

# Bird & Bird & Medical Devices

*White Paper on Medical Devices & In Vitro Diagnostic  
Medical Devices Reform*



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# Introduction

*The developments of the medtech industry have vastly outpaced the current regulatory framework for medical devices of the European Union ("EU") which framework dates back to the 1990's and is based on three Directives:*

- Directive 90/385/EEC, active implantable medical devices ("**AMDD**")
- Directive 93/42/EEC, medical devices ("**MDD**")
- Directive 98/79/EC, in vitro diagnostic medical devices ("**IVDD**").

The European regulators therefore considered that a change was needed. Following recent scandals such as the Poly Implant Prothèse ("**PIP**") scandal<sup>i</sup>, certain initiatives were have already been taken under the current regime (a) to minimise the risk to patients' and (b) to reduce so called "notified body tourism" by increasing scrutiny on notified bodies<sup>ii</sup>; further harmonisation measures to improve patient safety were nonetheless deemed necessary.

After several years of discussion and public consultations to capture stakeholders' views on the current framework, the European Commission ("**Commission**") published in 2012 its proposal for two new Regulations, which are intended to replace the existing Directives as follows:

- a proposal for a Regulation on medical devices, to replace the AMDD and the MDD<sup>iii</sup> ("**MDR**");
- a proposal for a Regulation on in vitro diagnostic medical devices, to replace the IVDD<sup>iv</sup> ("**IVDR**").

The Commission initiated a shift from Directives to Regulations<sup>v</sup>, in order to ensure a wider scope of protection and more effective implementation of the rules on medical devices ("**MDs**") and in vitro diagnostic medical devices ("**IVDs**").

These new Regulations, once finally adopted, will be immediately binding for all EU Member States

without a transposition into national law being necessary. Following a lengthy legislative process, the EU reached a political agreement on these new Regulations on 25 May 2016<sup>vi</sup>. Thereafter, the formal procedure was initiated whereby the consolidated regulatory texts are being translated in all EU Member State languages, followed by a formal publication within the Official Journal of the European Union ("**OJEU**"), which has yet to take place.

The MDR and IVDR will enter into force 20 days after this formal publication, which is expected by early 2017. There will then be a transition period of three years for MDs and five years for IVDs before the Regulations will become effectively applicable. This will be most probably early 2020 for the MDR and early 2022 for the IVDR.

Whilst Regulations seem to give plenty of time for implementation, manufacturers are nonetheless advised to be prepared and meticulously plan implementation beforehand in order to avoid problems later on when marketing affected devices. This White Paper discusses the main changes introduced by the Regulations and the problems which may arise for the economic players when preparing for implementation.

# Executive Summary

## 1. Following the MDR and IVDR reform the scope has changed:

- Manufacturers are to check qualification of their existing products against the new rules and determine whether they are in or out of scope of these new rules.
- More specifically, manufacturers need to pay attention to the new definitions of MDs and IVDs as well as the enlarged scope of 'accessory' to MDs and IVDs.
- Changed definitions of key concepts such as 'devices for near patient testing', 'self-testing', 'companion diagnostics' under the IVDR and for example 'single use devices' under the MDR will vary the existing regulatory requirements so appropriate conformity assessments will need to be applied, and labelling, etc. of current applications will need to be verified by the economic players.

## 2. Also the classification rules have been altered:

- Manufacturers are to check classification against the new rules and plan for different conformity assessment procedures, if appropriate.
- More specifically, manufacturers should pay attention to the fact that certain riskier products will be reclassified as Class III, that rules for software classification have been introduced and that substance-based devices administered via a body orifice or applied on skin are covered by a new special rule.
- In particular, IVDs are covered by new classification rules, and most will need to use a notified body for some form of conformity assessment (representing a big departure from the current system where most fall under self-certification). Certain self-testing devices are reclassified from class C to B.

## 3. The rules on clinical evidence have been strengthened:

- Manufacturers are to check the new clinical requirements of the new legal framework versus their current clinical evaluation (including PMCF methods outcome) and investigation plans and to assess whether their current internal procedures on clinical evaluation and investigations should be reviewed– it may be that additional data will be required in order to be able to (continue to) market their products.
- The generation of additional clinical evidence would need to be assessed in a timely manner and planned in accordance with the availability of whichever notified body is to perform the conformity assessments.

## 4. Clear and additional responsibilities of the members of the supply chain have been introduced:

- All participants in the supply chain should be aware of their respective role and responsibilities under the new rules and are to verify their respective distribution, supply chain and other agreements accordingly and to amend these agreements where needed.
- While manufacturers are explicitly obliged to have sufficient financial protection for potential liability under the PLD, the other participants are also advised to also take additional insurance policies as to cover their respective risks.

## 5. The MDR introduced an opt-in option on reprocessing for Member States, partially harmonising the rules on reprocessing but mainly increasing the questions for industry:

- Will Member States permit reprocessing of SUDs and – if so – how will they shape their national laws?
- Can reprocessing be prevented using the original manufacturer's IPRs?
- What impact will the reprocessor's product liability have on the reprocessing business?
- How will original manufacturers react to increased liability risks caused by reprocessing?

## 6. More powers for notified bodies towards manufacturers in relation to the conformity assessment procedures and post-marketing surveillance obligations were introduced, but equally increased the scrutiny on these notified bodies. These new obligations raise certain questions:

- Will notified bodies be able to meet these new stringent requirements and will they be on time?
- How will the increased scrutiny on notified bodies impact manufacturers?
- What will be the impact of CJEU case, C-219/15, on the responsibility of notified bodies?

## 7. Hazardous chemicals

- The MDR and IVDR do not introduce significant change in respect of the rules surrounding the use of hazardous or potentially hazardous substances in medical devices or in vitro diagnostics;
- The main obligations are duties to inform the users appropriately in cases where exposure to hazardous substances is likely;
- Specific guidance is to be issued by the Commission on the use of certain hazardous substances such as phthalates.

## 8. New transparency provisions were introduced including a mandatory UDI system, facilitating the traceability of devices, as well as an enhanced EUDAMED, including the obligation to publish clinical investigation reports and summary hereof on EUDAMED. These provisions raise the following questions:

- Will manufacturers be prevented from bringing new and innovative products to market as their data would be easily accessible by competitors?
- Will more Medtech companies go down the pharma-route and increase patent filings? Would there be a need for SPCs for MDs?
- How will the roll-out of EUDAMED, including the UDI-database, which differs from the normal transposition regime, influence manufacturer's implementation planning?

## 9. The implications of Brexit will depend on the model which will be adopted by the UK, either joining the EEA or the EFTA or leaving the CEN.

# 1. Scope and Key Definitions

*The two new Regulations altered their scope without introducing major changes, but nonetheless some key concepts were clarified.*

The two new Regulations altered their scope without introducing major changes, but nonetheless some key concepts were clarified.

The scope of the MDR is largely equivalent to the MDD and AMDD. The MDR nonetheless introduced some considerable changes to the existing definitions of the MDR including the concept of MDs itself, resulting in the inclusion within the scope of the MDR certain products that are currently not classified as MDs, such as products intended for cleaning, disinfecting or sterilising MDs, which were previously considered to be solely accessories to MDs. The scope of the definition of 'accessories' was also enlarged. Accessories will now include devices that specifically or directly assist another device in its intended purpose<sup>vii</sup>. Also, products based on human cell or tissue derivatives in relation to MDs are now expressly included within the scope of the Regulation<sup>viii</sup>. The EU legislator indicated that EU legislation is insufficient in relation to certain products which are manufactured utilising derivatives of tissue or cells of human origin that are non-viable or are rendered non-viable. Finished products utilising those derivatives should come under the scope of the MDR provided they comply

with the definition of MDs or are covered by the MDR. Furthermore, the MDR now also explicitly covers implantable or other invasive products without a medical purpose (i.e. only an aesthetic purpose), but which are similar to MDs in terms of their characteristics and risk profile, as non-corrective contact lenses, fillers, tattoo or hair removal treatments.<sup>ix</sup> Finally, the MDR clarified that software in its own right which is used for medical purposes will qualify as a MD, while software for life-style and well-being applications are not MDs<sup>x</sup>.

The scope of the IVDR also remains fairly similar to that of the current IVDD, with the main changes also extending the scope of the regulatory framework and providing some much needed clarification on certain important concepts. In summary, the IVDR now includes (i) tests to provide information about the predisposition of a medical condition or disease; (ii) tests to provide information to predict treatment response or reactions; and (iii) medical software, which is now explicitly mentioned in the definition of IVDs. As is the case under the MDR, the scope of 'accessories' was enlarged, now also including devices that specifically or directly assist another device in its intended purpose.



