The Louise Weiss building of the European Parliament. Strasbourg, France

How to prepare for and implement the upcoming IVDR – Dos and don'ts

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Introduction

In the previously published white paper, *The proposed EU regulations for medical and in vitro diagnostic devices: An overview of the likely outcomes and the consequences for the market*, an overview was given of the legislative changes likely to be brought about by the new EU Medical Devices Regulation (MDR) and In Vitro Diagnostic Devices Regulation (IVDR). Both regulations are in the final stages of the legislative procedure and are estimated to be finished sometime in 2016, allowing them to come into effect by the end of 2016, or early 2017. Some time would be needed to polish the agreed text and have it translated into the official EU languages.

The previous white paper, as above, gave an overview of the changes in general, however there is now a demand for more detailed guidance, including how the Regulations will impact current manufacturer operations before, during, and after the transitional period of the IVDR. A similar overview was provided for the MDR in the white paper, *How to prepare for and implement the upcoming MDR – Dos and don'ts*.

This white paper is built around a table (featured at the end of the previous white paper), which seeks to provide a checklist for IVDR preparation. This is based on our current understanding of how the final IVDR will look (the latest draft was consolidated on 13 June 2016). The checklist provides a comprehensive list of actions currently envisaged for the manufacturer before, during and after the transitional period of the IVDR.

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. The full table is listed in the Appendix.

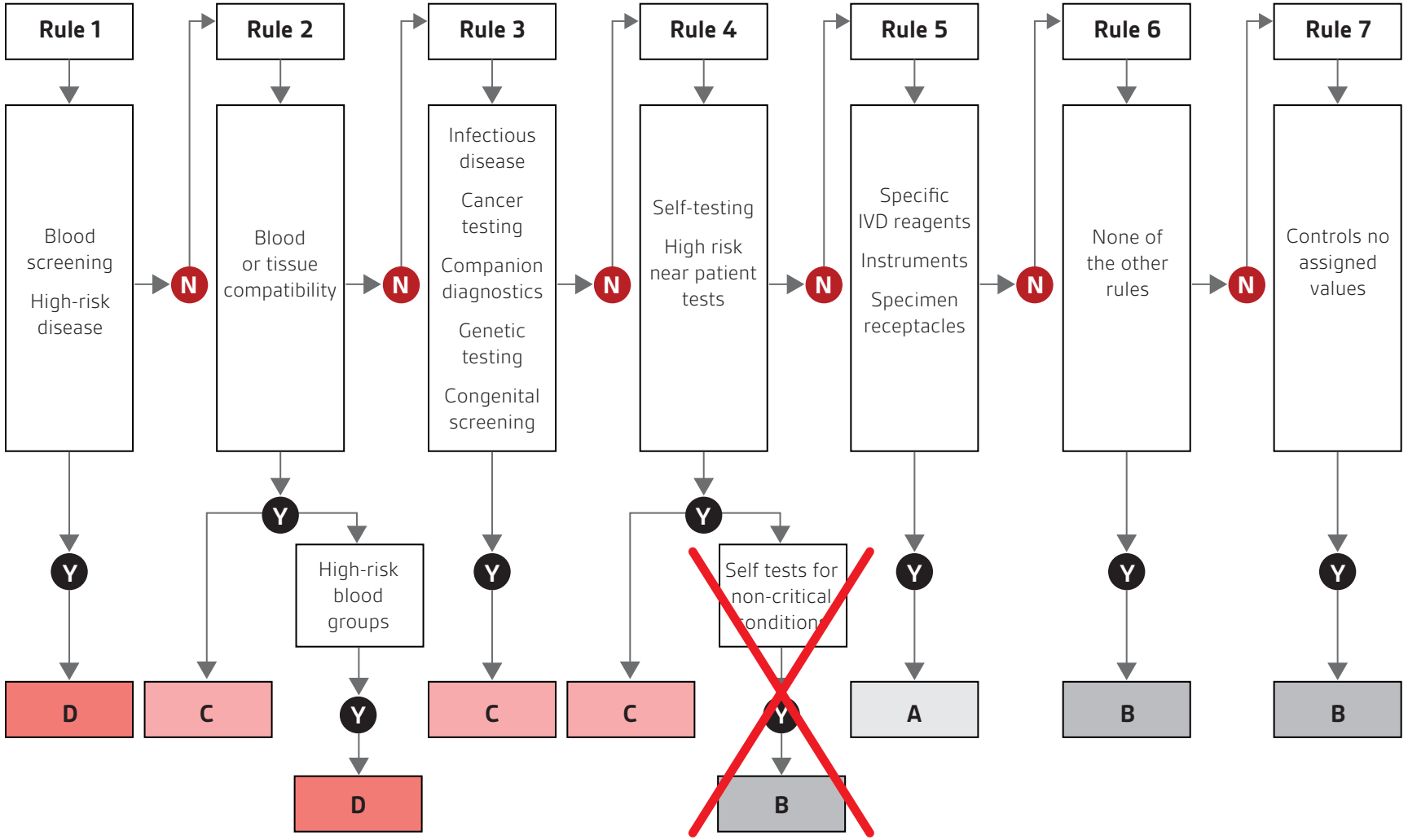
Overview of the biggest changes brought about by the IVDR

The IVDR shares the majority of its new features with the MDR proposal. Apart from the new elements shared with the MDR proposal[1] and the consequences for the market (like the new supply chain regime and a central database EUDAMED), there are four major developments in the IVD field:

1. Extension of the concept of in vitro diagnostic devices to include 'lifestyle tests' by including the elements of 'indirect medical purpose' and 'prediction' in the definition to include 'nutrigenetic tests and lifestyle tests', which are not covered by the current IVD Directive.
2. IVDs will no longer be subject to the list-based system currently in the IVD Directive, but to the risk classes developed by the Global Harmonization Task Force (GHTF), dividing the landscape of IVDs into risk classes A (low-risk) to D (high public and high patient risk) with seven classification rules (see Figure 1). With notified bodies having to perform conformity assessment on all but class A devices, the landscape is dramatically changing in terms of files to be reviewed and audits to be performed pre- and post-market.
3. 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 80% of all IVDs will need to be certified by a notified body under the IVDR, as compared to 20% currently under the IVD Directive. The change in classification of self-tests to class B instead of class C is under discussion at the current stage.
4. Clinical performance studies 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 will contain rules for interventional clinical performance studies and other clinical performance studies that largely overlap with the clinical studies regime in the MDR proposal. It is crucial for manufacturers of IVDs currently on the market to plan the generation of additional clinical evidence well, and timely assess what clinical evidence will likely be required, how long it will take to generate this and plan ahead for notified body slots for conformity assessment. In short, the clinical performance evaluation will include not only the classic clinical performance and analytical performance, but also scientific validity. With this change, the first steps towards manufacturers becoming fully responsible for the clinical utility of their devices are initiated.

