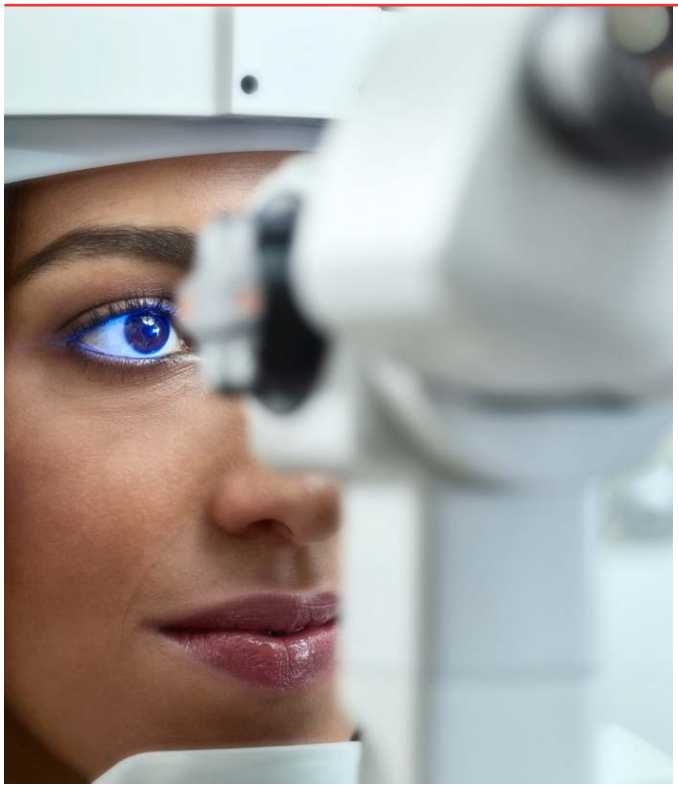
How to best implement the EU IVDR – dos and don'ts

Updated by Steve Lee, Director, IVD Solutions Ltd

BSI White Paper Series

Contents



Introduction

We are at the end of the original 5-year transition for the IVD Regulation, and the date of application remained as May 2022. However, there is a reprieve of sorts. Manufacturers of IVDs with an existing valid declaration of conformity, have additional time to engage with a designated notified body. The Commission has additional time to designate notified bodies, publish additional guidance and ensure regulatory structures are in place. The new Medical Device Coordination Group (MDCG) definition of 'legacy devices' includes IVDs, which can be placed on the market after the application date under IVD Directive (98/79/EC) certificates and declarations.

By keeping the original date of application, the Commission ensures legacy IVDs must comply with certain requirements for economic operators, post-market surveillance (PMS), market surveillance, registration and vigilance. Significant changes to the design or intended purpose of a legacy IVD bring an end to the transition for that device and all the relevant requirements of the IVDR will apply . From May 2022 onwards, IVDs that do not have a declaration of conformity and that do not need a notified body must apply the relevant requirements of the IVDR before they can be placed on the market or put into service. IVDs with a current NB certificate now have an additional extra year to be certified to the IVDR.

IVDs previously put into service in the EU via distance sales may not have previously needed a declaration of conformity and from May 2022 may need one if they are to be put into service. Changes to the way of regulating IVDs made and used in health institutions may mean that some previously exempt devices will need a new declaration of conformity from May 2022.

This white paper is built around a table that seeks to provide a checklist for IVDR preparation, based on the requirements of EU Regulation 2017/746. The checklist provides a comprehensive list of actions envisaged for the manufacturer for new

devices and for legacy IVDs during and after the new transitional periods of the IVDR. Whilst the checklist is intended to be supportive, it is the responsibility of the manufacturer (together with associated economic operators) to ensure the devices placed on the market and/or put into service in the EU meet the requirements of the regulations

In order to provide context to the checklist, each table is preceded by a short discussion of changes for that respective chapter in the IVDR.

1 MDCG 2022-08 Legacy devices are "covered by a valid EC certificate issued by a notified body in accordance with Directive 98/79/EC on in vitro diagnostic medical devices (IVDD) prior to 26 May 2022; or … for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with the IVDD and for which the conformity assessment procedure pursuant to the IVDR (contrary to the IVDD) requires the involvement of a notified body."

2 MDCG 2022-6 Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR

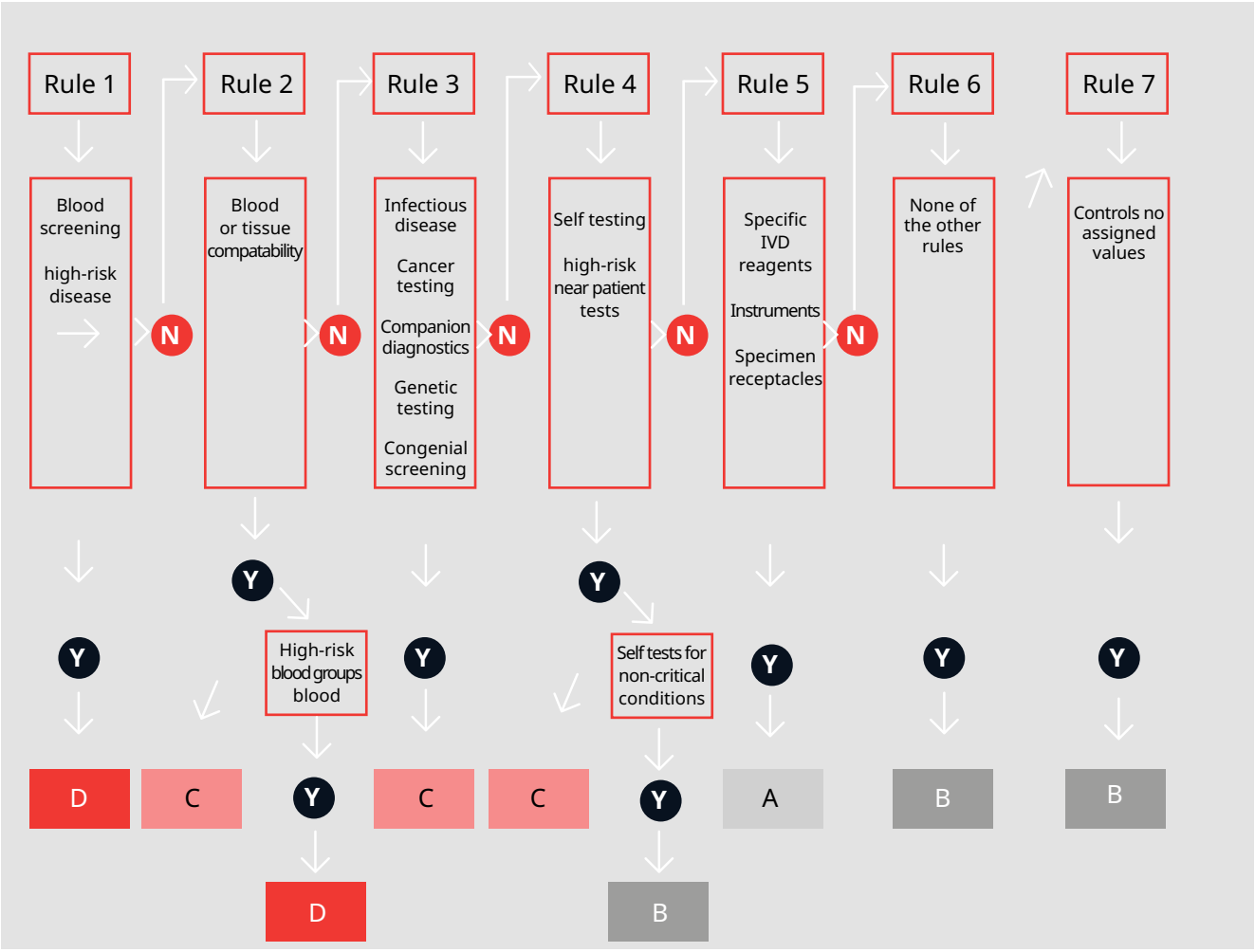
Overview of main changes brought about by the IVDR

