THE NEW EU MEDICAL DEVICE REGULATION (MDR):
Practical Implications for Manufacturers

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Introduction

After a prolonged and difficult political process, agreement has finally been reached over the new European Union Medical Device Regulation (MDR), which was approved by the European Parliament on April 5, 2017 and was published in the Official Journal of the European Union on 5th May 2017.


The MDR is a ‘fundamental revision... of the earlier Directives [and] is intended to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation’¹.

It is important to note that the Regulation has binding legal force throughout the EU and enters into force simultaneously in all the Member States. (By contrast, Directives lay down a set of specific results that must be achieved, but each Member State is free to decide how to transpose these directives into national laws.)

The new Regulation is a complex and lengthy document and the changes it embodies are significant. This white paper analyses the most influential changes and highlights their implications for regulated companies. Most of all it aims to provide practical steps that manufacturers should take as soon as possible to prepare for this substantial and unprecedented change in the European regulatory environment for medical devices.

NOTE: The consolidated text of another new EU Regulation, the In Vitro Diagnostic Regulation (IVDR) has also been published in parallel with the MDR. While this also merits the full attention of regulated manufacturers of IVDs and also involves significant changes, this regulation is beyond the scope of the current white paper and is not considered further here.

“This must-read guide comprehensively lists the changes to the regulatory framework and highlights a preferable course of action for manufacturers to take in order to sufficiently prepare for MDR.”
-Peter Rose
Managing Director, Europe
Significant changes in the Medical Device Regulation and their Implication for Manufacturers

There is an increasing awareness that the new MDR represents a very significant change in the regulatory environment:

IN A RECENT SURVEY OF INDUSTRY PROFESSIONALS:

- Most respondents are aware of coming changes to the European CE marking process as well as to the ISO 13485 quality system standard, but primarily on a high level.
- The majority of participants cited changing regulatory environments as their biggest challenge.
- A high proportion of firms based in Europe said they were already closely tracking proposed changes related to CE Marking, compared to much smaller percentages of North American and Asian respondents.

It is important that all affected manufacturers take a step further and build on this growing awareness, devoting time to fully consider and deeply understand the full impact of MDR in order to formulate their strategy for complying with this important regulatory event.

Significant changes include:

Reclassification

CHANGE
Certain products have received special consideration in the MDR and are subject to reclassification. (MDR Article 4). These new provisions variously apply to cosmetic implants, standalone software, products without an intended medical purpose (MDR Annex XVI), certain spine products and reusable Class 1 devices.

IMPLICATION FOR MANUFACTURER
Manufacturers of medical devices should carefully examine the MDR Classification rules in Annex VIII to determine whether new conformity assessment routes are now applicable to their product portfolio. If so, they should engage their Notified Body (where necessary) and take steps to evaluate the necessary timescales involved in implementing this change. In some cases, where reclassification has occurred, this may be the first time that such relationships and agreements with Notified Bodies have been required.
Market Access of Legacy Products

**CHANGE**

There is no provision for grandfathering certification (CE marks) obtained under the previous Directives – all products have to be CE marked under the new Regulation 2017/745, in order to be placed on the market or put into service (MDR Article 5), after the transition period.

**IMPLICATION FOR MANUFACTURER**

A comprehensive plan needs to be put in place to ensure that all products that will be maintained on the EU market are CE marked in accordance with the full requirements of the new MDR. This should include products currently under development. This review may provide an opportunity for rationalisation of the product portfolio and elimination of any marginal products.

Reprocessing of Single Use Devices

**CHANGE**

This has been a highly controversial topic during the evolution of the MDR. It is now specified in the MDR that the reprocessing and further use of single-use devices should only take place where permitted by national law, while complying with requirements laid down in the Regulation (MDR Article 17). Reprocessors are considered equivalent to manufacturers and therefore must ensure an equivalent level of safety and performance to that of the corresponding initial single-use device.

**IMPLICATION FOR MANUFACTURER**

Reprocessing must only take place if permitted by the relevant National Law and Reprocessors have the same obligations as device manufacturers. Reprocessors should check that reprocessing will be permitted in their National Law and if so, understand and embrace the full implications, requirements and obligations of a device manufacturer. Prior to the MDR, they may not have had to consider these aspects and up-skilling or additional staff may be required should relevant professionals not already exist in the company.

Technical Documentation

**CHANGE**

The MDR is significantly more prescriptive about the required content of technical documentation (Technical File/Design Dossier):

- Essential Requirements (ERs) are replaced by General Safety Requirements (MDR Annex I) and the number of requirements has been expanded.
- A Presumption of conformity still applies for devices that are in conformity with relevant harmonised standards (MDR Article 8), but the Commission may define Common Specifications where no harmonised standards exist or where they are considered insufficient.