[1]See white paper, *The proposed EU regulations for medical and in vitro diagnostic devices: An overview of the likely outcomes*, updated October 2015

Figure 1 – Risk classification



Chapter I – Definitions

A significant number of definitions will change, which may result in products currently not classified as medical devices or accessories under the IVD Directive being included in the scope of the IVDR. Examples are products falling within the enlarged scope of the definition of accessory, the changed definition of custom-made device, the (predictive) genetic testing and the inclusion of the definition of companion diagnostics.

Subject	Before coming into force	During	After
Chapter I Definitions	Article 2 (2) contains a new definition: 'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information: • concerning a physiological or pathological process or state; • concerning a congenital abnormality; • concerning the predisposition to a medical condition or a disease; • to determine the safety and compatibility with potential recipients; • to predict treatment response or reactions; and • to define or monitor therapeutic measures Action: Categorize existing devices and determine if they are in or out of scope of IVDR; new compared to the IVD Directive are the following definition elements: IVD provides information: • concerning the predisposition to a medical condition or a disease; and • to predict treatment response or reactions	During the transitional period the manufacturer may comply with the IVDR prospectively so the manufacturer must decide whether to CE mark new IVDs during the transitional period under IVDD, IVDR or neither depending on whether they are in the scope of the Directive and/or Regulation	CE mark new IVDs under IVDR if in scope

Continued

Subject	Before coming into force	During	After
	Article 1 (2): The IVDR Regulation shall not apply to: (a) products for general laboratory use or research-use only products, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination; (b) invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen; (c) internationally certified reference materials on higher metrological order; (d) materials used for external quality assessment schemes Action: Categorize existing devices and determine if they are in or out of scope of IVDR	Decide whether to CE mark new IVDs under IVDD, IVDR or neither depending on whether they are in the scope of the Directive and/or Regulation	CE mark new IVDs under IVDR if in scope
	Check if devices fall in enlarged scope of 'accessory': '"accessory to an in vitro diagnostic medical device' means an article which, whilst not being an in vitro diagnostic medical device, is intended by its manufacturer to be used together with one or several particular in vitro diagnostic medical device(s) to specifically enable the in vitro diagnostic medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in view of its/their intended purpose(s)" The element of "or to specifically and directly assist the medical functionality of the medical device(s) in view of its/their intended purpose(s)" is new compared to the IVD Directive	Obtain CE mark for accessory under new regime	Obtain CE mark for accessory under new regime

Continued

Subject	Before coming into force	During	After
	Categorize existing IVDs to check if in scope of 'device for near patient testing' or 'device for self-testing' or 'companion diagnostic' to determine future conformity assessment procedure	Check if IVD constitutes a 'device for near patient testing' or a 'device for self-testing' or 'companion diagnostic', to which a specific conformity assessment procedure applies	Check if IVD constitutes a 'device for near patient testing' or a 'device for self-testing' or 'companion diagnostic', to which a specific conformity assessment procedure applies
	Categorize existing IVDs to check if in scope of definition of 'single use device' or 'kit' to determine impact on labelling and UDI requirements	Check if IVD is in scope of definition of 'single use device' or 'kit' to determine impact on labelling and UDI requirements	Check if IVD is in scope of definition of 'single use device' or 'kit' to determine impact on labelling and UDI requirements
	Article 14: Assess parallel trade procedure in Article 14 and draft procedure/policy for dealing with parallel trader requests to sign off on amended labelling and/or packaging	Apply procedure/policy for parallel trade label and/or packaging sign-off requests	Apply procedure/policy for parallel trade label and/or packaging sign-off requests

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

This chapter contains a number of 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 supply 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 will be additional emphasis on (clinical) performance evaluation and integrated risk management. The IVDR will feature a regime for regulating laboratory-developed tests and for diagnostic services offered as an information society service, which will also apply to diagnostic testing services supplied from outside of the EU to EU citizens.

Laboratory-developed tests will be regulated, applying also to diagnostic testing services supplied from outside of the EU

Subject	Before coming into force	During	After
Chapter II Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement	Article 4 (5): Assess potential effect of laboratory developed tests ('home brews') under new home brew devices rules on company business model	Monitor compliance of hospitals with home brews under new laboratory developed test rules	Monitor compliance of hospitals with home brews under new laboratory developed test rules
	Article 4 (5f): For class C and D develop a set of compliance documentation in accordance with the rules set out in Annex VII		
	Article 5: Assess IVD testing provided as service via the internet	CE mark IVD as diagnostic service under new regime	CE mark IVD as diagnostic service under new regime
	Monitor harmonization of standards towards the new IVDR; develop rationales on continued use of standards currently harmonized under IVD Directive until they are harmonized under the new regime	Monitor harmonization of standards under IVDR and update technical documentation against standards that are re-harmonized	Monitor harmonization of standards under IVDR and update technical documentation against standards that are re-harmonized
	Monitor adoption of 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
	Article 8 (4): Assess Own Brand Labelling consequences of the requirements that a full technical file must be present at each manufacturer	Change business and certification set-up into virtual contract manufacturing, or get all required contracts to access key documentation from OEM in place	
	Article 8 (1a): Perform gap analysis against new risk management requirements set out in Annex I	Amend and implement new risk assessment; apply to devices elected to be compliant during transitional period	Apply new procedure
	Article 8 (1c): Perform gap analysis against new performance evaluation requirements in Article 47 and Annex XII, including post-market performance follow-up	Amend and implement new performance evaluation procedure; apply to devices elected to be compliant during transitional period	Apply new procedure

Continued

Subject	Before coming into force	During	After
	Article 8 (6) and 58a: Perform gap analysis against new post-market surveillance plan requirements	Amend and implement new post-market surveillance plan	Apply new criteria for post-market surveillance plan
	Article 8 (8); Article 8a: Perform gap analysis against new recall requirements: Manufacturers shall have a system for reporting incidents and field safety corrective actions as described in Article 59	Amend procedures and distribution agreements for new corrective action and reporting requirements	Apply procedures for new corrective action and reporting requirements
	Article 8 (5): Perform gap analysis against new QMS criteria; amend procedures	Implement amended QMS; consider revising directly into new ISO 13485:2016 at the same time	Apply amended QMS
	Article 8 (11): Mandatory insurance: monitor developments	Purchase and maintain relevant insurance	Maintain relevant insurance
	Article 9-10: Perform gap analysis against new Authorized Representative ("AR") requirements – amend AR agreement and procedures – expect AR renegotiations if liability requirements are adopted	Ensure continued access to AR services when relevant	
	Articles 11-12: Review general obligations of importers and distributors and their impact on the device groups' supply chains and amend contracts accordingly	Implement standard operating procedures (SOPs), amend agreements in supply chain	
	Article 13: Select and mandate candidate for person responsible for regulatory compliance. Verify if exception for micro-enterprises and SMEs applies	Make and keep available in the organization a person responsible for regulatory compliance; ensure training and, where appropriate, liability insurance	Keep available in the organization a person responsible for regulatory compliance
	Article 14: Prepare for new re-labelling/repackaging regime – draft SOP for new regime	Implement and apply SOP	Apply SOP