Notably, the IVDR extended the concept of IVDs to 'lifestyle tests' by referring to the notion of 'prediction' in the definition, including certain nutri-genetic and lifestyle tests which are currently not covered by the IVDD. Furthermore, the new definition of IVDs now explicitly includes genetic tests by making clear that tests that provide information on the predisposition to a medical condition or a disease (like genetic tests) and tests that provide information to predict treatment response or reactions, such as companion diagnostics, are in fact IVDs<sup>xi</sup>. Also the definitions of important notions as 'device for self-testing', 'device for near-patient testing' and 'companion diagnostics'<sup>xii</sup> were amended, possibly leading to new conformity assessment procedures for certain existing devices.

The IVDR still applies even if the device is not physically placed on the market, as long as therapeutic or diagnostic services are offered in a commercial context by means of information society to individuals in the EU. This clarification is important for genetic test services offered from outside the EU to EU citizens and generally in relation to distance sales of genetic testing kits.

## Key take away points

- Manufacturers are to check qualification of their existing products against the new rules and determine whether they are in or out of scope of these new rules.
- More specifically, manufacturers should pay attention to the new definitions of MDs and IVDs as well as the enlarged scope of 'accessory' to MDs and IVDs.
- The changed scope of key concepts such as 'devices for near patient testing', 'self-testing', 'companion diagnostics' under the IVDR and for example 'single use devices' under the MDR have an impact on the existing regulatory requirements as amongst others the appropriate conformity assessment to be applied, labelling, etc. and would need to be verified as to their current applications by the economic players.





## 2. Classification Rules

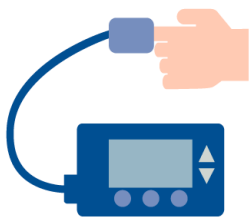
*Both new Regulations make changes to the classification rules and conformity assessment procedures for devices, and state that, to the extent possible, guidance developed for MDs at international level should be taken into account in applying the classification systems. Appropriate conformity assessment procedures, depending on the product's class, are set out in the Annexes to the Regulations.*

There are provisions allowing for reclassification of a device (derogating from the classification criteria) “for reasons of public health”, based on new scientific evidence or any information which becomes available in the course of vigilance / market surveillance activities; such decision is taken by the Commission either on its own initiative or at the request of a Member State, after consulting the Medical Devices Coordination Group (“MDCG”), which will be established by the reform. The Commission may also adopt implementing acts “to the extent necessary to resolve issues of divergent interpretation and practical application”, with the aim of ensuring uniform application of the classification criteria.

### 2.1 Medical Devices (MDs)

As with the MDD, the new MDR provides for a framework of risk-based classification for devices, leading to risk-appropriate conformity assessment procedures. The new rules follow the existing system, which provides for four classes (Classes I, IIa, IIb and III, in order of increasing potential risk); Chapter V is the section dealing with classification and conformity assessment. Classification should be based on “the purpose intended by the manufacturer and inherent risks”. Annex VII of the Regulation sets out the classification criteria, with new “special rules”.

In accordance with the Regulation’s aim of tightening up on control of riskier products, certain products will be reclassified into Class III (and thus undergo a more stringent assessment) under the new rules. Active implantable medical devices, now incorporated into the MDR, are Class III by default, as are their accessories (in contrast with other device accessories, which are classified in their own right unless they are software which drives or influences the use of a device, which automatically falls in the same class as the device). Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines patient management by the device also fall within Class III. All devices incorporating or consisting of nanomaterial are in class III if they present a high or medium potential for internal exposure (otherwise a lower class).





Rules for software classification are now included; software which provides information used to take diagnostic / therapeutic decisions is in class IIa, except if such decisions can have a serious impact on patient health, in which case the classification will be class III or IIb. Software intended to monitor physiological processes is in class IIa, except if intended to monitor “vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient”, in which case it is in class IIb. All other software is in class I.

There were considerable deliberations regarding the treatment of substance-based devices which are administered via a body orifice or applied on skin and absorbed by or locally dispersed in the human body; under a new special rule, such devices will be Class III if systemically absorbed (including where they achieve their intended purpose in the stomach or lower gastrointestinal tract), otherwise Class IIb, or IIa if just applied to the skin or applied in the nasal or oral cavity to achieve their intended purpose on those cavities. Invasive devices intended to administer medicines by inhalation are classed as IIa or IIb, according to risk-based criteria.

## 2.2 In Vitro Diagnostic Medical Devices (IVDs)

The new IVDR brings in new classification rules based on the Global Harmonisation Task Force system, with four risk-based classes for IVDs—Class A (lowest risk), B, C and D (highest risk). Annex VII sets out the classification rules. Conformity assessment for class A devices will be the sole responsibility of the manufacturer, except where they are intended for self-testing, near-patient testing or are sold sterile (in which case a notified body must verify the design or sterilisation process).

Other classes will all require notified body involvement. Whilst the majority of IVDs currently fall under self-certification, most will need to use a notified body for some form of conformity assessment under the new rules, so this represents a major shift in regulatory approach.

Certain self-testing devices (those for the detection of pregnancy, for fertility testing, for determining cholesterol level, and for the detection of glucose, erythrocytes, leucocytes and bacteria in urine) move from class C to B under the new rules; they will still be subject to notified body oversight but subject to different conformity assessment procedures.

### Key take away points

- Manufacturers are to check classification against the new rules and plan for different conformity assessment procedures if appropriate.
- More specifically, manufacturers should pay attention to the fact that certain riskier products will be reclassified as Class III, that rules for software classification have been introduced and that substance-based devices administered via a body orifice or applied on skin are covered by a new special rule.
- In particular, IVDs are covered by new classification rules, and most will need to use a notified body for some form of conformity assessment (representing a big departure from the current system where most fall under self-certification). Certain self-testing devices are reclassified from class C to B.



# 3. Clinical Evaluation and Clinical Investigations

*One of the most important aspects of the MDs reform is the reinforcement of (i) the rules for clinical investigations on devices and (ii) the required clinical data for the pre-market and the continuous post-market assessment of MDs.*

The new Regulations further align the provisions on ethical and methodological principles to those for clinical trials of medicinal products. The Regulations introduce many new concepts relating to clinical evaluation and clinical investigation, including mandatory post-market clinical follow-up ("PMCF")<sup>xiii</sup> and periodic safety update reports ("PSURs").

It is safe to say that following this reform, the requirements for clinical evidence for MD and IVD manufacturers will increase substantially and will require in most cases significantly higher investment from companies who wish to enter the European market.

Compliance with the current MEDDEVs on clinical evaluation and investigation is unlikely to be sufficient in order to ensure compliance with the Regulations requirements.

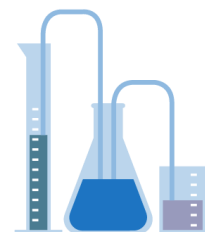
Manufacturers will most likely need to revise their clinical strategy and review their internal procedures on clinical investigations, as well as to identify any possible gaps in clinical evidence under the Regulations, not only in relation to new products but also in relation to their existing products.

Companies will most likely therefore need to invest in personnel with a deep knowledge of Good Clinical Practice ("GCP") and clinical investigation design, in order to work with and interpret clinical studies and communicate adequately with the competent authorities and notified bodies in question.

## 3.1 Clinical evaluation of MD

To demonstrate conformity of a MD, companies will have to demonstrate that their device has an acceptable *benefit to risk ratio* based on a clinical evaluation. This test will be based on '*clinical data*' and will include all the relevant clinical information on the '*safety*' and '*performance*' (including '*clinical benefits*', i.e. the positive impact of the device on the patient), of a particular MD when used as intended by the manufacturer.

The clinical data may consist of (i) clinical investigations and peer reviewed clinical literature of either the device in question or similar devices, and (iii) clinical data coming from the post-market surveillance system. These data are generated, collected, analysed and summarised within a part of the safety dossier, i.e. the '*clinical evaluation report*', and must be updated continuously throughout the lifetime of a device.



The systematic clinical evaluation was much debated during the deliberations of the Regulations, with industry claiming that the definition of 'clinical evaluation' provided during the negotiations was too simplistic and did not reflect the class or risk profile of the device, nor the different scientific approaches that could be taken, nor the contributing factors relating to the design or the intended purpose etc. In spite of these efforts from industry, the final proposal of the MDR does not include unpublished data within the notion of 'clinical data'<sup>xiv</sup>, thereby artificially excluding a vast amount of valid and available verifiable clinical data, like for example registry data, which may lead to unnecessary costs for industry.

### 3.2 Clinical investigation of MD

For certain high-risk devices, i.e. implantable devices and Class III devices<sup>xv</sup>, the MDR imposes the obligation to conduct '*clinical investigations*', i.e. systematic investigations in one or more human subjects, to demonstrate the product's safety and performance.

