 18 months after date of application of MDR*
Use single registration number when applying to NB for certification (Article 53) and accessing Eudamed (Articles 27 and 29).	Article 31(3)	Manufacturer	*Applies from 24 months after publication of notice of full functionality of Eudamed, but no earlier than 18 months after date of application of MDR*

Update information on electronic system for registration of economic operators (Annex VI Part A Section 1) within one week of changes	Article 31(4)	Manufacturer	*Applies from 24 months after publication of notice of full functionality of Eudamed, but no earlier than 18 months after date of application of MDR*
Confirm accuracy of data no later than one year after submission and every second year thereafter	Article 31(5)	Manufacturer	*Applies from 6 months after publication of notice of full functionality of UDI system/Eudamed, but no earlier than date of application*
[Where device is designed or manufactured by person other than manufacturer] Include information on that person as part of info to be submitted in accordance with Article 30(1)	Article 10(15)	Manufacturer subcontracting design/manufacture	
Compliance with common specifications and harmonised standards			
Common specifications concerning products without an intended medical purpose (Annex XVI)	Article 1(2)	Cion (required)	*Shall be adopted as soon as possible following entry into force and at the latest so that CS enter into force on date of application of MDR*
Common specifications concerning in-house reprocessing	Article 17(5)	Cion (required)	*Shall be adopted by date of application*
[Where no harmonised standards exist/HS are insufficient] Common specifications adopted by Cion regarding Annexes I, II, III, XIV & XV	Article 9(1)	Cion (optional)	
Comply with common specifications unless they can duly justify that they have adopted solutions ensuring equivalent safety/performance	Article 9(3)	Manufacturer	
Comply with common specifications concerning products without an intended medical purpose (Annex XV) (no alternative solutions permitted)	Article 9(4)	Manufacturer of aesthetic devices	*Once adopted*
Ensure that changes in harmonised standards or common specifications are taken into account in timely manner	Article 10(9)	Manufacturers	
Clinical evaluation and clinical investigations			
Clinical investigations started before date of application may continue	Article 120(11)		
Incident reporting for clinical investigations started before date of application	Article 120(11)		

must comply with MDR			
Review clinical evidence for devices currently on market against new requirements	Chapter VI (Articles 61-82), Annex XIV and XV	Manufacturer of devices on the market	
Plan timelines for collection of additional clinical evidence where required in order to obtain new certificate		Manufacturer of devices on the market	
Update internal procedures for clinical evaluation in line with MDR requirements concerning levels of evidence, clinical investigations, and reporting	Chapter VI (Articles 61-82), Annex XIV and XV	Manufacturer	
Specify and justify level of clinical evidence required to demonstrate compliance, appropriate to device characteristics and intended purpose for each device and plan, conduct and document a clinical evaluation (Article 61, Part A of Annex XIV) including post-market clinical follow-up	Article 10(3), Article 61(1)	Manufacturer	
[For class III devices and class IIb active devices intended to administer/remove medicinal products] Decide whether to take up option to **consult expert panel** prior to clinical evaluation/investigation (Article 106) to review strategy/proposal. Shall give due consideration to views of panel, to be documented in clinical evaluation report, but may not invoke rights to panel's views for future assessments.	Article 61(2)	Manufacturer of class III devices and class IIb active devices intended to administer/remove medicinal products	
[For class III and implantable devices] Assess whether evidence requirements can be satisfied in virtue of **equivalence** with existing device already on market, the clinical investigations of which are sufficient to demonstrate conformity. If yes, obtain Notified Body's endorsement of demonstration of equivalence, put into place clear contract with manufacturer of marketed device (where different) guaranteeing full and permanent access to technical documentation, provide evidence that original investigations were conducted in line with MDR requirements and description of nature of modification. If no, conduct clinical investigation.	Article 61(4)	Manufacturer of class III and implantable devices	
[Except for class III/implantable devices, where demonstration of conformity based on clinical data not deemed appropriate] Provide adequate justification for exception, substantiate adequacy of non-clinical testing in technical documentation	Article 61(10)	Manufacturer	
Put in place processes to update clinical evaluation and documentation throughout lifecycle of device based on clinical data from post-market clinical follow-up (Annex XIV Part B) and post-market surveillance plan (Article 84) (at least annually for class III and implantable devices)	Article 61(11)	Manufacturer	
Document clinical evaluation, results and resulting evidence in clinical evaluation report (Annex XIII, Section 4); [except for custom-made devices] include in technical documentation.	Article 61(12)	Manufacturer	