Continued

Subject	Before coming into force	During	After
	Article 15 Annex III: Declaration of conformity model – check for gaps	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	
	Article 19: Parts manufacturers to ensure that the part or component does not adversely affect the safety and performance of the device	Parts manufacturers are to generate supporting evidence for this. Supporting evidence shall be kept available to the competent authorities of the member states	Supporting evidence shall be kept available to the competent authorities of the member states
ANNEX III EU DECLARATION OF CONFORMITY	Perform gap analysis of existing declarations of conformity against new declaration of conformity requirements	Amending existing declarations of conformity against new declaration of conformity requirements and recertification based on amended technical file	Use new declaration of conformity requirements
ANNEX IV CE MARKING OF CONFORMITY	Add UDI details		

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 the European database on medical devices (EUDAMED). This is currently under construction for traceability, registration of devices and publication of information concerning medical devices on the EU market. 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 Unique Device Identifiers (UDI) for, eventually, all of their devices, although UDI will be implemented in phases based on the risk classes of the products.

Subject	Before coming into force	During	After
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 21 (1): UDI: Distributors and importers shall cooperate with the manufacturer or authorized representative to achieve an appropriate level of traceability of devices – implement changes to distribution agreements	Implement changes to distribution agreements and SOPs	

Continued

Subject	Before coming into force	During	After
	Article 21 (2): Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 8 (4): (a) any economic operator to whom they have supplied a device; (b) any economic operator who has supplied them with a device; (c) any health institution (or healthcare professional) to whom they have supplied a device Implement and improve traceability	Get traceability systems in place in a supply chain, where possible, based on UDI	
	Article 22 (3): Assign UDI to device and higher levels of packaging and (22 (4)) place that on the label and higher levels of packaging and (22 (a-c + 5) keep UDI administration for reporting and tech file	Choose type of UDI system to be applied, in line with global requirements towards UDI	
		Article 22b: If possible, manufacturers may apply new process for registration of devices prior to placing on the market	Article 22b: Apply new process for registration of devices prior to placing on the market
		If possible, companies may apply process for registration of manufacturers, and authorized representatives and importers, single registration number	Article 23a: Apply process for registration of manufacturers, authorized representatives and importers, single registration number
			Draw up and make available summary of safety and clinical performance for class C and D
		If available: Article 25: Enter data into EUDAMED	Article 25: Enter data into EUDAMED
ANNEX V INFORMATION TO BE SUBMITTED WITH THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS	Perform gap analysis of information to be provided in EUDAMED database and for UDI purposes Prepare for implementation for EU-UDI	Implement EU-UDI for existing and new devices	Use EU-UDI

Chapter IV – Notified bodies

Notified body oversight by member states will change considerably. All notified bodies will need to apply for a new designation during the transitional period. However, notified bodies may not be re-notified at all and may not have the same scope under the new regulation. 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 re-designation will take up the first part of the transitional period. This is because the designation criteria are still 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.

Subject	Before coming into force	During	After
Chapter IV Notified bodies	Perform assessment of notified body's potential to be re-notified under new system	Re-notification to be timely; with long delays in re-notification, consider alternative plans	
	Agree re-assessment plan with current notified body or agree transition plan to new notified body, if necessary		
		Article 36: Analyse and implement new transition procedures for dealing with consequences of changes in designation and cessation of notified bodies	
	Assess notified body resource availability to assess all IVD that are currently self-certifiable but will need to be assessed by a notified body under the new IVDR		

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%) 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 re-certify the majority of all IVDs on the market during the transitional period.

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

Subject	Before coming into force	During	After
Chapter V Classification and conformity assessment	Perform a gap analysis of all devices on the market against new classification rules and create transition plan if classification necessitates new conformity assessment	Implement transition plan for reclassified devices	
	Article 42: Determine new conformity assessment procedures under IVDR; class D IVDs will be subject to additional scrutiny procedures	Apply new conformity assessment procedures to devices already on the market and optionally to new devices to be placed on the market Select devices which have documentation to support the new essential principles	Apply new conformity assessment procedures to devices
	Article 40: Perform QMS gap analysis against the new rules	Apply new QMS optionally in case of new devices to be placed on the market	Apply new QMS in case of new devices to be placed on the market
			Article 44: Conclude tri-partite transition agreement with outgoing and incoming notified body in case of voluntary change of notified body
		Article 48: Uniform certificates of free sale will be issued by member states	Article 48: Uniform certificates of free sale will be issued by member states
	Article 40 (2): Prepare QMS procedures for batch verification by qualified person for class D IVDs for each batch	Article 40 (2): Implement batch verification by qualified person for class D IVDs for each batch	Article 40 (2): Apply batch verification by qualified person for class D IVDs for each batch
	Categorize existing devices for whether they are in scope of definition of 'device for near-patient testing'	Apply specific conformity assessment procedure to 'device for near patient testing'	Apply specific conformity assessment procedure to 'device for near patient testing'
	Categorize existing devices for whether they are in scope of definition of 'device for self-testing'	Apply specific conformity assessment procedure to 'device for self-testing'	Apply specific conformity assessment procedure to 'device for self-testing'
	Categorize existing devices for whether they are in scope of definition of 'companion diagnostic'	Apply specific conformity assessment procedure to 'companion diagnostic'	Apply specific conformity assessment procedure to 'companion diagnostic'