The new system proposed for clinical investigations is similar to the current system for medicinal products under the Clinical Trials Directive (Directive 2001/20/EC), introducing the notion of 'Sponsor', the obligation to notify in a centralised database on medical devices ("**EUDAMED**"), the assessment of the clinical investigations by ethics committees according to the Member States concerned, obtaining the informed consent of the subject of the trials, etc. The MDR foresees in this regard specific provisions on the consent of incapacitated subjects, minors pregnant or breastfeeding women, as well as the possibility for Member States to adopt additional measures on persons performing mandatory military services, persons deprived of liberty, persons who due to a judicial decision cannot take part in clinical investigations or persons in residential care institutions.

Notably, the MDR allows manufacturers of class III (highest risk) devices to consult with an expert panel to provide feedback on the company's clinical investigation strategy before commencing a clinical evaluation or investigation. The role of the expert panel will be to review the manufacturer's intended clinical development strategy and proposals for clinical investigations. The opinions expressed by the expert panel will form part of the clinical evaluation report to be submitted as part of the technical document.

Moreover, manufacturers of implantable devices and devices falling within Class III may also in certain cases rely on clinical data of an equivalent device, namely if:

- The device has been designated as a modification to a device that has already been marketed by the same manufacturer;
- The modified device has been demonstrated by the manufacturer to be equivalent and accepted by the notified body as equivalent to the marketed device; and
- The clinical evaluation of the marketed device is sufficient to demonstrate conformity with the relevant safety and performance requirements of the modified device;

In these circumstances, the notified body will need to determine whether the PMCF-plan is appropriate and whether it includes the necessary post-market studies to demonstrate the device's safety and performance.

For a different manufacturer to be able to rely on the clinical data of an equivalent device, the manufacturer has to in addition to the above, (i) have access to the technical documentation of the other manufacturer on an ongoing basis through a written agreement; and (ii) the original evaluation has been performed in compliance with the requirements of the MDR and the manufacturer of the second device provides clear evidence thereof to the notified body<sup>xvi</sup>.

In light of these new clinical investigations requirements, which are briefly summarised in this section, MD manufacturers are advised to already start analysing these new rules in detail in comparison with their existing clinical investigation plans to determine the true impact hereof.



### 3.3 Performance evaluation of IVDs

In principle clinical performance studies will be required in order to market an IVD under the IVDR on the European market. IVD manufacturers will be hence required to produce significantly more clinical evidence.

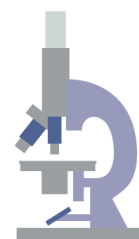
The concept of clinical evidence as provided within the IVDR expressly refers to the clinical benefit of IVDs, which is intended to provide accurate medical information on patients, appropriately assessed against other diagnostic options and technologies.

Notably, these clinical performance studies now also include the demonstration of scientific validity, next to the traditional analytical performance and clinical performance, introducing for the first time a sort of responsibility on the manufacturer towards the clinical utility of their IVDs. If devices have no analytical or clinical performance or if no specific performance requirements are applicable, the manufacturers will have to justify this absence in their performance evaluation plan and related reports. The data on clinical evidence stored within the performance evaluation report shall be updated throughout the life cycle of the devices with data obtained from the mandatory PMCF-plan.

Generally, the IVDR largely overlaps with the clinical studies regime in the MDR proposal. IVD manufacturers are also advised to already start studying the new rules and compare these with their existing performance evaluation plans to determine the next steps to be taken.

#### Key take away points

- Manufacturers are to check the new clinical requirements of the new legal framework vis à vis their current clinical evaluation (including PMCF methods outcome) and investigation plans and assess whether their current internal procedures on clinical evaluation and investigations are to be reviewed– as well as verify whether additional data will be required in order to be able to (continue to) market their products.
- The generation of such additional clinical evidence would need to be assessed in a timely manner and carefully planned with whichever notified bodies are to carry out the conformity assessments.



# 4. Participants in the Supply Chain

*Another important change introduced by the MD and IVD reform is the alignment of the requirements of the economic actors of the supply chain with the New Legislative Framework requirements listed in Decision 768/2008/EC.<sup>xvii</sup>*

Within the MDR and the IVDR each participant in the supply chain, including the distributor and importer, will have its own regulatory responsibilities. These major changes to the current system are set to impact the current distribution and other supply chain agreements of the various economic actors of the supply chain

The definitions of the economic operators reinforce the regulatory responsibility of the different economic players of the supply chain<sup>xviii</sup>:

- **Manufacturer:** produces or fully refurbishes a device, or has a device designed, manufactured or fully refurbished<sup>xix</sup>, and markets that device under his name or trademark.
- **Authorised representative:** received and accepted a written mandate from a manufacturer which is located outside the EU, to act on his behalf in relation to specific tasks of the Regulations.
- **Importer:** received and accepted a written mandate from a manufacturer located outside the EU.
- **Distributor:** makes a device available on the European market, up until the point of putting it into service, i.e. the stage at which a device has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose, and which is not the manufacturer or the importer.

Notably, the manufacturers' new obligations include:

- appointing a qualified person responsible for regulatory compliance<sup>xx</sup>;
- being responsible for conducting clinical evaluations, including PMCF's, respective performance evaluations for IVDs, which confirm the general safety and performance requirements applicable to the devices;
- setting up a risk management system covering the entire lifecycle of the devices and which is aligned to the clinical evaluation, respective performance evaluation of the respective devices;
- setting up quality management systems, organising the quality of processes and procedures applicable to the device;
- setting up a system reporting incidents and field safety corrective actions;
- complying with the unique device identifier system ("**UDI-System**"); and
- obtaining mandatory insurance to cover insolvency and any other claims for damages, proportionate to the risk class, type of devices and the size of the enterprise.



In a nutshell, by providing explicit provisions on manufacturers' responsibilities relating to the follow-up of the quality, performance and safety of devices placed on the market, manufacturers are to improve their devices continuously on the basis of actual data and act swiftly when concerns arise. The traceability of devices throughout the supply chain to the end-user or patient will also be improved via the UDI-system<sup>xxi</sup> (see chapter on traceability). The Regulations also require manufacturers to have sufficient financial coverage for potential liability under the European Product Liability Directive 85/374/EC<sup>xxii</sup> ("PLD").

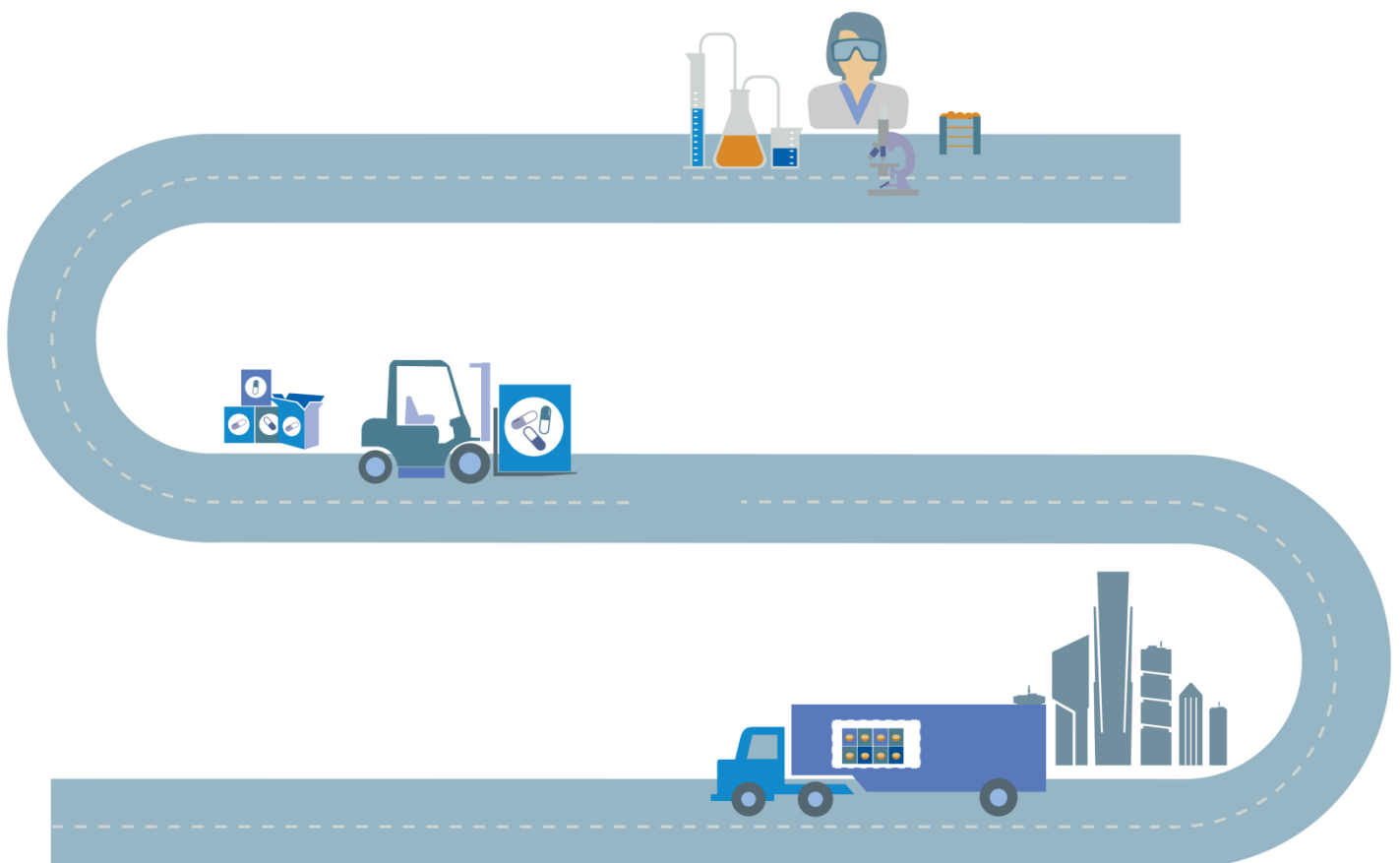
The new responsibilities of importers and distributors include specific verification, compliance, reporting storage and complaint duties. Importers will also be responsible for labelling and registration of the devices. Most importantly, however, the Regulations place the responsibility on importers and distributors to verify the compliance of their immediate upstream economic actor with the MDR or IVDR. Where the importer or distributor considers there is a risk of non-compliance, they must inform the upstream actors in the supply chain and the Competent Authority of the Member State where they are established<sup>xxiii</sup>.