Appoint natural or legal person established in Union as **legal representative**, responsible for compliance and addressee of all communications (except where MS choose to demand only a contact person on their territory)	Article 62(2)	Sponsor not established in Union	
Review new ethical requirements (ethical review, informed consent, protection of vulnerable populations etc.) and adapt procedures accordingly	Article 62(4); Article 64	Sponsor	
Ensure coverage under **system for compensation for any damage** suffered by subject resulting from participation in clinical investigation (insurance, guarantee or similar) appropriate to nature and extent of risk, is in place in MS where investigation is conducted	Article 69	Sponsor	*Applies from 6 months after publication of notice of full functionality of UDI system/Eudamed, but no earlier than date of application*
Prepare for use of **new electronic system on clinical investigations for applications** (submission to MS(s) where investigation is to be conducted, accompanied by documentation in Annex XIV; update of information within 1 week in case of changes) and for use of unique single identification number for all communication	Article 70(1); 73(2)	Sponsor	*Applies from 6 months after publication of notice of full functionality of UDI system/Eudamed, but no earlier than date of application*
Put in place processes to monitor conduct of clinical investigation to verify protection of rights, safety and well-being of subjects, reliability/robustness of reported data, and compliance of conduct with MDR; determine extent of monitoring based on assessment of objective, methodology, and degree of deviation from normal clinical practice of investigation	Article 72(2)	Sponsor	*Applies from 6 months after publication of notice of full functionality of UDI system/Eudamed, but no earlier than date of application*
Put in place mechanism to record, process, handle and store all information in such a way that it can be accurately reported, interpreted, and verified while confidentiality of records/personal data of subjects remain protected	Article 72(3)	Sponsor	*Applies from 6 months after publication of notice of full functionality of UDI system/Eudamed, but no earlier than date of application*
Implement appropriate technical and organisational measures to protect information and personal data	Article 72(4)	Sponsor	*Applies from 6 months after publication of notice of full functionality of UDI system/Eudamed, but no earlier than date of application*
Establish procedure for emergency situations enabling immediate identification and (where necessary) immediate recall of devices used in investigation	Article 72(6)	Sponsor	*Applies from 6 months after publication of notice of full functionality of UDI system/Eudamed, but no earlier than date of application*
Put in place process for notifying MS concerned via Eudamed of clinical investigations to further assess CE marked devices within stated intended purpose **(post-market clinical follow-up)** at least 30 days prior to commencement if investigation would submit subjects to additional invasive or burdensome	Article 74(1)	Sponsor	*Applies from 6 months after publication of notice of full functionality of UDI system/Eudamed, but no earlier*