Continued

Subject	Before coming into force	During	After
ANNEX I GENERAL SAFETY AND PERFORMANCE REQUIREMENTS	Perform gap analysis of consequences of changed 'essential requirements' for recertification of existing devices (e.g. risk management details, predictive value of test, labelling, IFU, UDI, sterility details) Perform gap analysis of requirements for new devices Documentation improvement for self-certifiable products that under IVDR will need notified body review	Updating of Technical Documentation and any checklists for new essential requirements if IVD is CE marked under IVDR Perform gap analysis of consequences of changed 'essential requirements' for recertification of existing devices Perform gap analysis of requirements for new devices	
ANNEX II TECHNICAL DOCUMENTATION	Perform gap analysis of existing technical files against new technical file requirements	Amending existing technical files against new technical file requirements and recertification based on amended technical file	Use new technical file requirements
ANNEX VII CLASSIFICATION CRITERIA	Analyse devices under new classification criteria to determine their class	Recertification of existing devices under new classification rules Certification of devices now needing notified body review	Apply new classification rules to new devices
ANNEX VIII CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM ASSURANCE AND ASSESSMENT OF TECHNICAL DOCUMENTATION	Perform gap analysis between current full QMS and new full QMS requirements, improve QMS where necessary	Recertification of existing devices under new QMS Certification of devices now needing notified body review	Apply new QMS
ANNEX IX CONFORMITY ASSESSMENT BASED ON TYPE EXAMINATION	Perform gap analysis between current type examination QMS and new type examination QMS requirements, improve QMS where necessary	Recertification of existing devices under new QMS Certification of devices now needing notified body review	Apply new QMS
ANNEX X CONFORMITY ASSESSMENT BASED ON PRODUCT QUALITY ASSURANCE	Perform gap analysis between current product verification QMS and new product verification QMS requirements, improve QMS where necessary	Recertification of existing devices under new QMS Certification of devices now needing notified body review	Apply new QMS

Chapter VI – Clinical evaluation and clinical investigations

The IVDR will put in place a self-contained regimen for clinical performance evaluations. It will introduce many new concepts relating to clinical performance evaluation and, to some extent, clinical usefulness of the tests, as well as a mandatory post-market clinical follow-up (PMCF). This will require a thorough review of manufacturers' clinical performance strategy and PMCF plans. Manufacturers will need to revisit their clinical strategy for new devices. Because the performance evidence for existing devices might need significant updates, manufacturers will also need to perform an extensive gap analysis. This is to identify gaps in clinical performance evidence under the new rules for devices currently on the market. For high-risk devices (classes C and D) a summary of safety and performance will be made publicly available.

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

Subject	Before coming into force	During	After
Chapter VI Performance evaluation and performance studies	Article 47: Understand new performance requirements; define gap between current performance evaluation of IVDs and future model; perform (clinical) performance evaluation studies if necessary	Consider prior review of performance evaluation and performance studies and possibly clinical performance studies; initiate (clinical) performance evaluation/ studies as required in accordance with new model	
	Draft process for determining applicability of clinical performance evaluation studies, in case of: • invasive sampling for the purpose of the study • an interventional clinical performance study; • where study includes additional invasive procedures; and • companion diagnostics		

Continued

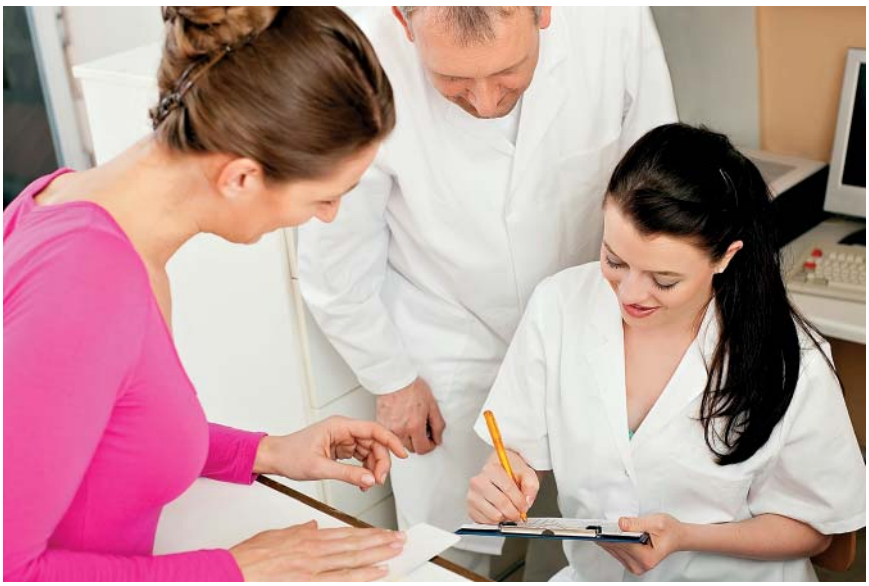
Subject	Before coming into force	During	After
	Article 48-58: Understand new performance study regime	Prepare for any scrutiny reviews and for scientific pre-meetings with European expert committee yet to be named	
		Understand and implement new application and modification mechanism for performance studies as well as recording/reporting requirements	Use new application and modification mechanism for performance studies as well as recording/reporting requirements
	Prepare for mandatory Post-Market Performance Follow-Up (PMPF)		
ANNEX XII PERFORMANCE EVALUATION AND POST-MARKET FOLLOW-UP	Perform gap analysis of current performance evaluation method and outcomes per devices against new requirements	Implement new requirements for performance evaluation, generate clinical evidence to meet new requirements Apply new requirements	Generate performance evidence to new requirements; apply new requirements
ANNEX XIII CLINICAL PERFORMANCE INVESTIGATIONS	Perform gap analysis to determine new clinical performance investigations requirements and impact on existing performance investigation plans	Apply new clinical investigation criteria	Apply new clinical performance investigation criteria

Chapter VII – Post-market surveillance, vigilance and market surveillance

Post-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:

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

PMS will need to adopt a continuous evaluation and improvement loop



Subject	Before coming into force	During	After
Chapter VII Post-market surveillance, vigilance and market surveillance	Understand new post-market surveillance system (including periodic safety update reports (PSURs)) required and perform a gap analysis against the current system used	Design and implement a new post-market surveillance plan (plan for consequences of ongoing Prepare for mandatory Post-Market Performance Follow-Up (PMPF) and Post-Market Surveillance (PMS) obligations as long as devices remain in the market) Gather PMS performance data as early as possible on any product currently based on equivalence	Use new post-market surveillance system (deal with consequences of ongoing PMPF and PMS obligations as long as devices remain in the market)
			Prepare periodic safety update to notified body reporting according to prescribed model, where appropriate

Continued

Subject	Before coming into force	During	After
	Understand new vigilance reporting requirements	Implement new vigilance reporting requirements	Apply new vigilance reporting requirements
ANNEX XII PERFORMANCE EVALUATION AND POST-MARKET FOLLOW-UP	Perform gap analysis of current post-market follow-up method and outcomes per device or device family against new requirements	Implement new requirements for PMCF, generate clinical evidence to meet new requirements Apply new requirements	Generate PMPF to new requirements; apply new requirements

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

The new Regulation will put 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 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 much like the Common Technical Specifications currently possible under the IVD Directive. These Common Specifications will focus heavily on the expected clinical performance data sets.