The Regulations also introduce express liability of the authorised representative.<sup>xxiv</sup> The authorised representative shall be legally liable for defective

devices on the same basis, i.e. jointly and severally with the importer and manufacturer. The liability of the authorised representative is without prejudice to the provisions of the PLD. Considering the responsibilities of authorised representatives, it is generally advised that they have a person available which has similar tasks to the person responsible for regulatory compliance for the manufacturer. Authorised representatives are in this regard likely to scrutinise non-EU based manufacturers more carefully before working with manufacturers and will most probably seek additional insurance policies to cover these additional risks.

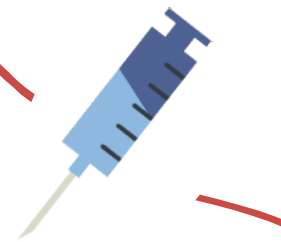
## Key take away points

- All participants in the supply chain should be aware of their respective role and responsibilities under the new rules and are to verify their respective distribution, supply chain and other agreements accordingly and amend where needed.
- While manufacturers are obliged to have sufficient financial coverage for potential liability under the PLD, the other economic actors are also advised to also take additional insurance policies as to cover their respective risks.





# 5. Single Use Device and reprocessing



*The reprocessing and re-use of medical single-use devices ("SUD")<sup>xxv</sup>, i.e. devices that are intended to be used on an individual during a single procedure, has been a controversial issue in the field of MD law for years. While not creating a strictly unified legal framework, the MDR aims at a partial harmonisation in this field. The IVDR does not contain any provision on the reprocessing of SUDs.*

The MDR allows reprocessing in accordance with the Regulation if permitted by national law, thus creating a so-called “Opt-In”-option for the Member States. Further, they can deviate from the Regulation’s manufacturing provisions if they ensure certain standards. The MDR distinguishes between reprocessing within a health institution and with an external provider. For both types, the Member States can create different rules. Since there are also rules regarding the original manufacturing of the devices, this could mean that within a Member State, SUDs according to three different standards could be marketed. Thus, the European legal framework remains fragmented in this regard.

Problems could arise with regards to manufacturer liability. The MDR regards the reprocessor as the manufacturer of a device and refers explicitly to the European Product Liability Directive 85/374/EC<sup>xxvi</sup> (“PLD”), which stipulates strict manufacturer’s liability.

As the reprocessing of single-use products may be categorised as a manufacturing process according to the PLD, reprocessors could in the future also be liable without own negligence or own fault, even if the fault lies with the original manufacturer. On the flipside, although not explicitly addressed by the Regulation, the original manufacturer could be held strictly liable for damages caused by the reprocessed product in addition to the reprocessor. Hence, reprocessing of SUD's according to the MDR could significantly increase the liability exposure of original manufacturers. According to

the PLD, multiple parties can be considered a manufacturer and all can be held liable for the same product defect. While the reprocessor would be considered the producer of the final product, the original manufacturer provides the basic material and could thus also be considered a manufacturer of the reprocessed product in accordance with the PLD. The original manufacturer could only avoid liability by proving that the original product was not defective before reprocessing which may turn out difficult in practice.

In light of this increased liability, original manufacturers could attempt to counter the spread of reprocessing by enforcing their intellectual property rights (“IPR”) against the reprocessed original product. The MDR gives Member States the power to restrict reprocessing and the transfer and making available of reprocessed devices<sup>xxvii</sup>. The existing national IP framework could be regarded as such a restriction. The reprocessing of a SUD could be classified as manufacturing a new product and thus be considered an infringement, according to German patent law for example if the original product is covered by patent rights of the original manufacturer.

The MDR, through its “opt-in”-Option, offers modest incremental harmonisation in the field of reprocessed SUDs, while posing liability and IPR enforcement questions.

## Key take away points

- Will Member States permit reprocessing of SUDs and – if so –how will they shape their national laws?
- Can reprocessing be prevented through the original manufacturer’s IPRs?
- What impact will the reprocessor’s product liability have on the reprocessing business?
- How will original manufacturers react to increased liability risks caused by reprocessing?

# 6. Hazardous Substances

*Medical devices and in vitro medical devices may be made of, or contain, many different substances, ingredients or components, including chemicals of which some can be hazardous or otherwise subject to particular restrictions.*

Several legislative frameworks are in place at EU level that regulate the commercialisation and use of hazardous substances, including REACH<sup>xxviii</sup> and RoHS<sup>xxix</sup>. Both the MDR and the IVDR provide for certain specific requirements in respect of hazardous substances.

## 6.1 Obligations under other Community legislation

### 6.1.1 REACH

REACH is a Regulation that sets out harmonised rules relating to the commercialisation of chemicals on the EU market, be it as substances or mixtures, or in what qualifies as 'articles' under the Regulation.

Obligations under REACH relevant for the medical devices sector include registration requirements and the provision of information in the form of safety data sheets ("**SDS**").



The REACH Regulation also subjects the use of certain substances to an authorisation regime, but a particular rule applies to certain substances when they are used in medical devices (see below).

### 6.1.2 Registration of substances or mixtures and registration or notification of substances in articles

#### 6.1.2.1 Substances and mixtures

The Regulation requires that any substance, either on its own or in one or more mixtures, that is manufactured or imported in quantities of one tonne or more per year must be registered.

Registration implies the submission of a dossier that contains data relating to a.o., substance identity, toxicity and environmental impact. The dossier requirements vary in function of the volume in which the substance is manufactured or imported, with tonnage bands being respectively 1 to 100 tonnes, 100 to 1000 tonnes or more than 1000 tonnes. For example, as from a threshold of 10 tonnes a year, a chemical safety report needs to be submitted as part of the registration dossier.

#### 6.1.2.2 Substances in articles

The registration requirement applies to substances contained in articles, provided three cumulative conditions are met: (i) the use of the substance in the article has not been registered already, (ii) the substance is present in the articles in quantities totalling over one tonne per producer or importer per year and (iii) the substance is intended to be released under normal or reasonably foreseeable conditions of use.

Further to this, a notification requirement applies for substances of very high concern ("**SVHCs**") present in articles above a concentration of 0.1 % weight by weight (w/w), placed on the market in quantities totalling over one tonne per producer or importer per year. Suppliers of articles containing a SVHC in a concentration above 0.1% w/w must provide the recipient of the article with sufficient information to allow safe use of the article including, as a minimum, the name of that substance. The same rule applies to articles supplied to consumers.