The IVDR shares many of its new features with the MDR (EU regulation 2017/745). Apart from the new elements shared with the MDR and the consequences for the market entry and surveillance (like the new supply chain regime, use of unique device identifiers (UDI) and a central database that is the European database on medical devices (EUDAMED)), there are three major reforms in the IVD field:

IVDs will no longer be subject to the list-based system currently in the IVD Directive, but to a new system based on the risk classes developed by the Global Harmonization Task Force, dividing the landscape of IVDs into risk classes A (low-risk) to D (high risk) with seven classification rules (see Figure 1) based on the intended purpose of the IVD. With notified bodies having to perform conformity assessment on all but class A (non-sterile) devices, the landscape is dramatically changing in terms of files to be reviewed and audits to be performed pre- and post-market.

The conformity assessment routes for IVDs are amended to fit the new classification logic. IVDs that do not fit any of the other classification rules fall into class B and have to be certified by a notified body. This is a major change compared to the IVD Directive, which allows such IVDs to be self-certified. As a consequence, approximately 90 per cent of all IVDs will need to be certified by a notified body under the IVDR, as compared to less than 20 per cent currently under the IVD Directive.

Performance evaluation will be required to support the CE mark under the IVDR. As a consequence, IVD manufacturers will need to produce significantly more clinical evidence. The IVD Regulation contains rules for performance studies. It is crucial for manufacturers of IVDs to plan the generation of additional clinical evidence well, and to assess what clinical evidence will be required, how long it will take to generate this and to plan for notified body review timing for conformity assessment. The performance evaluation will include a qualified assessment of the clinical evidence for the device including the benefit/risk and the clinical and analytical performance and scientific validity of the IVD.



Chapter I – Scope and definitions

The IVDR lists 74 definitions, many of them new or significantly changed, which may result in products currently not classified as medical devices or accessories under the IVD Directive being included into the scope of the IVDR and some products falling out of the definition of IVD. Examples are products falling within the enlarged scope of the definition of accessory, human genetic testing, the inclusion of the definition of companion diagnostics. Some products without a specific medical purpose may no longer meet the accepted definition of an IVD and will not be eligible for a CE mark under IVDR.

Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
Chapter I, Section 1: Scope and definitions	Article 2(2) contains an updated definition of an IVD The product must first meet the definition of a medical device in MDR before it can qualify as an IVD under IVDR Compared to the IVD Directive the following definition elements have been added. Software is now more specifically included in the definition of an IVD, the definition of a medical device includes devices which are intended for one or more of the 'specific medical purposes' listed in MDR. IVD provides information: • concerning a pathological process • concerning the predisposition to a medical condition or a disease • to predict treatment response or reactions • define or monitoring therapeutic measures	Following any changes to intended purpose, confirm that your product continues to qualify as an IVD	Qualify devices and determine if they are in or out of scope of IVDR. Intended purpose is an important factor in determining whether the product qualifies as IVD or not CE mark all IVDs in scope to all relevant requirements of IVDR including all relevant NB certification	Qualify and classify existing devices and determine if they are in or out of scope of IVDR. It may be necessary to review the previous intended purpose to meet the IVDR requirements before qualifying as IVD or not Follow the new IVDR classification-based transition requirements (see later for further details) The manufacturer has until the end of the transition period to obtain full certification provided there is no significant change to the design or intended purpose of the device and they comply with IVDR requirements for PMS, market surveillance, registration and vigilance In addition to following these IVDR requirements for legacy devices, manufacturers must continue compliance with IVDD and should prepare for compliance with the remaining requirements of IVDR Consider approaching relevant member states for an authorization (derogation) if necessary Discontinue products as CE marked IVDs if they no longer qualify as an IVD or if they do not meet the requirements of the IVDR