Subject	Before coming into force	During	After
Chapter VIII Cooperation between member states, Medical Device Coordination Group, EU Expert laboratories, Expert panels and device registers		Investigate which scientific discussions in this early phase might help smooth market introduction at a later stage	
	Monitor for developments that point to an adoption of Common Specifications in field(s) relevant to the manufacturer	Monitor for developments that point to an adoption of Common Specifications in field(s) relevant to the manufacturer Check if Common Specifications apply to IVDs already on the market and in pipeline and perform gap analysis	

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	Before coming into force	During	After
Chapter IX Confidentiality, data protection, funding, penalties	Prepare for new penalties regime under IVDR	Ensure compliance to avoid penalties	Ensure compliance to avoid penalties

Chapter X – Final provisions

In the consolidated final draft of 13 June 2016, the IVDR states a transitional period of five years, with the possibility for certificates to be issued under the old IVD Directive during the transitional period to be valid for a maximum of two years after the end of the transitional period.

The Regulation will permit 'sunshine compliance', i.e. the possibility to comply with the new rules during the transitional period. Manufacturers will need to carefully consider their strategy regarding when they will comply with the new rules for certain devices (groups) as there are many factors to consider. This will include factors such as:

- when the first notified bodies will be notified under the new rules (likely in the second half of the first year of the transitional period, but depending on the member state concerned this may take longer); and
- the availability of notified body resources to assess and certify the devices concerned.

Under all circumstances, 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.

Subject	Before coming into force	During	After
Chapter X Final provisions	Understand transitional regime for devices placed on the market during the transitional period Note exception for Annex VI certificate in Article 87	Apply transitional regime for devices placed on the market during the 5 year transitional period Determine and add to transition plan which products will remain certified for a further period on an IVD Directive certificate after the transition period. This period is currently two years but may be extended to give manufacturers more time to transition IVDs already on the market into the IVDR system	Recertify devices on certificates issued during the transitional period under the old rules (up to 2–5 years after the end of the transitional period)

Conclusion

The IVDR will bring about extremely significant changes that will affect all devices from manufacturers currently on the European market. Most critical is the full revision of the classification system into a rule-based risk classification matrix. In contrast to the current situation, this means the vast majority of products will need to be evaluated by the notified bodies. Most manufacturers will have to revisit all technical files and the quality system for all their devices currently on the market. They will also need to generate additional clinical and performance evidence for devices currently on the market in order to be able to transition them to the new regime implemented by the IVDR.

In addition, the administrative burden will increase substantially as a result of registration requirements and UDI.

Consequently, manufacturers must take a proactive approach to the new regulation, plan and budget for the transition of existing devices in a timely and detailed way, and allocate resources for this effort. Since their notified body may not be around anymore to recertify devices on the market, and in the majority of cases certify devices currently on the market as self-declared, manufacturers must plan for success.

For new devices that will need notified body clearance, manufacturers must decide whether they want to comply with the new rules already during the transitional period, or only from the moment that period expires. Again, a proactive approach is needed as the IVDR will require more clinical and performance evidence, especially for higher risk devices, which will take time to generate.

Appendix A

Checklist of manufacturer actions before, during and after transitional period

Subject	Before coming into force	During	After
Chapter I Definitions	Article 2 (2) contains a new definition: 'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information: • concerning a physiological or pathological process or state; concerning a congenital abnormality; • concerning the predisposition to a medical condition or a disease; • to determine the safety and compatibility with potential recipients; • to predict treatment response or reactions; and • to define or monitor therapeutic measures Action: Categorize existing devices and determine if they are in or out of scope of IVDR; new compared to the IVD Directive are the following definition elements: IVD provides information: • concerning the predisposition to a medical condition or a disease; and • to predict treatment response or reactions	During the transitional period the manufacturer may comply with the IVDR prospectively so the manufacturer must decide whether to CE mark new IVDs during the transitional period under IVDD, IVDR or neither depending on whether they are in the scope of the Directive and/or Regulation	CE mark new IVDs under IVDR if in scope

Continued

Subject	Before coming into force	During	After
	Article 1 (2): The IVDR Regulation shall not apply to: (a) products for general laboratory use or research-use only products, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination; (b) invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen; (c) internationally certified reference materials on higher metrological order; (d) materials used for external quality assessment schemes Action: Categorize existing devices and determine if they are in or out of scope of IVDR	Decide whether to CE mark new IVDs under IVDD, IVDR or neither depending on whether they are in the scope of the Directive and/or Regulation	CE mark new IVDs under IVDR if in scope
	Check if devices fall in enlarged scope of 'accessory': '"accessory to an in vitro diagnostic medical device means an article which, whilst not being an in vitro diagnostic medical device, is intended by its manufacturer to be used together with one or several particular in vitro diagnostic medical device(s) to specifically enable the in vitro diagnostic medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in view of its/their intended purpose(s)" The element of "or to specifically and directly assist the medical functionality of the medical device(s) in view of its/their intended purpose(s)" is new compared to the IVD Directive	Obtain CE mark for accessory under new regime	Obtain CE mark for accessory under new regime

Continued

Subject	Before coming into force	During	After
	Categorize existing IVDs to check if in scope of 'device for near patient testing' or 'device for self-testing' or 'companion diagnostic' to determine future conformity assessment procedure	Check if IVD constitutes a 'device for near patient testing' or a 'device for self-testing' or 'companion diagnostic', to which a specific conformity assessment procedure applies	Check if IVD constitutes a 'device for near patient testing' or a 'device for self-testing' or 'companion diagnostic', to which a specific conformity assessment procedure applies
	Categorize existing IVDs to check if in scope of definition of 'single use device' or 'kit' to determine impact on labelling and UDI requirements	Check if IVD is in scope of definition of 'single use device' or 'kit' to determine impact on labelling and UDI requirements	Check if IVD is in scope of definition of 'single use device' or 'kit' to determine impact on labelling and UDI requirements
	Article 14: Assess parallel trade procedure in Article 14 and draft procedure/policy for dealing with parallel trader requests to sign off on amended labelling and/or packaging	Apply procedure/policy for parallel trade label and/or packaging sign-off requests	Apply procedure/policy for parallel trade label and/or packaging sign-off requests
Chapter II Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement	Article 4 (5): Assess potential effect of laboratory developed tests ('home brews') under new home brew devices rules on company business model	Monitor compliance of hospitals with home brews under new laboratory developed test rules	Monitor compliance of hospitals with home brews under new laboratory developed test rules
	Article 4 (5f): For class C and D develop a set of compliance documentation in accordance with the rules set out in Annex VII		
	Article 5: Assess IVD testing provided as service via the internet	CE mark IVD as diagnostic service under new regime	CE mark IVD as diagnostic service under new regime
	Monitor harmonization of standards towards the new IVDR; develop rationales on continued use of standards currently harmonized under IVD Directive until they are harmonized under the new regime	Monitor harmonization of standards under IVDR and update technical documentation against standards that are re-harmonized	Monitor harmonization of standards under IVDR and update technical documentation against standards that are re-harmonized
	Monitor adoption of 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