Until the CJEU rendered a decision on a request for preliminary ruling in September 2015<sup>xxx</sup>, the text of the REACH Regulation was subject to diverging interpretations on the issue of whether the concentration threshold needed to be calculated by taking into consideration the whole article, or whether it also needed to include "sub-articles" forming that article. The Court essentially held that the producers are to determine whether a SVHC is present in a concentration above 0.1% w/w of any article they produce, and that importers of a product made up of more than one article are to determine for each component article whether such a substance is present in a concentration above 0.1% w/w of that article. In respect of the information obligation applicable to suppliers under Article 33 of the REACH Regulation, the Court held that this information applies when suppliers supply a product, one or more constituent articles of which contain(s) a SVHC in a concentration above 0.1% w/w of that article. The difference between producers and importers is that it is not necessary to require the producer to report candidate substances in the component articles used, because ECHA obtains that information without there being any need to call on the producer of the entire article. If the products are manufactured in the EU or imported into the EU, the duty to provide information applies to the producer or the importer of the component article.

### 6.1.2.3 Substances subject to authorisation

In cases where a substance is subject to authorisation under REACH, that substance is listed in Annex XIV. The use of such substance must thus be authorised before the product in which the substance is used, or the substance itself, can be (further) commercialised. However, an application for authorisation is not required for a substance used in a medical device or an in vitro medical device if that substance has been identified in Annex XIV for human health concerns only.

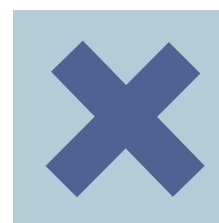
An application for authorisation is not required either for the incorporation of the substance into the medical device during the manufacturing process or for the uses and corresponding volumes of that substance upstream preceding the end-use.

### 6.1.3 Safety Data Sheet requirements

For all substances and articles, a safety data sheet has to be provided in the following cases:

- a where a substance or mixture meets the criteria for classification as hazardous in accordance with the CLP Regulation<sup>xxxi</sup>;
- b where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of the REACH Regulation;
- c where a substance is included in the candidate list established in accordance with Article 59(1) of the REACH Regulation for reasons other than the substance being hazardous, PBT or vPvB.

An exemption<sup>xxii</sup> applies to medical devices which are invasive or used in direct physical contact with the human body. For these products, no safety data sheet has to be provided by the supplier, insofar other community legislation (such as the legislation on medical devices) ensures the same level of information provision and protection as Directive 1999/45/EC.



## 6.2 RoHS Directive

The RoHS Directive bans the placing on the EU market of electrical and electronic equipment (EEE) that contains more than the permitted level of 6 hazardous substances: lead, mercury, cadmium, hexavalent chromium, PBBs and PBDEs. This rule applies to medical devices that qualify as EEE since 22 July 2014 and to IVDs that qualify as EEE since 22 July 2016. The RoHS Directive does not apply to active implantable medical devices.

The RoHS Directive also includes rules that aim at restricting the use of phthalates (butyl benzyl phthalate, dibutyl phthalate and diisobutyl phthalate) as of 2019. These additional restrictions will not apply to medical devices before 2021. From that date, it will be prohibited to place on the market medical devices and IVDs that contain these phthalates. Under the new MDR, specific guidance is due to be issued by the Commission in respect of the use of phthalates in medical devices (see below).

Specific exemptions apply in respect of certain applications, such as the use of heavy metals such as lead, cadmium and mercury in equipment utilising or detecting ionising radiation, or in sensors, detectors and electrodes.

## 6.3 Obligations under the MDR and IVDR

Both medical devices and in vitro medical devices are subject to similar design and construction requirements – they are required to be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances that may leach or leak from the device.

Following on calls from the healthcare sector to phase out dangerous chemicals in healthcare, the MDR provides for certain restrictions in respect of the use of chemical substances in certain medical devices, in particular medical devices (i) that are invasive and come into direct contact with the human body, or (ii) that (re)administer medicines, body liquids or other substances, including gases, to/from the body or (iii) that transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body.





If medical devices contain substances that are classified as carcinogenic, mutagenic or toxic (CMR substances) or as endocrine disruptors, these substances may not be present in a concentration above 0.1% weight by weight (w/w) and their presence must be justified on the basis of analyses of patient exposure and possible alternative substances. The label of such devices must also identify the substances concerned. The MDR requires the Commission to issue guidance in respect of the use of phthalates in medical devices. Further guidance will be issued at a later stage in respect of other CMR substances and endocrine disruptors.

Obligations under the IVDR further include certain requirements in terms of information to be supplied with the device. In particular, in case of devices containing a substance or a mixture which may be considered as being dangerous hazard pictograms and labelling requirements as defined under the CLP Regulation must be provided. Where there is insufficient space to put all the information on the device itself or on its label, the relevant hazard pictograms must be put on the label and the other

information required by the CLP Regulation must be given in the instructions for use. Also the provisions on the Safety Data Sheet as provided for under REACH apply to IVDs, but no safety data sheet needs to be provided in case all relevant information as appropriate is already made available by the instructions for use.

## Key take away points

- The MDR and IVDR do not bring significant change in respect of the rules surrounding the use of hazardous or potentially hazardous substances in medical devices or in vitro diagnostics;
- The main obligations are duties to inform the users appropriately in cases where exposure to hazardous substances is likely;
- Specific guidance is to be issued by the Commission on the use of certain hazardous substances such as phthalates.



# 7. Notified Bodies

*Under the previous framework, notified bodies were established and regulated in accordance with the AMDD and MDD. While these Directives were amended over the years, the discipline applicable to notified bodies was not substantially modified.*

It is however crucial that notified bodies designation criteria and assessment standards are harmonised throughout EU so to ensure an equally high level of health and safety protection and avoid at the same time distortions on competition. Irrespective of their place of establishment, manufacturers can revert to any notified body within the EU for certification. Once the respective MDs or IVDs have been certified by the selected notified body following the appropriate conformity assessment, which may vary in terms of complexity in accordance to the features of the concerned product and which result in the devices being CE-marked, they can be sold anywhere in the EU.

More recently, rules on notified bodies were integrated by the Commission Implementing Regulation (EU) No 920/2013, which introduced more stringent rules on designation and supervision of notified bodies with the aim of increasing transparency, control and monitoring of notified bodies by the designating authorities. The introduction of these new rules followed from the well-known PIP scandal and metal-on-metal hip replacements problems occurring in the MD sector and anticipated the overall recast of the MD legislation.

Both Regulation (EU) No 920/2013 and the recast of the MD and IVD considered that since EU Member States interpreted and implemented the existing rules on notified bodies in different ways, it was necessary to introduce procedural obligations for Member States to constantly share information on their general practices and on *ad hoc* questions. More specifically, it was noted that on one side, the technical progress had increased and that therefore there was an increased risk that notified bodies did not possess the necessary competence with regard to new technologies or devices emerging within their scope of designation, and that on the other

side, the existing differences amongst assessment methods of notified bodies established throughout the EU was likely to increase due to the increased complexity of conformity assessments. This was likely to cause further discrepancies on the assessment of new technologies and devices.

The recast of the MD legislation contains, therefore, new provisions aimed at ensuring both a better supervision of notified bodies by national authorities and more competences for notified bodies, including powers to perform testing and regular checks on manufacturers, also through unannounced factory inspections. The wording of both the MDR and IVDR is virtually identical. They detail the role of all the players, including the Commission, the MDCG, the notified bodies and the manufacturers and their representatives.

These new provisions include the following measures:

## *Designation procedure:*

Both the MDR and IVDR leave the ultimate responsibility for designating and monitoring notified bodies with the individual Member State where the relevant notified body is established. Nonetheless, they both introduce stricter and detailed criteria which are laid down respectively in Annex VI and X of the MDR and IVDR. In particular, it is provided that (i) notified bodies should have permanently at their disposal, and directly employed by them, sufficient administrative, technical and scientific personnel, (ii) that any new designation of notified bodies should be subject to “joint assessments” with experts from the Commission and MDCG (which is an expert committee composed of persons designated by the Member States based on their role and expertise in the field of MD and IVDs and is being set up by the Regulations) as to ensure an effective control at EU level, and (iii) that monitoring of notified body should include an yearly reassessment of the compliance of the notified body with the requirements and obligations set out respectively in Annex VI and X of the MDR and IVDR, including an on-site visit to audit the relevant notified body and, when necessary, its subsidiaries and subcontractors.



### *More powers for notified bodies:*

The MDR and IVDR strengthen the powers of notified bodies towards manufacturers in relation to conformity assessments and post marketing surveillance. New rules include the right and duty of notified bodies to carry out unannounced on-site audits and to conduct physical or laboratory tests on the devices. It is also provided - in order to ensure full impartiality of the organisation and operation of the notified bodies- that notified bodies' personnel involved in the assessment of MDs rotate at appropriate intervals. Hereby decisions by notified bodies would not be influenced by non-legitimate circumstances.