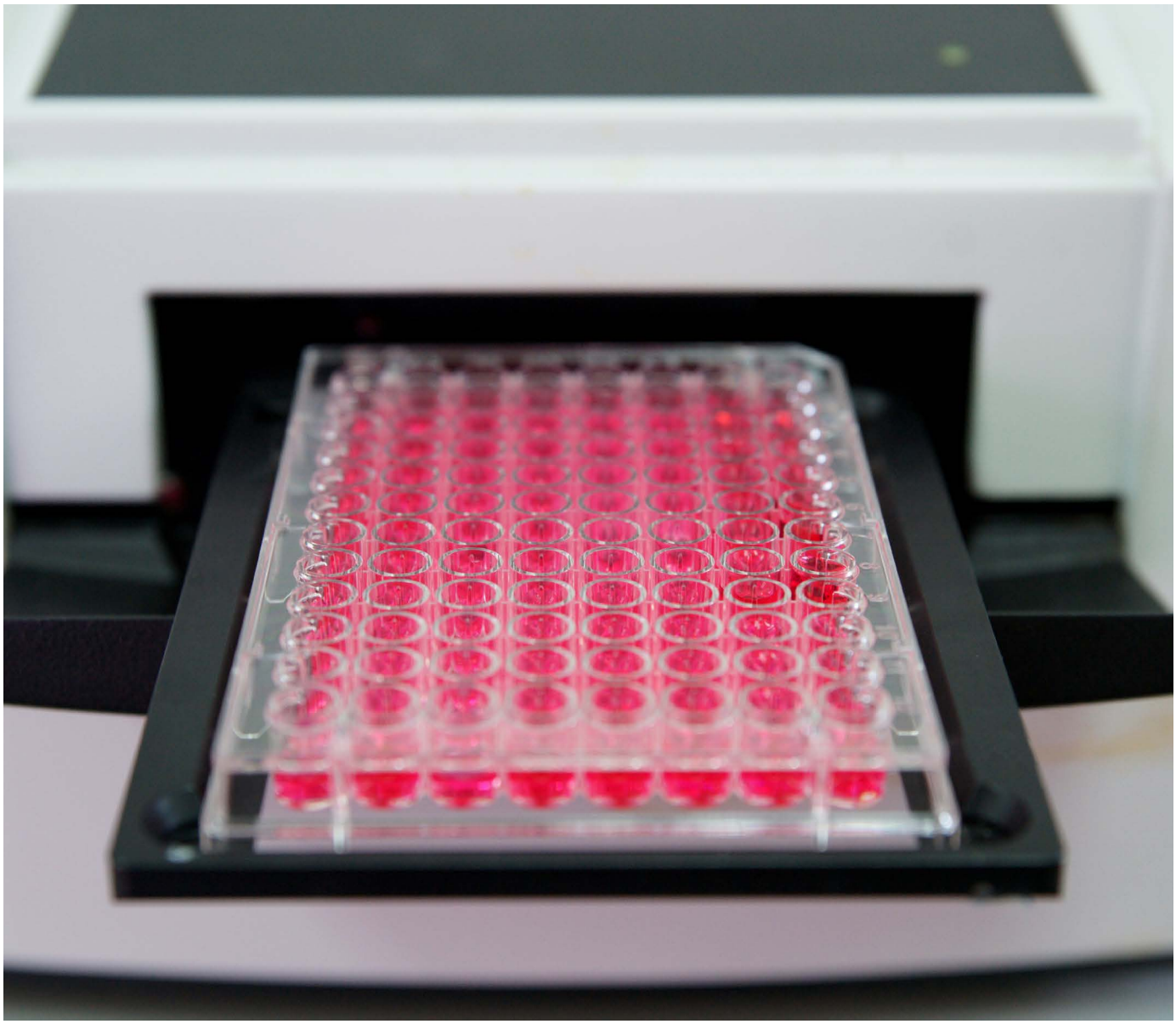
Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
	Article 2(4) The element of 'or to specifically and directly assist the medical functionality of the in vitro medical device(s) in view of its/their intended purpose(s)' is new compared to the IVD Directive definition of IVD accessory		Check if devices fall in scope of 'accessory'	The new definitions do not apply to legacy devices. Continue compliance with the IVD Directive and prepare for IVDR
	Article 2(5) 2(6) and 2(7) New definitions for 'device for near patient testing' or a 'device for self-testing' or 'companion diagnostic'		Check if the IVD qualifies as a 'device for near patient testing' or a 'device for self-testing' or 'companion diagnostic', to which a specific conformity assessment procedure applies	The new definitions do not apply to legacy devices. Continue compliance with the IVD Directive and prepare for IVDR
	Article 2(9) and 2(11) New definitions for 'single use device' and 'kit'		Check if the IVD is in scope of definition of 'single use device' or 'kit' to determine impact on labelling and UDI requirements	The new definitions do not apply to legacy devices. Continue compliance with the IVD Directive and prepare for IVDR

Chapter II

Making available of devices, obligations of economic operators, CE marking, free movement

This chapter contains changes that will impact the existing quality system and its resources (such as the obligation to have a person responsible for regulatory compliance available within the organization). In addition, this chapter contains a distribution chain regime that will necessitate changes to current distribution and other supply chain agreements. Each actor in the supply chain will have its own regulatory responsibility, a big change from the current situation. Some of the changes include liability of various operators for defective devices, including the authorized representatives. There is enhanced emphasis on performance evaluation and integrated risk management. The IVDR features a regime for regulating laboratory-developed tests or tests made and used within a healthcare institution and 'distance sales' tests used in diagnostic services offered for EU citizens.

Laboratory-developed tests and IVDs used in testing services are regulated in IVDR



Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
Chapter II: Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement	Article 5 (5): IVDs that are manufactured and used within the same health institution (home-brews) are exempt from some provisions of the IVDR, but many other requirements will apply for the first time. Devices manufactured on an industrial scale are not exempt		Health Institutions should monitor compliance with home brews under new IVDR rules	A revision to Article 113 sets out a new transition timetable for the health institution exemption From May 2022, all exempt devices must meet all relevant requirements for safety and performance in Annex I and cannot be transferred to another legal entity Member states can demand information about the device and inspect premises From May 2024 all other requirements of Article 5(5) will apply, except 5(5)d which applies from May 2028
	Article 6: IVDR applies to IVDs used in a testing service via the internet or other means		If the service has previously been provided without a declaration of conformity to IVDD, then it will only be possible to provide the testing service with a declaration of conformity to IVDR (including relevant NB certification)	If a declaration of conformity to IVD Directive was prepared prior to 26 May 2022, then the test will be able to apply the new classification-based transition dates in Article 110
	Article 7: Claims	Ensure new marketing materials do not make potentially misleading claims	Check the intended purpose, name of device and relevant marketing materials for any potentially misleading claims	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR
	Article 8: Harmonized standards	Monitor harmonization of standards under IVDR Update technical documentation against standards that are reharmonized Develop rationales on continued use of standards currently harmonized under IVD Directive until such a time they are harmonized under IVDR	Monitor harmonization of standards under IVDR Update technical documentation against standards that are reharmonized Develop rationales on continued use of standards currently harmonized under IVD Directive until such a time they are harmonized under IVDR	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR Perform a gap analysis between existing standards that have been applied and any new standards Consider if any changes to standards represent a change to state of the art

Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
	Article 9: Common specifications	Monitor adoption of common specifications, assess gaps in technical documentation and/or clinical evidence and address gaps	Monitor adoption of common specifications, assess gaps in technical documentation and/or clinical evidence and address gaps	This new requirement does not apply to legacy devices. Check any local requirements by each Member state. Continue compliance with the IVD Directive and prepare for IVDR Perform a gap analysis between existing common technical specifications that have been applied and new specifications Consider if any changes to specifications represent a change to state of the art
	Article 10: Manufacturer obligations			Some manufacturer obligations also apply to legacy devices from May 2022. There is no transition Check MDCG guidance 2022-08 for specific IVDR requirements that apply to legacy devices including post-market surveillance, vigilance and market surveillance
	Article 10 (4): Manufacturer obligations: virtually manufactured devices		Ensure full technical file is present at each manufacturer Ensure business and certification setup meets virtual contract manufacturing requirements, or get all required contracts to access key documentation from OEM in place	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR Assess virtually manufactured devices and the consequences of the requirements that a full technical file must be present at each manufacturer Change business and certification setup into virtual contract manufacturing, or get all required contracts to access key documentation from OEM in place

Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
	Article 10 (8) (e): Manufacturer obligations: risk management requirements		Apply risk management requirements set out in Annex I Amend and implement new risk assessment	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR Perform gap analysis against new risk management requirements set out in Annex I
	Article 10 (8) (f): Manufacturer obligations: performance evaluation requirements	Periodically update performance evaluation report (PER)	Apply performance evaluation requirements in Article 56 and Annex XIII, including post-market performance follow-up (PMPF) Amend and implement new performance evaluation procedure	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR Perform gap analysis against new performance evaluation requirements in Article 56 and Annex XIII, including PMPF
	Article 10 (8) (i) and 78: Manufacturer obligations: post-market surveillance requirements	Implement PMS plan Update PMS report	Set out PMS plan Apply criteria for PMS plan	Set out PMS plan Apply criteria for PMS plan
	Article 10 (8) (k): Manufacturer obligations: processes for reporting incidents and field safety corrective actions	Report incidents, trends and FSCA that meet criteria for reporting	Apply FSCA requirements: Manufacturers shall have a system for reporting incidents and field safety corrective actions as described in Article 82–85 Apply revised procedures for new corrective action and reporting requirements	Apply FSCA requirements: Manufacturers shall have a system for reporting incidents and field safety corrective actions as described in Article 82–85 Apply revised procedures for new corrective action and reporting requirements
	Article 10 (8): Manufacturer obligations: QMS criteria		Implement and apply QMS; consider revising directly into new BS EN ISO 13485:2016 +A11:2021 at the same time	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR Perform gap analysis against new QMS criteria

Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
	Article 10 (15): Manufacturer obligations: financial coverage for potential liability	Monitor developments and determine coverage needed	Purchase and maintain relevant insurance	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR
	Article 11: Authorized representatives			
	Articles 11–12: Authorized representative requirements	Ensure continued access to AR services when relevant	Put an AR agreement and procedures in place	New requirements in this article do not apply to legacy devices. Existing IVD Directive requirements continue to apply. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR Perform gap analysis against new Authorized Representative ('AR') requirements – expect AR renegotiations if liability requirements are adopted
	Articles 13 and 14 Importer obligations			Some importer and distributor obligations also apply to legacy devices from May 2022. There is no transition Check MDCG guidance 2022-08 for specific IVDR requirements that apply to legacy devices
	Articles 13–14: General obligations of importers and distributors		Implement standard operating procedures (SOPs), ensure agreements in supply chain are in place	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR Review general obligations of importers and distributors and their impact on the device groups' supply chains and amend contracts accordingly

Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
	Article 14: General obligations of distributors – parallel trade		Apply procedure/policy for parallel trade label and/or packaging signoff requests	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR Assess parallel trade procedure in Article 14
	Article 15: Person responsible for regulatory compliance	Keep available in the organization a person responsible for regulatory compliance; maintain procedures and update where necessary	Have a person responsible for regulatory compliance. Verify if exception for micro-enterprises and SME applies Ensure training and, where appropriate, liability insurance; provide adequate demonstration for training; ensure auditable IT tools for the person and implement procedures in case of multiple persons sharing responsibilities	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR
	Article 14: New re-labelling/ repackaging regime		Distributors engaging in repacking/relabelling must have QMS	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR Prepare for new relabelling/repackaging regime – draft SOP for new regime
	Article 17 (and Annex IV): EU Declaration of conformity		Prepare declaration of conformities (DoCs) according to new requirements and template	Check MDCG guidance 2022-6 to determine whether updates to IVDD DoC for legacy devices constitute a significant change post May 2022 Prepare to amend existing declarations of conformity upon transfer per product (group) into the new requirements aligned with overall transfer plan of IVDs into the IVDR regime

Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
	Article 20: Parts manufacturers to ensure that the part or component does not adversely affect the safety and performance of the device	Supporting evidence shall be kept available to the competent authorities of the member states	Parts manufacturers are to generate supporting evidence	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR
ANNEX IV	EU DoC		Have declarations of conformity against requirements	Perform gap analysis of existing IVDD declarations of conformity against IVDR declaration of conformity requirements Check whether updates to IVDD DoC for legacy devices constitute a significant change post May 2022

Chapter III

Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European databank on medical devices

The EU will rely heavily on the new version of EUDAMED. This is currently under construction for traceability, registration of devices, registration on clinical studies, market surveillance and vigilance/recall detailing, and publication of information concerning medical devices on the EU market. Though some modules are now active, the EUDAMED system is still not considered fully functional; voluntary use of these modules is encouraged. Apart from manufacturers, healthcare professionals, end users and the general public may also have access to certain parts of the information in EUDAMED. Manufacturers will need to prepare for and implement UDI for, eventually, all their devices, although UDI will be implemented in phases based on the risk classes of the products.

Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
Chapter III: Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European databank on medical devices	Article 22 (1): Supply chain – distributors and importers	Implement changes to distribution agreements and SOPs	Prepare changes to distribution agreements with distributors and importers to achieve an appropriate level of traceability of devices	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR
	Article 22 (2): Supply chain – all economic operators	Implement traceability requirements	Prepare traceability systems in a supply chain, where possible, based on UDI	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR
	Article 24(3): UDI		Assign UDI to device and higher levels of packaging and (24(4)) place that on the label and higher levels of packaging and (24(1a–c + 7) keep UDI administration for reporting and tech file Choose type of UDI system to be applied, in line with global requirements towards UDI	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR

Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
	Article 29: SSP	Prepare and upload SSP	For class C and D devices, be prepared to draw up a summary of safety and performance to be uploaded to EUDAMED and to include in your conformity assessment process	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR
	Article 27–28; 30: EUDAMED	If available, enter data into EUDAMED		This requirement also applies to legacy devices from May 2022. There is no transition Follow same actions as for devices with an IVDR CE mark Pending application of EUDAMED
Annex VI	Information to be submitted with the registration of devices and economic operators	Implement EU-UDI requirements Use EU-UDI depending on roll-out calendar in Article 113 (3) (e): IVDR: Class D as of 26 May 2023 Class C and B as of 26 May 2025 Class A as of 26 May 2027	Understand and prepare for information to be provided in EUDAMED database and for UDI purposes	This requirement also applies to legacy devices from May 2022. There is no additional transition Follow same actions as for devices with an IVDR CE mark

Chapter IV

Notified bodies

Notified body oversight by member states will change considerably. All notified bodies need to apply for a new designation during the transitional period in a process subject to EU and other member states oversight. However, notified bodies may not be redesignated at all and if they do, they may not have the same scope under the new Regulation as they currently have. Some new bodies might arise at this stage. Therefore, manufacturers must be aware that they may need to change notified body as a result of this development, and act accordingly if their current notified body is not able to support the manufacturer anymore.

The process of redesignation will take up the first part of the transitional period. This is because the designation criteria still needed to be fully defined and, although in recent months some additional inspectors have been trained, the resource-heavy process of joint assessments of notified bodies will be challenging in terms of timelines to completion. These joint assessments will be performed by an assessment team of representatives of two member states and the EU Commission. IVDR designation started in early 2020.

Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
Chapter IV: Notified bodies	Up to 95% of IVDs will need some form of notified body scrutiny NB resource is very limited with only seven NB have been designated at the time of publication	Continue to work with your notified body Prepare for audits, including unannounced audits Understand what, when and how you will communicate with your notified body	Engage with a notified body Understand what their scope and timescales for designation Prepare for audits, including unannounced audits Understand what, when and how you will communicate with your notified body	Ensure that you can obtain necessary NB certification by the end of transition Understand the meaning of 'significant change in design or intended purpose'. Be prepared to obtain necessary NB certification if your device needs to undergo a significant change before you can return it to the market Perform assessment of notified body's potential to be renotified under new system. With long delays in renotification, consider alternative plans

Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
				Agree reassessment plan with current notified body or agree transition plan to new notified body, if necessary Analyse and implement new transition procedures for dealing with consequences of changes in designation and cessation of notified bodies for IVDR certificates Apply for orphan protection or national product specific exemption in case of expiry of IVDD CE certificate before IVDR certificate is granted or in case of notified body ceasing activities Assess notified body resource availability Monitor notified body designation process and planning of IVDR certification audits Develop contingency plan in case IVDR certification does not complete before date of application of IVDR, e.g. increase placed on the market stock in EU temporarily

Chapter V

Classification and conformity assessment

The IVD classification system will be completely changed from a list-based to a decision tree-based system. This will impact all IVDs currently on the market as they will need to be reclassified pursuant to the new classification rules, and their conformity assessed to the corresponding revised procedures. The vast majority of the IVDs (estimated 90 per cent) currently on the market in the EU are self-certified, but this will change to almost all IVD products being CE certified by a notified body under the new IVDR. Given the currently limited capacity for certification of IVDs by notified bodies, it will be a challenge to recertify the majority of all IVDs on the market during the transitional period. You will need to beat the queue at notified bodies by being ready for assessment early. When relying on recertification under the IVDD for reliance on the soft transition period you will have to realize that by the time notified bodies have been notified for the IVDR they will likely not have the capacity to handle recertification request under the IVDD.

Changes in the conformity assessment rules will impact existing quality systems and will also require manufacturers to revisit the structure and content of current technical files. For example, the regulation features new essential safety and performance requirements (the current essential requirements) and lists mandatory technical documentation content.

Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
Chapter V: Classification and conformity assessment	Section 1: New classification rules	Understand the impact of any revision to intended purpose	Understand how IVDR classification rules apply to your device	You will need to follow the new classification rules so that you can determine which transition deadline applies to your device Follow same actions as for devices with an IVDR CE mark
	Section 2: New conformity assessment procedures		Determine conformity assessment procedures under IVDR Apply appropriate conformity assessment route	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR Determine conformity assessment procedures under IVDR

Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
	Article 50: Class D devices		Ensure you plan for any new certifications of class D IVDs, which are subject to additional scrutiny procedures involving the NB, the EU reference laboratory, EUDAMED and an expert panel	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR Ensure you are fully aware of the requirement for new certifications of class D IVDs to be subject to additional scrutiny procedures involving the NB, the EU reference laboratory, EUDAMED and an expert panel
	Article 55: Certificates of free sale	Uniform certificates of free sale will be issued by member states	Uniform certificates of free sale will be issued by member states	New requirements in this article do not apply to legacy devices. Existing IVD Directive requirements continue to apply. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR
	Article 48: Specific conformity assessment procedure for 'devices for near-patient testing'		Apply specific conformity assessment procedure to 'device for near patient testing'	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR
	Article 48: Specific conformity assessment procedure for 'devices for self-testing'		Apply specific conformity assessment procedure to 'device for self-testing'	New requirements in this article do not apply to legacy devices. Existing IVD Directive requirements continue to apply. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR

Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
	Article 48: Specific conformity assessment procedure for 'companion diagnostics'		Apply specific conformity assessment procedure to 'companion diagnostics'	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR
Annex I **Annex II**	General safety and performance requirements (GSPRs) technical documentation	Maintain TD and GSPR	Prepare technical documentation and checklists for GSPR	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR Perform gap analysis of consequences of changed GSPR for recertification of existing devices (e.g. risk management details, predictive value of test, labelling, IFU, UDI, sterility details)
Annex VIII	Classification criteria	Following any changes to intended purpose, confirm IVD class	Ensure you have reviewed the intended purpose of the device and use IVDR classification criteria to determine IVD class	You will need to follow the new classification rules so that you can determine which transition deadline applies to your device Follow same actions as for devices with an IVDR CE mark
Annex IX	Conformity assessment based on a quality management system assurance and assessment of technical documentation		Decide which conformity assessment route should apply	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR Perform gap analysis between current full QMS and new full QMS requirements, improve QMS where necessary

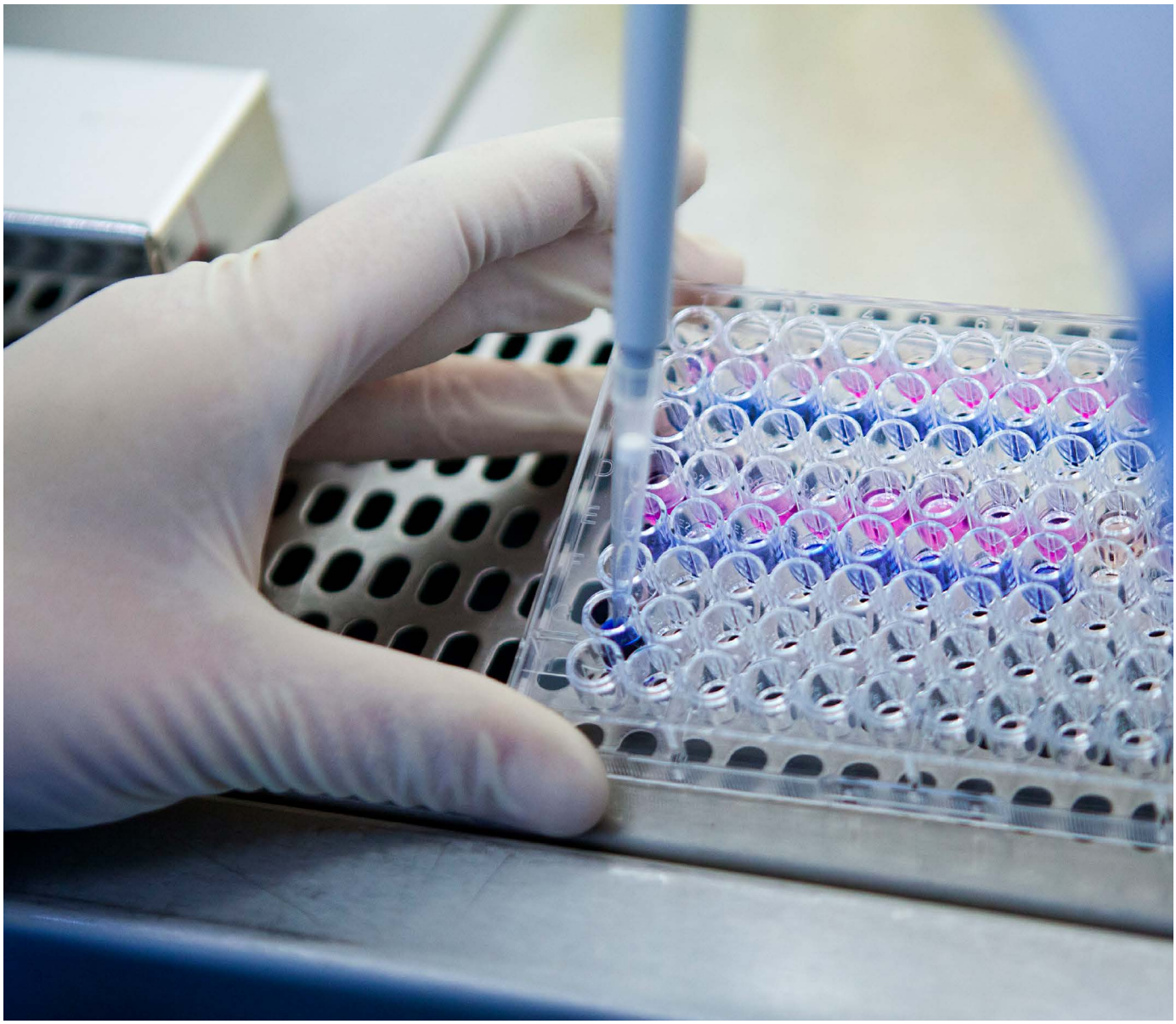
Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
Annex X	Conformity assessment based on type examination New type examination QMS requirements		Decide which conformity assessment route should apply	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR Perform gap analysis between current type examination QMS and new type examination QMS requirements, improve QMS where necessary
Annex XI	Conformity assessment based on product quality assurance New product verification QMS requirements		Decide which conformity assessment route should apply	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR Perform gap analysis between current product verification QMS and new product verification QMS requirements, improve QMS where necessary

Chapter VI

Clinical evidence, performance evaluation and performance studies

The IVDR introduces many new concepts relating to performance evaluation of the tests, as well as a PMPF. This will require a thorough review of manufacturer's performance strategy and PMPF plans. Manufacturers will need to either start new or revisit their performance evaluation strategy for IVDs. Because the clinical evidence for existing devices might need updating, manufacturers will also need to perform an extensive gap analysis to identify deficiencies in clinical evidence under the new rules for devices currently on the market.