Continued

Subject	Before coming into force	During	After
	Article 8 (4): Assess Own Brand Labelling consequences of the requirements that a full technical file must be present at each manufacturer	Change business and certification set-up into virtual contract manufacturing, or get all required contracts to access key documentation from OEM in place	
	Article 8 (1a): Perform gap analysis against new risk management requirements set out in Annex I	Amend and implement new risk assessment; apply to devices elected to be compliant during transitional period	Apply new procedure
	Article 8 (1c): Perform gap analysis against new performance evaluation requirements in Article 47 and Annex XII, including post-market performance follow-up	Amend and implement new performance evaluation procedure; apply to devices elected to be compliant during transitional period	Apply new procedure
	Article 8 (6) and 58a: Perform gap analysis against new post-market surveillance plan requirements	Amend and implement new post-market surveillance plan	Apply new criteria for post-market surveillance plan
	Article 8 (8); Article 8a: Perform gap analysis against new recall requirements: Manufacturers shall have a system for reporting incidents and field safety corrective actions as described in Article 59	Amend procedures and distribution agreements for new corrective action and reporting requirements	Apply procedures for new corrective action and reporting requirements
	Article 8 (5): Perform gap analysis against new QMS criteria; amend procedures	Implement amended QMS; consider revising directly into new ISO 13485:2016 at the same time	Apply amended QMS
	Article 8 (11): Mandatory insurance: monitor developments	Purchase and maintain relevant insurance	Maintain relevant insurance
	Article 9-10: Perform gap analysis against new Authorized Representative ("AR") requirements – amend AR agreement and procedures – expect AR renegotiations if liability requirements are adopted	Ensure continued access to AR services when relevant	

Continued

Subject	Before coming into force	During	After
	Articles 11-12: Review general obligations of importers and distributors and their impact on the device groups' supply chains and amend contracts accordingly	Implement standard operating procedures (SOPs), amend agreements in supply chain	
	Article 13: Select and mandate candidate for person responsible for regulatory compliance. Verify if exception for micro-enterprises and SMEs applies	Make and keep available in the organization a person responsible for regulatory compliance; ensure training and, where appropriate, liability insurance	Keep available in the organization a person responsible for regulatory compliance
	Article 14: Prepare for new re-labelling/repackaging regime – draft SOP for new regime	Implement and apply SOP	Apply SOP
	Article 15 Annex III: Declaration of conformity model – check for gaps	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	
	Article 19: Parts manufacturers to ensure that the part or component does not adversely affect the safety and performance of the device	Parts manufacturers are to generate supporting evidence for this. Supporting evidence shall be kept available to the competent authorities of the member states	Supporting evidence shall be kept available to the competent authorities of the member states
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 21 (1): UDI: Distributors and importers shall cooperate with the manufacturer or authorized representative to achieve an appropriate level of traceability of devices – implement changes to distribution agreements	Implement changes to distribution agreements and SOPs	

Continued

Subject	Before coming into force	During	After
	Article 21 (2): Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 8 (4): (a) any economic operator to whom they have supplied a device; (b) any economic operator who has supplied them with a device; (c) any health institution (or healthcare professional) to whom they have supplied a device Implement and improve traceability	Get traceability systems in place in a supply chain, where possible, based on UDI	
	Article 22 (3): Assign UDI to device and higher levels of packaging and (22 (4)) place that on the label and higher levels of packaging and (22 (a-c + 5) keep UDI administration for reporting and tech file	Choose type of UDI system to be applied, in line with global requirements towards UDI	
		Article 22b: If possible, manufacturers may apply new process for registration of devices prior to placing on the market	Article 22b: Apply new process for registration of devices prior to placing on the market
		If possible, companies may apply process for registration of manufacturers, and authorized representatives and importers, single registration number	Article 23a: Apply process for registration of manufacturers, authorized representatives and importers, single registration number
			Draw up and make available summary of safety and clinical performance for class C and D
		If available: Article 25: Enter data into EUDAMED	Article 25: Enter data into EUDAMED

Continued

Subject	Before coming into force	During	After
Chapter IV Notified bodies	Perform assessment of notified body's potential to be re-notified under new system	Re-notification to be timely; with long delays in re-notification, consider alternative plans	
	Agree re-assessment plan with current notified body or agree transition plan to new notified body, if necessary		
		Article 36: Analyse and implement new transition procedures for dealing with consequences of changes in designation and cessation of notified bodies	
	Assess notified body resource availability to assess all IVD that are currently self-certifiable but will need to be assessed by a notified body under the new IVDR		
Chapter V Classification and conformity assessment	Perform a gap analysis of all devices on the market against new classification rules and create transition plan if classification necessitates new conformity assessment	Implement transition plan for reclassified devices	
	Article 42: Determine new conformity assessment procedures under IVDR; class D IVDs will be subject to additional scrutiny procedures	Apply new conformity assessment procedures to devices already on the market and optionally to new devices to be placed on the market Select devices which have documentation to support the new essential principles	Apply new conformity assessment procedures to devices
	Article 40: Perform QMS gap analysis against the new rules	Apply new QMS optionally in case of new devices to be placed on the market	Apply new QMS in case of new devices to be placed on the market
			Article 44: Conclude tri-partite transition agreement with outgoing and incoming notified body in case of voluntary change of notified body
		Article 48: Uniform certificates of free sale will be issued by member states	Article 48: Uniform certificates of free sale will be issued by member states