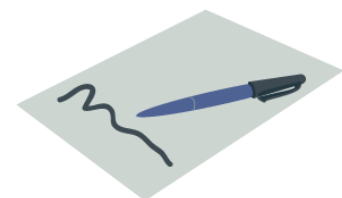


### *Scrutiny procedure:*

The MDR and IVDR also introduce a mechanism for 'scrutiny' conformity assessments performed by notified bodies. This procedure only applies for certain high-risk devices (i.e. class III and class IIb devices, such as implantable devices classified as class III and for Class IIb active devices intended to administer and/or remove a medicinal product, and Class D IVDs). The procedure essentially foresees that (a) notified bodies notify an expert panel of new applications for the above mentioned high-risk devices; (b) that the competent authority and, where applicable, the Commission may, based on reasonable concerns apply further procedures; (c) that the MDCG and, where applicable, the Commission, may, based on reasonable concerns, request the above mentioned expert panel to provide a scientific advice in case where this is not available yet.



The aim of these additional procedures is essentially: (i) to review the notified body assessment of technical documentation and clinical evaluation and, when deemed necessary, (ii) to enable competent authorities to take appropriate measures such as to prohibit or restrict the making available of the device on the market, or to subject the making available of the device to specific requirements, or to withdraw the device from the market, or to recall it within a reasonable period.



## Key take away points

### *Will notified bodies be able to meet the new stringent requirements?*

- It is still uncertain if and to what extent existing notified bodies will be able to meet new stringent requirements, both vis-a-vis to designating authorities and vis-a-vis to manufacturers.
- In case not all existing notified bodies will be able to cope with these new rules and eventually decide to cease their activities, also the CE certificates of conformity granted by these notified bodies will eventually cease to be valid.
- Relevant manufacturers may be therefore required to apply for new certificates before other EU notified bodies.
- It is advisable therefore for manufacturers to ascertain whether relevant notified bodies are actually due to continue their activities once the new rules will become effective and to act accordingly.

### *How will this increased scrutiny on notified bodies impact manufacturers?*

- It is still uncertain how new obligations imposed on notified bodies and their new powers will actually impact manufacturers.
- It may be expected that the obligation to conduct a more thorough assessment by notified bodies will require additional efforts by manufacturers, either more economically than technically, when applying for CE certificate of conformity (see for example request for additional information and data).
- It may also be expected that the additional powers assigned to notified bodies, which include also testing and unannounced inspections powers, will require a more structured approach by manufacturers so to enabling them to monitoring their supply chain, which might also be subject to inspection.
- Relationship between manufactures and the players of their supply chain shall therefore be regulated by adequate written agreements (also insofar right to conduct inspections are concerned).

### *What will be the impact of recent CJEU case-law increasing the responsibility of notified bodies?*

- Recent case law shows a possible increase in responsibility of notified bodies.
- According to the AG Sharpston opinion of 15 September 2016 in case C-219/15, notified bodies can in principle be liable towards patients when they negligently violate their obligations.
- AG Sharpston – whose opinion has not yet been endorsed by the European Court of Justice ("CJEU") - notes that "*although the MDD imposes primary liability for the product's compliance on the manufacturer, it does not prevent this liability from being extended to other actors, including Notified Bodies.*" She bases her argument on previous case-law of the CJEU, in which the Court had already recognised that national legislation may impose liability on importers for specific obligations arising from EU product safety rules. She observes that, given the crucial role played by Notified Bodies in the procedure of placing MDs on the market; those bodies should be capable of bearing liability under national law to patients and users for a culpable failure to fulfil their obligations, provided that the principles of equivalence and effectiveness are respected. For more details, please see our previous Bird & Bird article on the topic, available [here](#).
- If this opinion is eventually confirmed by the CJEU, this may increase the liability of notified bodies towards patients, and may also lead to more stringent scrutiny in occasion of the assessment of MD and IVDS.

### *What will be the impact of Brexit?*

- Brexit also may lead to a similar outcome as the one described above for all MDs certified by UK notified bodies.
- There are currently five notified bodies in the UK which are authorised to conduct conformity assessment procedures in relation to MDs and IVDS.
- If the UK leaves the EU, CE Certificates of Conformity granted by these notified bodies to MDs manufacturers marketing products in the EU may also cease to be valid and relevant manufacturer may be required to apply for new certificates before other EU notified bodies.
- Also in this case it is therefore advisable for manufacturers to ascertain in due time how to deal with such a possibly.

# 8. Traceability and Transparency

*The new Regulations introduce a mandatory UDI-system<sup>xxxiii</sup> for MD and IVDs. This is new for the EU. Under the umbrella of the International Medical Device Regulators Forum similar systems are being developed, and already implemented in other jurisdictions, such as in the United States.*

The UDI system will allow for improved identification, and will facilitate the traceability of individual devices<sup>xxxiv</sup>. In that context, it will also be used for reporting serious incidents and field safety corrective actions.

The UDI system consists of three basic elements:

- The UDI
- UDI Carrier
- The UDI database

A UDI is unique series of numeric or alphanumeric characters, and consists of two parts:

- a. a device identifier ("**UDI-DI**"), which is a mandatory, fixed portion of a UDI specific to a manufacturer and a device. The UDI-DI shall be unique at all levels of device packaging.
- b. a production identifier ("**UDI-PI**"), which is a conditional, variable portion of a UDI, and may include the device's serial number, its lot/batch number, software identification and/or its manufacturing/expiration date.

The UDI shall be affixed to the label of the device and to all higher levels of its packaging (excluding shipping containers). Only the device manufacturer is entitled to do this. The UDI is affixed in the form of a so-called 'UDI Carrier', which enables conveying the UDI through automatic identification and data capture<sup>xxxv</sup> and, if applicable, through human readable interpretation.

Before placing a device on the market, the manufacturer shall include the Basic UDI-DI (not the UDI-PI) and certain core data elements<sup>xxxvi</sup> into an electronic 'UDI Database'. This database shall be

accessible to the public, and is key to ensuring appropriate traceability of devices, also in the distribution chain. Currently the infrastructure and capability is not yet in place to support the UDI-system.<sup>xxxvii</sup>

Transparency, and also surveillance by European authorities, will be further enhanced by EUDAMED, in which information regarding devices, the relevant economic operators, certain aspects of conformity assessment, notified bodies, certificates, clinical investigations<sup>xxxviii</sup>, vigilance and market surveillance shall be collated and processed. The objectives of EUDAMED are to streamline and facilitate the flow of information between economic operators, notified bodies or Sponsors and Member States as well as between Member States themselves and with the Commission, to avoid multiple reporting requirements and to enhance the coordination between Member States. The UDI database will integrate with EUDAMED. The actual functionality of EUDAMED will depend on the publication of a notice by the Commission following an independent audit report that the system has achieved full functionality and meets the functional specifications which will be drawn up by the Commission in collaboration with the MDCG at the latest one year following the entry into force of the Regulations.



Other measures enhancing transparency are also provided, such as the provision of an implant card to patients with an implantable medical device, allowing for the identification of the device (*e.g.* batch number, name manufacturer, warnings).

According to the MDR and IVDR, "commercially confidential information" (CCI) and "trade secrets" shall be protected, including IPRs, unless disclosure is in the public interest. Here, one needs to consider the interplay between on the one hand the MDR and IVDR, and on the other the EU Trade Secrets Directive (2016/943) and the relevant intellectual property legislation.

## 8.1. Post-market Surveillance and Vigilance

The MDR and IVDR clearly lay down that for every device, proportionate to the risk class and type of device, manufacturers need to have a post-market surveillance (PMS) system in place<sup>xxxix</sup>. This system shall be an integral part of the manufacturer's quality management system. It shall be suitable to actively and systematically collect, record and analyse data about the quality, performance and safety of a device throughout its lifetime, in order to draw conclusions and, if needed, to implement and monitor any preventive and corrective actions.

The scope of the definition of 'incident' has broadened. Incidents now entail:

- any malfunction or deterioration in that characteristics or performance of a device made available on the market;
- any inadequacy in the information supplied by the manufacturer;
- *under the MDR*: any undesirable side-effect;
- *Under the IVDR*: any harm as a consequence of the medical decision, action taken or not taken on the basis of information or result(s) provided by the device.

It will be considered a *serious* incident when such incident directly or indirectly leads, might have led, or might lead to:

- death of a person,
- a serious deterioration in a person's state of health, or
- a serious public health threat.

The MDR and IVDR now capture formally the obligation for the manufacturer to immediately report serious incidents to the competent authorities, and no later than within a term specified in the MDR/IVDR taking account of the severity of the serious incident. A corresponding obligation is formulated for field safety corrective actions. However, the manufacture shall report to the competent authorities prior to taking the corrective actions, unless urgency requires the manufacturer to take the action without any delay. As personal data are involved here, compliance with data protection rules should not be overlooked: the fines are high and will even become higher when the General Data Protection Regulation (2016/679) will enter into force<sup>xl</sup>.