The IVDR will put in place a self-contained regimen for performance evaluations



Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
Chapter VI: Performance evaluation and performance studies	Article 56: Performance evaluation	Update the PER throughout the life cycle of the device with data from PMPF and PMS reports according to device class (annually for C and D IVDs)	Ensure you have sufficient quantity and quality of clinical evidence If necessary, conduct performance studies to generate additional clinical evidence Document the clinical evidence and your PMPF in a PER according to the requirements of Annex XIII	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR Define the gap between current performance evaluation of IVDs and IVDR and ensure you have sufficient quantity and quality of clinical evidence before approaching an NB
	Article 57: New general requirements for all performance studies		Understand new requirements and apply to your performance study	Performance studies which begin after May 2022 will need to comply with these IVDR requirements It is not clear if performance studies that began before May 2022 will need to comply with IVDR or if they can continue compliance with IVDD Note that the IVD Directive includes registration requirements for devices for performance evaluation that do not appear in the IVDR
	Article 58: Additional requirements for certain performance studies (Articles 59–77)		Determine whether the additional requirement for performance studies apply Understand new performance study regime additional requirements for Article 58 studies Understand and implement application and modification mechanism for performance studies as well as recording/ reporting requirements	Performance studies which begin after May 2022 will need to comply with these IVDR requirements It is not clear if performance studies that began before May 2022 will need to update the study for compliance with IVDR or if they can continue compliance with IVDD Note that the IVD Directive includes registration requirements for devices for performance evaluation that do not appear in the IVDR

Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
Annex XIII	New requirements for performance evaluation	Update the PER throughout the life cycle of the device with data from the PMPF report and the PMS report	Set out a performance evaluation plan (PEP) according to the IVDR requirements Implement requirements for performance evaluation, generate clinical evidence to meet requirements Ensure you have a documented PER	Perform gap analysis of current performance evaluation and outcomes per devices against requirements Prepare a PEP to ensure you have a PER in place ready for submission to your notified body
	PMPF	Update the PER and risk management Implement any preventive and/or corrective measures	Decide whether you need to PMPF in place. If not, ensure you have a robust justification otherwise, ensure you have a PMPF plan	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR
Annex XIV	Clinical performance investigations		Seek competent authority approval for starting a performance study listed in Article 58	Perform gap analysis to determine new clinical performance studies requirements and impact on existing performance study plans Understand the additional requirements for studies listed in Article 58

Chapter VII

Post-market surveillance, vigilance and market surveillance

PMS and vigilance requirements will change, and manufacturers will need to amend their current procedures. PMS will need to adopt a continuous evaluation and improvement loop in order for manufacturers to:

- feed into a process of continuous reflections on risk management
- (for high-risk devices) annually update the public summary of safety and performance
- perform a clinical performance evaluation

In addition, market surveillance (the supervision by the competent authorities for the market) is expected to change. Much more activity and focus on the part of the authorities are anticipated, as well as cooperation between member states to work more efficiently using all available resources in cross-border matters.

PMS will need to adopt a continuous evaluation and improvement loop

Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
Chapter VII: Post-market surveillance, vigilance and market surveillance	Articles 78–81: New post-market surveillance system (including periodic safety update reports (PSURs)) required	Implement the PMS plan Prepare periodic safety update report	Prepare a PMS plan	This requirement also applies to legacy devices from May 2022. There is no transition Follow same actions as for devices with an IVDR CE mark
	Articles 82–87: New vigilance and trend reporting requirements	Implement your plan for vigilance and trend reporting requirements	Prepare your plan for vigilance and trend reporting requirements	This requirement also applies to legacy devices from May 2022. There is no transition Follow same actions as for devices with an IVDR CE mark
	Articles 88–95: Market surveillance	Be prepared for market surveillance checks including unannounced inspections by competent authorities	Be prepared for market surveillance checks including unannounced inspections by competent authorities	This requirement also applies to legacy devices from May 2022. There is no transition Follow same actions as for devices with an IVDR CE mark
Annex III	Technical documentation on PMS	Implement your PMS plan in place. Prepare and submit your PSUR and PMS report	Ensure you have a PMS plan in place Ensure you document your PSUR and PMS report	This requirement also applies to legacy devices from May 2022. There is no transition Follow same actions as for devices with an IVDR CE mark
Annex XIII	Performance evaluation and post-market follow-up	Implement PMPF to generate clinical evidence to meet requirements	Prepare PMPF method and outcomes per device or device family against new requirements	With respect to PMS, this requirement also applies to legacy devices from May 2022. There is no transition Follow same actions as for devices with an IVDR CE mark

Chapter VIII

Cooperation between member states, Medical Device Coordination Group, EU Expert laboratories, Expert panels and device registers

The new Regulation puts in place improved and more centralized governance structures, which means that the member states will cooperate closer in cross-border matters on borderline devices and on enforcement. It is expected that groups of experts will write a growing number of guidance documents and minimum requirements.

These will take the form of 'common specifications', which will look somewhat like the common technical specifications currently possible under the IVD Directive. These common specifications will focus heavily on the performance data sets; and may provide for some further requirements as regards clinical data for specific device groups.

Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
Chapter VIII: Cooperation between member states, Medical Device Coordination Group, EU Expert laboratories, Expert panels and device registers	Articles 98–99 MDCG		Keep up to date with MDCG meetings, planned and draft guidance documents and recent MDCG publications Investigate which scientific discussions in this early phase might help smooth market introduction at a later stage	Review MDCG guidance and determine which will apply to your device(s)
	Adoption of common specifications	Monitor for developments and adoption of common specifications	Apply common specification to all new IVDs in scope	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR
	Article 101: Registers and databanks	Keep up to date with developments of any new registers or databanks for devices that may contribute to the independent evaluation of the safety and performance of devices	Be aware of any new registers or databanks for devices that may contribute to the independent evaluation of the safety and performance of devices	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR

Chapter IX

Confidentiality, data protection, funding, penalties

The Regulation makes provision for a penalties regime as well as for the possibility for member states to institute market-funded market surveillance based on the Regulation. Companies will need to prepare for additional local costs for market surveillance, as well as for member states' changing enforcement policy to align with the Regulation.

Subject/relevant IVDR ref	Notable changes from IVDD to IVDR	Maintaining the IVDR CE mark (IVDs with a CE mark to IVDR)	Preparing for IVDR (IVDs without a CE mark)	Transition to IVDR legacy devices
Chapter IX: Confidentiality, data protection, funding, penalties	Article 104: New fees and penalties regime under IVDR	Ensure compliance to avoid penalties	Ensure compliance to avoid penalties	This new requirement does not apply to legacy devices. Check any local requirements by each member state. Continue compliance with the IVD Directive and prepare for IVDR

Chapter X

Final provisions

Although now updated, the IVDR originally stated a transitional period of 5 years up to 2022 with a 'hard stop' for all but those IVDs with an existing NB certificate, Article 110 was updated early in 2022 with new transition provisions.