Additionally, there are more detailed requirements for the Quality Management Systems (QMS) (MDR Annex IX). EN ISO 13485:2016 was re-written and issued in 2016 with the new MDR very much in mind. It should be noted that while EN ISO 13485:2016 is not an absolute requirement there will be a general expectation that this standard will be used.

**IMPLICATION FOR MANUFACTURER**

The required technical file/design dossier documentation is heavily based on the current GHTF STED Guidance document reflecting the harmonisation intent of global regulators. Accordingly, the continuing sufficiency of the Technical File/Design Dossier including associated checklists will need to be checked in detail. Manufacturers will need to remain alert to the publication on new Common Specifications. In addition, manufacturers should be aware of a new sub section related to required Post Market Surveillance (PMS) information.
Clinical Evaluation

CHANGE
The MDR is more specific about the need for clinical evidence and clinical evaluation, proportionate with the risk associated with a given device (MDR Annex XIV, Part A).

Reliance on the scientific literature to demonstrate equivalence will be more tightly regulated, and clinical evaluations will be more closely aligned with clinical trials associated with medicinal products.

IMPLICATION FOR MANUFACTURER
This may require manufacturers to obtain additional clinical data from clinical studies. There will be additional scrutiny of Clinical Evaluation Reports (CERs) by Notified Bodies as outlined by new guidance (MEDDEV 2.7.1 rev. 4). CERs that previously were of a suitable level and standard and accepted by Notified Bodies, may no longer be accepted. Manufacturers should plan to review all of their CERs if not reviewed within the last 1-2 years and ensure that CERs include Post Market Surveillance data; especially where devices are new to market and where clinical data was limited at the time of first CE Marking.

Vigilance and Post Market Surveillance (PMS)

CHANGE
Under the new Regulation 2017/745, device manufacturers will be required to collect post-market clinical data as part of their on-going assessment of potential safety risks. Post Market Clinical Follow up (PMCF) is a continuous process with the objective of constantly updating the clinical evaluation (MDR Annex XIV, Part B).

Additionally, reporting timeframes are tightened from 30 days to 15 days for reporting serious incidents (MDR Article 87).

There will be new electronic vigilance reporting (MDR Article 92) and Periodic Safety Update Reports (PSUR) for all devices (MDR Article 86) subject to differing frequency and submission requirements.

IMPLICATION FOR MANUFACTURER
Manufacturers need to review their procedures for PMS and ensure that the responsibility for the provision of this additional data and associated support is clearly established. This is likely to require additional resources in functions that support products on the market such as Regulatory and Medical Affairs.

Mandatory Product Liability Insurance

CHANGE
Manufacturers must be able to provide sufficient financial coverage for their potential liability. This provision will be based on risk class, type of device and the size of the enterprise (MDR Article 10.16).

IMPLICATION FOR MANUFACTURER
Manufacturers need to review their Product Liability provisions under advice from legal counsel.
**Transparency**

**CHANGE**

Transparency is one of the guiding principles expounded in the MDR preamble, “transparency and adequate access to information, appropriately presented for the intended user, are essential in the public interest, to protect public health, to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system”.

This will (eventually) take the form of a European Data Bank on Medical Devices (EUDAMED) (MDR Article 33) which will also be made public for certain devices. On their part, manufacturers will need to notify all products to EUDAMED database.

**IMPLICATION FOR MANUFACTURER**

Manufacturers should closely follow the continuing evolution of the EUDAMED system and prepare for its implementation so as to be able to notify all products to the EUDAMED database.

**Supply Chain**

**CHANGE**

Each manufacturer will be required to appoint a Person Responsible for Regulatory Compliance (PRRC). In early drafts of the MDR this was first referred to as a “Qualified Person” however this was deemed to be confusing with the pharmaceutical industry QP and is now PRRC (MDR Article 15). The PRRC must have a university degree or equivalent in a relevant scientific discipline, and at least one year of professional experience; or four years of professional experience.

There are also more prescriptive and onerous requirements placed on EU Authorised Representatives (EUAR) (MDR Article 11). The MDR states that “the authorised representative should be jointly and severally liable with the importer and the manufacturer”. The EUAR will also be required to be registered and must also have a PRRC.

The MDR extends the scope of the regulation beyond the device manufacturer to other Economic Operators in the supply chain. Distributors and Importers are now specifically regulated (MDR Article 25) and have specific regulatory obligations too.

**IMPLICATION FOR MANUFACTURER**

Manufacturers should consider their entire Supply Chain to ensure that these provisions are adequately addressed and agreed with their business partners. In addition, they should identify a person who is suitably qualified to assume the PRRC role. Agreements with EUARs, if used, should be revisited and updated together ensuring that EUARs have defined plans to be registered and also have appropriate levels of insurance to cover their new liability.
Labelling

**CHANGE**
Requirements for product labelling are more prescriptive under MDR than before. For example, information supplied by the manufacturer shall be made available and kept up to date on the manufacturer’s website (MDR Chapter III, 23.1)

There are requirements for:
- Specific details for labels and for sterile packages (MDR Annex I).
- Inclusion of information on residual risks for vulnerable patient groups (e.g. children, pregnant or nursing women) and, if applicable, on appropriate precautionary measures in the instructions for use.
- Hazardous Substances

**IMPLICATION FOR MANUFACTURER**
Manufacturers should carefully review the adequacy of their product labelling and precautionary statements and consider how this will be reflected on their web-sites.