Serious incidents or field safety corrective actions that have been or are to be undertaken within their territory will, at national level, be evaluated by the competent authority involved, if possible together with the manufacturer and, where relevant, with the notified body concerned<sup>xli</sup>.

Furthermore, if the device presents an 'unacceptable risk' to the health or safety of persons, competent authorities shall require the manufacturer without delay to take all appropriate corrective actions to bring the product in compliance, withdraw, and/or recall the device from the market – proportionate to the nature of the risk or non-compliance<sup>xlii</sup>. It is noted that the MDR and IVDR define a risk as a combination of the probability of occurrence of harm and the severity of that harm<sup>xliii</sup>. The term 'unacceptable risk' has not been defined as such<sup>xliiv</sup>, but the adjective 'unacceptable' seems to refer to the combination of the probability of occurrence of harm and the severity of that harm.

If the device is non-compliant, but does not present an unacceptable risk to the health or safety of persons, competent authorities shall require the economic operator to put an end to the non-compliance within a proportional timeframe, communicated to the economic operator<sup>xliv</sup>. In case non-compliance is not ended within this timeframe, the Member State concerned shall take all appropriate measures to restrict or prohibit the device being made available on the market or to ensure that it is being recalled or withdrawn from the market.

Furthermore, under the new Regulations manufacturers should:

- prepare PSURs annually, per device, summarising the results and conclusion of the post market-surveillance data. The PSUR also sets out the volume of sales and user population estimate;
- report trends, *i.e.* statistically significant increases in the frequency or severity of (non-serious) incidents<sup>xlvi</sup>.

## Key take away points

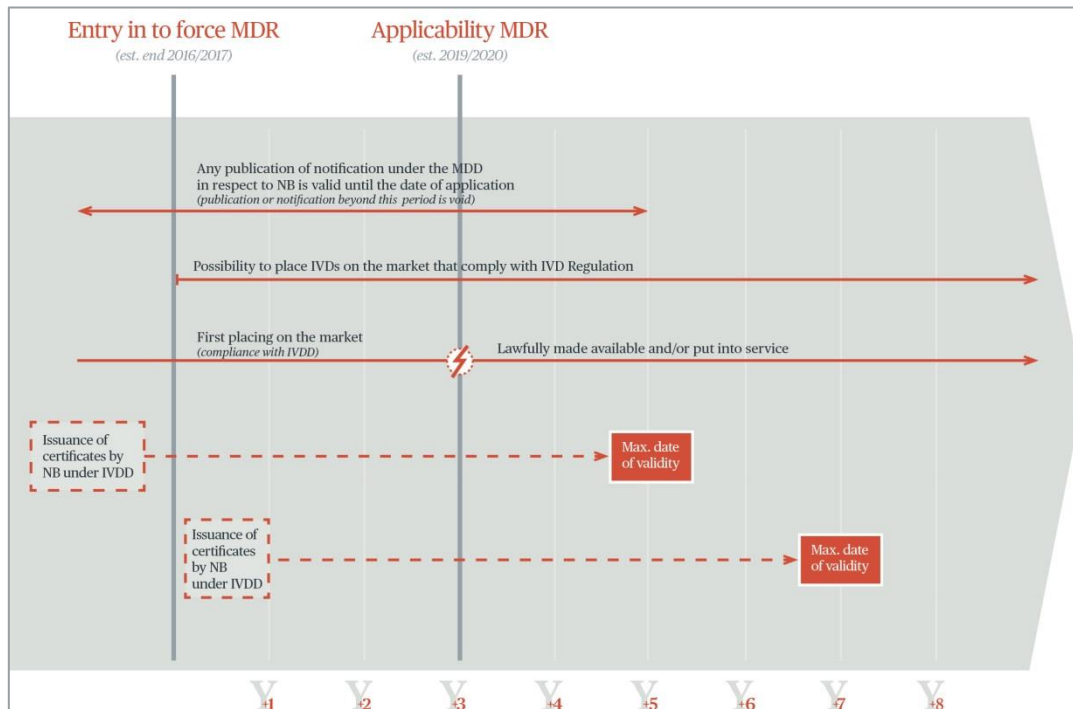
- The new transparency provisions raise the following questions:
- Will manufacturers be prevented from bringing new and innovative products to market as their data would be easily accessible by competitors?
- Will more Medtech companies go down the pharma-route and increase patent filings
- Would there be a need for SPCs for MDs?
- How will the roll-out of EUDAMED including the UDI-database influence manufacturer's implementation planning?



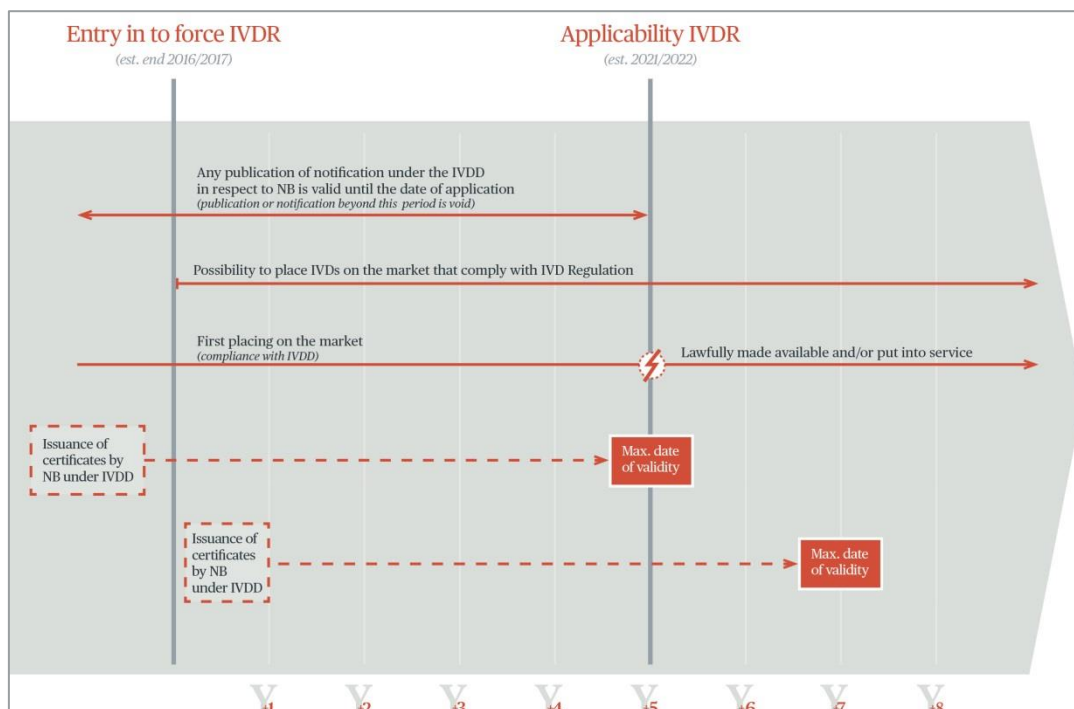
# 9. Transition Regime

The transition regime of both the MDR and IVDR may be summarised as follows:

## MDR:



## IVDR:



Nonetheless, the transition regime of the MDR and IVDR is complex on itself raises many questions as to the feasibility hereof, notably as to whether the national competent authorities will be ready in time to pass on the necessary accreditations to notified bodies, whether the notified bodies will be ready in time to ensure a smooth transitioning, whether the infrastructure of EUDAMED will be ready in time and what will be the implications of late implementation hereof towards manufacturers etc.



# 10. Brexit Implications

*On 23 June 2016, the UK public voted to leave the EU. Under Article 50 of the Lisbon Treaty, the EU Treaties shall cease to apply to the UK:*

- from the date of entry into force of the withdrawal agreement that the UK negotiates with the Union, acting through the Council; or
- two years after the UK has notified the European Council of its intention to withdraw, unless the European Council, in agreement with the UK, unanimously decides to extend this period. The UK Government has indicated that Article 50 will be invoked no later than March 2017.

Therefore, in practice the British exit ("Brexit") date is most unlikely be before March 2019.

## What is the immediate effect of the Brexit vote?

As the UK will remain within the EU for at least the next two years, in the short term the answer is that it should be "business as usual" for the medical devices sector in the UK. Furthermore, for now at least, the UK is a full voting member of the European Committee for Standardisation (CEN), which is unlikely to change, no matter what the UK's new relationship with the EU looks like.

The decision as to which model will be adopted by the UK and the EU post-Brexit will determine how the medical devices sector is truly affected.