If you have an NB certificate under IVDD

- certificates issued before 25 May 2017 shall remain valid until they expire [except IVDD Annex VI (EC verification) certificates which expire 27 May 2025 at the latest]
- certificates issued after 25 May 2017 expire 27 May 2025 at the latest
- The issuing NB continues to be responsible for surveillance of compliance

If you *do not* have an NB certificate under IVDD
but you do have an IVDD declaration of conformity prior to May 2022,
your IVD may be placed on the market or put into service until the following dates:

- 26 May 2025, for class D devices (+1 year for sell-off)
- 26 May 2026, for class C devices (+1 year for sell-off)
- 26 May 2027, for class B devices (+1 year for sell-off)
- 26 May 2027, for class A (sterile) devices (+1 year for sell-off)

Provided:

- they continue to comply with IVDD
- there are no significant changes in the design or the intended purpose
- IVDR requirements apply for:
  - registration (Articles 22–30, Annex VI)
  - classification (Article 47, Annex VIII)
  - PMS (Articles 78–81, Annex III)
  - vigilance (Articles 82–87)
  - market surveillance (Articles 88–95)

The following need to comply with all of the relevant requirements of the IVDR before they can be placed on the market or put into service in the EU:

- class A (non-sterile) IVDs
- 'new' IVDs (i.e. without a declaration of conformity prior to May 2022)
- IVDs that have undergone a significant change compared to the IVDD CE marked device

These new transition provisions are included in the previous tables, though it is important to verify this information against the MDCG guidance (2022-08).

Manufacturers will need to invest resources in developing a transition plan for their devices currently on the market. All medical devices currently on the market will need to be (re)certified under the new rules, as no grandfathering has been foreseen in the new Regulations.

Conclusion

The IVDR has brought about extremely significant changes that affect all devices on the EU market and beyond. Most critical is the full revision of the classification system into a rule-based risk classification matrix, and the fact that devices on the market are not grandfathered into the new system. In contrast to the current situation, this means the vast majority of products will need to be evaluated by the notified bodies. Manufacturers will have revisited all technical files and the quality system for all their devices on the market. They will have generated additional clinical evidence in order to be able to transition them to the new regime implemented by the IVDR. There are also additional EUDAMED registration and UDI requirements.

Consequently, manufacturers must take a proactive approach to the new Regulation, plan and budget for the transition of new devices in a timely and detailed way and allocate resources for this effort. Manufacturers must plan for success. For devices that need notified body approval, manufacturers must comply with the new requirements although there is some respite in the updated dates of application deadlines. Again, a proactive approach is needed as the IVDR requires more clinical evidence, especially for higher-risk devices, which takes time to generate.

BSI is grateful for the help of the following people in the development of the white paper series.

Updated by Steve Lee, IVD Solutions.

Steve has 30 years' experience of in vitro diagnostic medical devices. He trained as a Biomedical Scientist before moving to industry as company microbiologist. Steve joined MHRA in 1996 when the IVD Directive had yet to be implemented. While at MHRA, Steve was Chair of the European Commission's IVD working group when the IVD regulations where being developed. Steve now works for the UK trade body – the Association of British Healthtech Industries as Director of Diagnostics regulation and heads up a small business offering regulatory strategy advice.

Reviewers

Richard A. Vincins, Vice President Global Regulatory Affairs, Oriel STAT A MATRIX
is responsible for regulatory affairs and quality activities. He brings over 30 years of experience in the medical industry including worldwide regulatory compliance efforts for medical device, IVD and pharmaceutical companies. His work experience at companies like C.R. Bard, Medtronic and bioMerieux include establishing quality systems to ISO standards, 510(k) submissions and CE marking of multiple product lines. Richard is a Chartered Quality Professional, ASQ Certified Medical Device Auditor and Certified Quality Auditor and holds a Regulatory Affairs Certification for Medical Devices through the Regulatory Affairs Professional Society. Richard graduated from Bridgewater State College, MA, with a bachelor's degree in Biomedical Biology.

Jane Edwards
is Head of Communications, Global Product Management, at the British Standards Institution (BSI). She holds a BSc in Chemistry and an MBA from Durham University. She has over 13 years' experience in the medical device industry, having previously worked for Coloplast in its ostomy and continence business. Jane's experience includes working within the pharmaceutical, chemical and telecoms industries for Glaxo Wellcome, ICI and Ericsson, allowing her to bring depth of knowledge from many industries and technologies. Her current role at BSI allows her to work with technical reviewers across all disciplines, ensuring that BSI communications are accurate and relevant. She is a member of the European Medical Writers Association.

Eamonn Hoxey
is a technical author, trainer and consultant in a range of life science areas, including regulatory compliance, quality management, sterility assurance and standards development. Eamonn worked for Johnson & Johnson (J&J) for 17 years in positions of increasing responsibility for quality and regulatory compliance for medical devices, pharmaceuticals and consumer products. These included Vice President of Compliance, Vice President of Market Quality and Vice President of Quality & Compliance Strategic Programs, leading quality implementation for the EU MDR for J&J's medical devices companies. Prior to joining J&J, Eamonn spent 16 years with the UK Medical Devices Agency, including 6 years as Head of Device Technology and Safety. Eamonn is Chair of CEN/TC 204 — *Sterilization of medical devices*, and chaired ISO/TC 198 — *Sterilization of health care products*, from 2011 to 2019. Eamonn is also a past chair of ISO/TC 210 — *Quality management and corresponding general aspects for medical devices*, and the current Chair of the Board of Directors of AAMI. He received the BSI Wolfe Barry medal in 2016 for his contribution to standards development.

Paul Sim
has worked in the healthcare industry for over 40 years, joining BSI in 2010 to lead the organization in Saudi Arabia where BSI had been designated as a Conformity Assessment Body. Since October 2015, he has been working on various initiatives to promote BSI as thought leader in the global healthcare space. Previously he held senior RA/QA business leadership positions at Spacelabs Healthcare, Teleflex Medical, Smiths Medical and Ohmeda (formerly BOC Healthcare). During the time in the healthcare industry Paul has gained significant experience and expertise in Standards Development at National, European and International level.
Paul is a member of the ABHI Regulatory Policy Group, BAREMA Council Member, industry member on UK Government Working Groups and involved in several other industry related activities. He has a very keen interest in Education/Mentoring and for 12 years was a Module Advisor and member of the Leadership Group at Cranfield University on their MSc Program covering Regulatory Affairs for medical devices.

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BSI is keen to hear your views on this paper, or for further information please contact us here: julia.helmsley@bsigroup.com

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