Continued

Subject	Before coming into force	During	After
	Article 40 (2): Prepare QMS procedures for batch verification by qualified person for class D IVDs for each batch	Article 40 (2): Implement batch verification by qualified person for class D IVDs for each batch	Article 40 (2): Apply batch verification by qualified person for class D IVDs for each batch
	Categorize existing devices for whether they are in scope of definition of 'device for near-patient testing'	Apply specific conformity assessment procedure to 'device for near patient testing'	Apply specific conformity assessment procedure to 'device for near patient testing'
	Categorize existing devices for whether they are in scope of definition of 'device for self-testing'	Apply specific conformity assessment procedure to 'device for self-testing'	Apply specific conformity assessment procedure to 'device for self-testing'
	Categorize existing devices for whether they are in scope of definition of 'companion diagnostic'	Apply specific conformity assessment procedure to 'companion diagnostic'	Apply specific conformity assessment procedure to 'companion diagnostic'
Chapter VI Performance evaluation and performance studies	Article 47: Understand new performance requirements; define gap between current performance evaluation of IVDs and future model; perform (clinical) performance evaluation studies if necessary	Consider prior review of performance evaluation and performance studies and possibly clinical performance studies; initiate (clinical) performance evaluation/ studies as required in accordance with new model	
	Draft process for determining applicability of clinical performance evaluation studies, in case of: • invasive sampling for the purpose of the study • an interventional clinical performance study; • where study includes additional invasive procedures; and • companion diagnostics		
	Article 48-58: Understand new performance study regime	Prepare for any scrutiny reviews and for scientific pre-meetings with European expert committee yet to be named	
		Understand and implement new application and modification mechanism for performance studies as well as recording/reporting requirements	Use new application and modification mechanism for performance studies as well as recording/reporting requirements

Continued

Subject	Before coming into force	During	After
	Prepare for mandatory Post-Market Performance Follow-Up (PMPF)		
Chapter VII Post-market surveillance, vigilance and market surveillance	Understand new post-market surveillance system (including periodic safety update reports (PSURs)) required and perform a gap analysis against the current system used	Design and implement a new post-market surveillance plan (plan for consequences of ongoing Prepare for mandatory Post-Market Performance Follow-Up (PMPF) and Post-Market Surveillance (PMS) obligations as long as devices remain in the market) Gather PMS performance data as early as possible on any product currently based on equivalence	Use new post-market surveillance system (deal with consequences of ongoing PMPF and PMS obligations as long as devices remain in the market)
			Prepare periodic safety update to notified body reporting according to prescribed model, where appropriate
	Understand new vigilance reporting requirements	Implement new vigilance reporting requirements	Apply new vigilance reporting requirements
Chapter VIII Cooperation between member states, Medical Device Coordination Group, EU Expert laboratories, Expert panels and device registers		Investigate which scientific discussions in this early phase might help smooth market introduction at a later stage	
	Monitor for developments that point to an adoption of Common Specifications in field(s) relevant to the manufacturer	Monitor for developments that point to an adoption of Common Specifications in field(s) relevant to the manufacturer Check if Common Specifications apply to IVDs already on the market and in pipeline and perform gap analysis	
Chapter IX Confidentiality, data protection, funding, penalties	Prepare for new penalties regime under IVDR	Ensure compliance to avoid penalties	Ensure compliance to avoid penalties

Continued

Subject	Before coming into force	During	After
Chapter X Final provisions	Understand transitional regime for devices placed on the market during the transitional period Note exception for Annex VI certificate in Article 87	Apply transitional regime for devices placed on the market during the 5 year transitional period Determine and add to transition plan which products will remain certified for a further period on an IVD Directive certificate after the transition period. This period is currently two years but may be extended to give manufacturers more time to transition IVDs already on the market into the IVDR system	Recertify devices on certificates issued during the transitional period under the old rules (up to 2–5 years after the end of the transitional period)

IVDR Annexes

Subject	Before coming into force	During	After
ANNEX I GENERAL SAFETY AND PERFORMANCE REQUIREMENTS	Perform gap analysis of consequences of changed 'essential requirements' for recertification of existing devices (e.g. risk management details, predictive value of test, labelling, IFU, UDI, sterility details) Perform gap analysis of requirements for new devices Documentation improvement for self-certifiable products that under IVDR will need notified body review	Updating of Technical Documentation and any checklists for new essential requirements if IVD is CE marked under IVDR Perform gap analysis of consequences of changed 'essential requirements' for recertification of existing devices Perform gap analysis of requirements for new devices	
ANNEX II TECHNICAL DOCUMENTATION	Perform gap analysis of existing technical files against new technical file requirements	Amending existing technical files against new technical file requirements and recertification based on amended technical file	Use new technical file requirements
ANNEX III EU DECLARATION OF CONFORMITY	Perform gap analysis of existing declarations of conformity against new declaration of conformity requirements	Amending existing declarations of conformity against new declaration of conformity requirements and recertification based on amended technical file	Use new declaration of conformity requirements

Continued

Subject	Before coming into force	During	After
ANNEX IV CE MARKING OF CONFORMITY	Add UDI details		
ANNEX V INFORMATION TO BE SUBMITTED WITH THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS	Perform gap analysis of information to be provided in EUDAMED database and for UDI purposes Prepare for implementation for EU-UDI	Implement EU-UDI for existing and new devices	Use EU-UDI
ANNEX VI MINIMUM REQUIREMENTS TO BE MET BY NOTIFIED BODIES	Inform notified body if it can meet the new requirements and prepare for transition, if needed Look for notified body if needed for the first time; ensure resources are committed; get a certification plan in place, agreed by the notified body	Notified body may or may not be re-notified under new criteria; move to new notified body in case notified body not re-notified	
ANNEX VII CLASSIFICATION CRITERIA	Analyse devices under new classification criteria to determine their class	Recertification of existing devices under new classification rules Certification of devices now needing notified body review	Apply new classification rules to new devices
ANNEX VIII CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM ASSURANCE AND ASSESSMENT OF TECHNICAL DOCUMENTATION	Perform gap analysis between current full QMS and new full QMS requirements, improve QMS where necessary	Recertification of existing devices under new QMS Certification of devices now needing notified body review	Apply new QMS
ANNEX IX CONFORMITY ASSESSMENT BASED ON TYPE EXAMINATION	Perform gap analysis between current type examination QMS and new type examination QMS requirements, improve QMS where necessary	Recertification of existing devices under new QMS Certification of devices now needing notified body review	Apply new QMS
ANNEX X CONFORMITY ASSESSMENT BASED ON PRODUCT QUALITY ASSURANCE	Perform gap analysis between current product verification QMS and new product verification QMS requirements, improve QMS where necessary	Recertification of existing devices under new QMS Certification of devices now needing notified body review	Apply new QMS