procedures			*than date of application*
Put in place process for notifying MS concerned via Eudamed of **intention to modify clinical investigations** in ways that are likely to have substantial impact on safety, health or rights of subjects or reliability or robustness of clinical data generated, accompanied by updated documentation (Chapter II, Annex XV)	Article 75(1); Article 78(12)	Sponsor	*Applies from 6 months after publication of notice of full functionality of UDI system/Eudamed, but no earlier than date of application*
Put in place process for informing MSs concerned via Eudamed of end / early termination / temporary halt of clinical investigation within 15 days [24 hours if halted/terminated on safety grounds]	Article 77(1, 2, 3)	Sponsor	*Applies from 6 months after publication of notice of full functionality of UDI system/Eudamed, but no earlier than date of application*
Put in place process for submission to MSs concerned via Eudamed a **clinical investigation report** (Annex XV, Chapter I, Section 2.8) (within one year of end of clinical investigation/3 months from early termination) and **summary of report** (at latest within one year following provision of report, in style readily understood by intended user); reports shall become publicly available at latest when device is CE marked	Article 77(4, 5, 6, 7)	Sponsor	*Applies from 6 months after publication of notice of full functionality of UDI system/Eudamed, but no earlier than date of application*
Decide whether to take up option to submit single applications for clinical investigation to be conducted in more than one MS where MS agree to **coordinated procedure**	Article 78(1, 2)	Sponsor	*Applies from 6 months after publication of notice of full functionality of UDI system/Eudamed, but no earlier than date of application*
Put in place process for recording adverse events identified in clinical investigation plan as critical to evaluation of results; serious adverse events; device deficiencies that might have led to serious adverse events in absence of suitable action/intervention/under less fortunate circumstances; or new findings concerning the above	Article 80(1)	Sponsor	*Applies from 6 months after publication of notice of full functionality of UDI system/Eudamed, but no earlier than date of application*
Put in place process for reporting to all MSs where investigation conducted without delay via Eudamed: serious adverse event that has (reasonably probable) causal relationship with device, comparator or procedure; device deficiency that might have led to serious adverse event; and new findings; including any such events occurring in 3rd countries in which investigation is performed under same plan	Article 80	Sponsor	*Applies from 6 months after publication of notice of full functionality of UDI system/Eudamed, but no earlier than date of application*

Post-market surveillance and vigilance			
Put in place processes for use of data from PMS system to update benefit/risk determination, risk management, design and manufacturing info, IFU, and labelling; update clinical evaluation; update summary of safety and clinical performance (Article 32); identify needs for preventive/corrective/field safety corrective action; identify possibilities to improve usability, performance and safety of device; (where relevant) contribute to PMS of other devices; detect and report trends (Article 61a). Update technical documentation accordingly	Article 83(3)	Manufacturer	
Put in place processes for producing and keeping up-to-date periodic safety update reports summarising results and conclusions of analyses of PMS data (Annex III) and rationale and description of any preventative or corrective actions for each device/category/group of devices; [for class III or implantable devices] prepare capabilities for submitting reports to Notified Body via Eudamed	Article 86(1)	Manufacturer	
[For devices made available on Union market, except investigational devices] Put in place processes for reporting via Eudamed: serious incidents (except expected side effects clearly documented in product information and quantified in technical documentation and subject to trend reporting (Article 88)) and field safety corrective action	Article 87(1)	Manufacturer	
Agree with concerned Competent Authority/Authorities on types of incidents [repeated similar serious incidents with same device (type) for which root cause identified/FSCA taken/incidents common and well-documented] for which to provide periodic summary reports instead of individual serious incident reports, and on format, frequency, and content of reports	Article 87(2)	Manufacturer	
[In post-market surveillance plan (Article 84)] Define methodology for detecting trends and statistically significant increases (relative to expected levels specified in technical documentation and product information) in frequency / severity of incidents that are not serious incidents or of expected undesirable incidents that could have significant impact on risk/benefit analysis; prepare processes for reporting trends via Eudamed	Article 88(1)	Manufacturer	
Identify reporting requirements involving Eudamed and adapt internal procedures accordingly	Chapter VII Section 1 & 2 (Articles 83-92)	Manufacturer	
Prepare systems for use of UDI and SRN for reporting serious incidents and FSCA, in field safety notices	Article 27(5); 89(8)	Manufacturer	

Respect confidentiality of information and data obtained in carrying out tasks in order to protect personal data (Article 110), commercially confidential information and trade secrets (unless disclosure is in public interest), and effective implementation of MDR	Article 109(1)	All parties involved	