Initially, it seemed likely that the UK would remain within the European Economic Area (EEA), and the effects would likely to have been minimal on the sector, as the UK would keep access to many of the benefits of the EU system. Similarly, if the UK joins the European Free Trade Association (EFTA) and negotiates sector specific access to the single market, then, depending on the exact nature of the relationship, effects may again be limited and there would be little or no impact on UK's regulatory approval of medical devices. If, however, the UK chooses to move further away from the EU (as seems most likely given recent pronouncements) and decides to leave the CEN, or cannot agree the terms of a continued close association with the EU, then the effects may be more severe. The most likely scenario is that it would establish a UK-based regulatory system that unilaterally recognises CE Mark certification as evidence on which to grant approval.

Furthermore, there are currently five notified bodies in the UK which are authorised to conduct conformity assessment procedures in relation to MDs and IVDs. If the UK leaves the EU, CE Certificates of Conformity granted by these notified bodies to MDs manufacturers marketing products in the EU may also cease to be valid and relevant manufacturer may be required to apply for new certificates before other EU notified bodies. Also in this case it is therefore advisable for manufacturers to ascertain in due time how to deal with such a possibly. See further the Brexit related paragraphs in (7) above.



# References

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- <sup>i</sup> The French regulatory authorities found that PIP had used industrial grade silicone instead of medical grade silicone to manufacture breast implants, contrary to the product specifications and the approval granted by the Notified Body TÜV Rheinland (TÜV) harming thousands of women around the world.
- <sup>ii</sup> Commission Implementing Regulation (EU) No 920/2013.
- <sup>iii</sup> Commission (EC) Proposal for a Regulation of the European Parliament and of the Council on Medical Devices and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, COM (2012) 542 final, 26 September 2012.
- <sup>iv</sup> Commission (EC) Proposal for a Regulation of the European Parliament and of the Council on in Vitro Diagnostic Medical Devices COM (2012) 541 final, 26 September 2012.
- <sup>v</sup> Directives must be implemented within national legislation, creating divergence in interpretation and implementation. Regulations are directly applicable and better apt to increase harmonisation.
- <sup>vi</sup> Consolidated compromise text of 15 June 2016 on the Proposal for a Regulation of the European Parliament and of the Council on medical devices and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (COM (2012)0542 – 2012/0266 (COD)); Consolidated compromise text of 15 June 2016 on the Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices (COM (2012)0541 – 2012/0267 (COD)).
- <sup>vii</sup> Article 2(2) MDR.
- <sup>viii</sup> Article 2(1) MDR and recital 10 of the MDR.
- <sup>ix</sup> Article 1a MDR. The devices are listed in Annex XV MDR, common specifications on risk management, general safety and performance requirements, and clinical investigations, will be adopted on a later stage by the Commission. The MDR will be applicable to such products from the date of adoption of these common specifications.
- <sup>x</sup> The qualification of standalone software as MDs is not always clear, as shown by ongoing case-law of the European Court of Justice, C-329/16 where the question was raised whether medical software that provides support to healthcare professionals in prescribing medicinal products should be considered a medical device under MDD ([Case C-329/16](#)).
- <sup>xi</sup> While during the negotiations, the EU Parliament proposal put a particular emphasis on genetic testing and its mode of provision, the final IVDR proposal distanced itself from this detailed regulated approach, focusing primarily on pre-market assessment and post-market surveillance and introducing a continuous process of performance evaluation that should demonstrate the scientific validity and the analytical and clinical performance. The recitals state in this regard that the divergent national rules regarding the provision of information and counseling in relation to genetic testing "*may only have a limited impact on the smooth functioning of the internal market to a limited extent*". EU regulators opted to lay down only limited requirements on this topic having regard to the need to ensure the principles of proportionality and subsidiarity.
- <sup>xii</sup> The new definition of a 'companion diagnostic' partially mirroring the FDA's definition for companion diagnostics. Contrary to the FDA definition the EU definition, excludes devices which monitor responses to treatment for the purpose of adjusting treatment. The final version did hereby not fully respond to calls for harmonisation between the US and EU regulatory approaches for these type of devices. See In Vitro Companion Diagnostic Devices, Guidance for industry and Food and Drug Administration Staff, issued on August 6, 2014 available at <http://www.fda.gov/downloads/medicaldevices/deviceRegulationandguidance/guidancedocuments/ucm262327.pdf>.
- <sup>xiii</sup> Hereby the proposal essentially implemented the PMCF MEDDEV.
- <sup>xiv</sup> Clinical data are (i) clinical investigations and peer reviewed clinical literature of either the device in question or similar devices and (iii) clinical data coming from the PMCF. These data are to be updated continuously throughout the lifetime of the device.
- <sup>xv</sup> This is subject to limited exceptions e.g. modifications to a device on the market by the same manufacturer.
- <sup>xvi</sup> Article 49 (2a) MDR.
- <sup>xvii</sup> See the definitions of the economic actors within the MDR, article 2(19-23) MDR.
- <sup>xviii</sup> See article 2 MDR or IVDR respectively.
- <sup>xix</sup> Fully refurbishing means the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices to bring it in conformity with the MDR. Fully refurbished products are assimilated with new products.
- <sup>xx</sup> Unless recognised as a micro or small enterprise as defined within the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises 2003/361/EC.
- <sup>xxi</sup> Article 24 MDR, respectively article XX MDR.
- <sup>xxii</sup> Council/European Parliament proposal 9364/3/16 REV 3 Art. 15 Sec. 1 Cl. 2.
- <sup>xxiii</sup> Article 11- 12 MDR; respectively article 11-12 IVDR.
- <sup>xxiv</sup> Manufacturers without a registered place of business in the EU will be required to have an EU based authorised representative (article 9(4a) MDR).

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- <sup>xxv</sup> Council/European Parliament proposal 9364/3/16 REV 3 Art. 2 No. 1 (8).
- <sup>xxvi</sup> Council/European Parliament proposal 9364/3/16 REV 3 Art. 15 Sec. 1 Cl. 2.
- <sup>xxvii</sup> Council/European Parliament proposal 9364/3/16 REV 3 Art. 15 Sec. 6.
- <sup>xxviii</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.
- <sup>xxix</sup> Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
- <sup>xxx</sup> EU Court of Justice, Case C-106/14, *FCD and FMB v Ministre de l'Écologie, du Développement durable et de l'Énergie*, 10 September 2015.
- <sup>xxxi</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
- <sup>xxxii</sup> Provided for by Article 2(6) of the REACH Regulation.
- <sup>xxxiii</sup> Although rules on the UDI are found throughout the MDR and the IVDR, the most relevant rules are found in Chapter III and Annex V of both the MDR and the IVDR.
- <sup>xxxiv</sup> Exempted from the UDI-system are: (a) under the MDR – 'custom-made devices' and 'investigational devices', (b) under the IVDR – 'devices for performance studies'.
- <sup>xxxv</sup> M2M technologies, which include the use of bar codes, smart cards, biometrics and RFID.
- <sup>xxxvi</sup> Listed in Annex V, Part B of both the MDR and the IVDR.
- <sup>xxxvii</sup> The timing for implementation hereof differs from the normal transition provisions. The system shall be applicable 3 years after the entry into force of the Regulations and at the latest 6 months following the publication of the Commission's notice on the functionality of EUDAMED. (see later)
- <sup>xxxviii</sup> Manufacturers have the obligation to publish the clinical investigation report and a summary into EUDAMED within a year after the trial, which will become public upon CE marking and immediately in case of halt or termination of the study. If the device is not CE marked within a year after entry into EUDAMED of the report and summary, then the report and summary become automatically publicly available in EUDAMED.
- <sup>xxxix</sup> Article 60a MDR, article 58a IVDR.
- <sup>xl</sup> This is likely to be in the first half of 2018.
- <sup>xli</sup> Article 63 MDR, article 61 IVDR.
- <sup>xlii</sup> Article 70 MDR.
- <sup>xliii</sup> Article 2 under 15d draft MDR.
- <sup>xliv</sup> Moreover, 'safe' is defined as the absence of unacceptable risks, when using the device according to the manufacturer's instructions for use.
- <sup>xlv</sup> Article 73 MDR, article 71 IVDR.
- <sup>xlvi</sup> Article 61a MDR.



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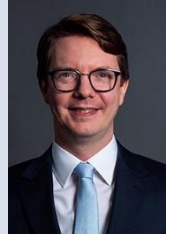
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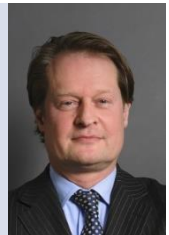
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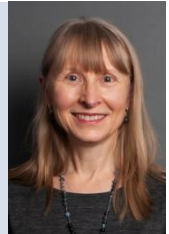
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