Continued

Subject	Before coming into force	During	After
ANNEX XI MINIMUM CONTENT OF CERTIFICATES ISSUED BY A NOTIFIED BODY	No action required by the manufacturer	No action required by the manufacturer	No action required by the manufacturer
ANNEX XII PERFORMANCE EVALUATION AND POST-MARKET FOLLOW-UP	Perform gap analysis of current performance evaluation method and outcomes per devices against new requirements	Implement new requirements for performance evaluation, generate clinical evidence to meet new requirements Apply new requirements	Generate performance evidence to new requirements; apply new requirements
ANNEX XIII CLINICAL PERFORMANCE INVESTIGATIONS	Perform gap analysis to determine new clinical performance investigations requirements and impact on existing performance investigation plans	Apply new clinical investigation criteria	Apply new clinical performance investigation criteria

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

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Gert has 21 years of experience in life sciences (devices and pharma), in university, industry as well as in four notified bodies. His last notified body roles were Head of Regulatory and Clinical Affairs of BSI Medtech and Head of Notified Body at BSI-Germany (NB0535). He has been President of the Notified Body association TEAM-NB, and Vice Chair of the Medical Notified Body forum NB-Med in Brussels. In these roles for many years, he represented notified bodies in a.o. the Clinical Investigation and Evaluation Group (CIE), Medical Device Expert Group (MDEG) and the MDEG workgroups on animal tissue, on MRAs, e-labeling, EUDAMED and on IVDs, as well as the IMDRF workgroup on Regulated Product Submissions and Table of Content. In addition, he served as NB-representative at EMA/CAT and Medical Device Collaboration group. He is a founding board member of the Dutch RAPS chapter. (*please note this paper was commissioned when Dr Gert Bos was at BSI and does not imply any relationship with, or endorse, Qserve).

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Erik is a lawyer specializing in EU legal issues relating to medical devices. He has wide experience in life sciences legislation and regulatory issues, at both the EU and Dutch level. Vollebregt was trained as an intellectual property and competition lawyer. He has gained experience in contentious matters, commercial contracts, and transactional work at the Directorate-General for Competition of the European Commission. He is a prolific writer and publishes in life sciences legal and regulatory journals on a wide variety of subjects. Vollebregt authored several medical technology chapters of RAPS Fundamentals of EU Regulatory Affairs and is writing a chapter on software for Fundamentals of International Regulatory Affairs.

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Erica joined BSI in their IVD team at the beginning of 2014, and is now Global IVD Team lead. Her industrial experience started at GSK in the regulation of pharmaceuticals; she worked in the arena of clinical trials for medicinal products for Quintiles. Erica then progressed into the field of IVDs when she became the Regulatory Affairs Manager for Axis-Shield Diagnostics (now Alere). Following this, she moved into consultancy work as a continued member of BIVDA. Erica worked for a small start-up IVD company prior to joining BSI, where she set up a Quality Management System to ISO 13485 and ISO 17025.

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Terry has been employed in the medical equipment industry all his working life. Having qualified as a mechanical engineer he then, over the following 40+ years, experienced both sides of the medical industry, the technical side and the commercial side, with various companies that manufactured everything from capital medical equipment to consumable medical devices.

Since 1995, he has been a self-employed consultant specializing in all matters related to standards including advising companies on compliance with the European Medical Device Directive and US FDA directives. He represents the members of the British Anaesthetic and Respiratory Manufacturers Association (BAREMA) at BSI meetings. BAREMA comprises manufacturers from all parts of the Anaesthetic and Respiratory industry. He also represents several individual companies at ISO and CEN meetings. Terry is on several national, European and international standards committees, the following as Chairman: CEN/TC/215, CH/121, CH/121/1, CH/121/5, CH/121/9 and CH/210/5.

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SMTL, based in Bridgend in South Wales, is funded by the Welsh Government to test medical devices for the Welsh NHS and to provide technical advice on medical devices. Pete has worked in the medical devices field for 30+ years, and sits on a number of BSI, CEN and ISO medical device committees and groups. He chairs the Welsh Non-Luer Connectors Reference Group (WNCRG) for Welsh Government, which is coordinating the implementation of new ISO-compliant non-Luer connectors across the Welsh NHS, and represents Welsh Government on medical devices on various other groups.

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Rebecca has over 25 years of experience in the medical device industry both at industry-leading corporations and small business start-ups. Her background includes all aspects of domestic and international medical device regulatory, clinical and quality management for a wide range of products, including cardiovascular, orthopedic, animal tissue, electromedical devices, nuclear medicine, and in vitro diagnostics (IVD). She is a member of the Regulatory Affairs Professionals Society (RAPS) and the Association for the Advancement of Medical Instrumentation (AAMI).

Published white papers

How to prepare for and implement the upcoming MDR – Dos and don'ts, Gert Bos and Erik Vollebregt

The Proposed EU Regulations for Medical and In Vitro Diagnostic Devices: An Overview of the Likely Outcomes and Consequences for the Market, Gert Bos and Erik Vollebregt

The Differences and Similarities between ISO 9001 and ISO 13485, Mark Swanson

Generating Clinical Evaluation Reports – A Guide to Effectively Analysing Medical Device Safety and Performance, Hassan Achakri, Peter Fennema and Itoro Udofia

Effective Post-market Surveillance – Understanding and Conducting Vigilance and Post-market Clinical Follow-up, Ibim Tariah and Rebecca Pine

What You Need to Know About the FDA's UDI System Final Rule, Jay Crowley and Amy Fowler

Engaging Stakeholders in the Home Medical Device Market: Delivering Personalized and Integrated Care, Kristin Bayer, Laura Mitchell, Sharmila Gardner and Rebecca Pine

Negotiating the Innovation and Regulatory Conundrum, Mike Schmidt and Jon Sherman

The Growing Role of Human Factors and Usability Engineering for Medical Devices: What's Required in the New Regulatory Landscape? Bob North

ISO 13485: The Proposed Changes and What They Mean for You, Bill Enos and Mark Swanson

Forthcoming white papers

Sterilization Practices in Response to Device Innovation (working title)

Clinical Data: Away from Clinical Equivalence in Europe (working title)

The Future of Standards in Europe – Harmonization and other Recognitions of Standards (working title)

Cyber Security for Medical Devices (working title)

About BSI Group

BSI (British Standards Institution) is the business standards company that equips businesses with the necessary solutions to turn standards of best practice into habits of excellence. Formed in 1901, BSI was the world's first National Standards Body and a founding member of the International Organization for Standardization (ISO). Over a century later it continues to facilitate business improvement across the globe by helping its clients drive performance, manage risk and grow sustainably through the adoption of international management systems standards, many of which BSI originated. Renowned for its marks of excellence including the consumer recognized BSI Kitemark™, BSI's influence spans multiple sectors including aerospace, construction, energy, engineering, finance, healthcare, IT and retail. With over 70,000 clients in 150 countries, BSI is an organization whose standards inspire excellence across the globe.

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This paper was published by BSI Standards Ltd.

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