UDI System

**CHANGE**
The MDR requires the traceability of all devices placed on the EU market (except custom made devices) by means of a Unique Device Identification system (UDI System) based on international guidance to significantly improve the effectiveness of post-market safety related activities for devices (MDR Articles 27, 29 and 31 and MDR Annex VI).

Each device will need to have an assigned UDI obtained from a UDI supplier and this information must be uploaded into EUDAMED. The UDI must be established before the product is placed on the market, and the UDI carrier must be provided on the device label/packaging, and, in the case of reusable devices, on the device itself.

It should be noted that, for logistical reasons relating to EUDAMED and a Delegated Act on UDI, the UDI requirements cannot be immediately implemented and will be phased in beginning in 2021, starting with the highest risk devices (Class III and implantables) and continuing to Class IIb, Class IIa, and Class I devices over time.

**IMPLICATION FOR MANUFACTURER**
Detailed project planning for UDI Implementation in the EU (additional to that currently required by the FDA in the US) will be required. While the detailed specification of the EU UDI system is still under discussion, current information suggests it will not differ significantly from the newly established US system. Manufacturers who do not supply their products to the US will have the steepest learning curve on EU UDI, however they can also learn from the successes and mistakes of US UDI implementation.
Some Important Practicalities of Implementation

Timeline

Following its recent formal adoption, the MDR was published in the Official Journal of the European Union 5th May 2017. The new regulation is associated with a three year transition period following its publication and therefore enters fully into force in 2020 (the “Date of Application”). After this date it will no longer be possible to put a new medical device on the market with a CE mark issued against the former Directive 93/42/EEC.

Projected Timeline of Implementation of MDR

MDR published in official journal and entry in force.

June 2017

January 2018

January 2019

January 2020

3 year transition period

Grace period for Certificates granted under prior directive

June 2020

January 2022

January 2023

June 2024

Expiry of Certificates granted under prior directive.

Devices placed on the market under the Directive 93/42/EEC before the MDR Date of Application (2020) may continue to be made available on the market or put into service for 4 years after that date provided they have not expired (MDR Article 94.3a). However, this situation will come to an end around 2024.

It is clear that manufacturers should be taking practical steps now to plan for implementation.
UK Brexit

The decision of the UK to exit the EU (Brexit) following a referendum held in June 2016 and formalised by the triggering of Article 50 in March 2017 complicates the situation for UK based manufacturers, non-EU companies with Authorised Representatives in the UK and companies wanting to continue to access the UK market. However, it seems unlikely that the UK government will devise any sort of national regulatory regimen that differs significantly in its requirements from that of the EU MDR. Thus any future UK regulatory regimen is likely to closely mirror that of the EU.

To this end, The UK Association for British Health Industries (ABHI) has recently published a white paper on its web site advocating a pragmatic UK approach to compliance with the current and future EU regulation for medical devices and for the UK remaining part of the CE marking regime. Nonetheless, the possibility that additional bureaucratic overheads may be encountered in the UK going forward certainly exists. Manufacturers should closely monitor further developments in the UK so as to anticipate any significant consequences for their business.

Notified Body Capacity

After some well publicised safety issues in recent years that have strongly influenced the evolution of the MDR, Notified Bodies (NBs) are themselves under considerable pressure from their respective Competent Authorities to heighten scrutiny of their client medical device manufacturers. Notified Bodies will themselves need to seek designation under the MDR in the months after the MDR is adopted.

Notified Bodies across Europe are already, and are expected to continue to encounter capacity issues. There has been a significant decrease in the number of Notified Bodies accredited to deal with medical devices in spite of a substantial increase in workload and with the MDR coming into play, Notified Bodies will also need time to prepare and train their staff. In the EU there are currently just 56 Notified Bodies in total (including 3 MRAs from Australia and Switzerland), reduced from 70+ notified bodies in 2014. Germany and Italy have 10 Notified Bodies each, the UK has five and the remaining countries have 4 or less each, the majority having just 1 Notified Body.

This suggests there will be significant over-demand from the industry for Notified Body services as manufacturers compete for their services during the transitional period. It is vital that manufacturers engage with their Notified Body early and ensure they have the capacity to assist them and that they agree on timescales.

UNANNOUNCED INSPECTIONS

Notified Bodies have already started to conduct unannounced inspection of manufacturers, their critical subcontractors and suppliers. As an example, TÜV SÜD carried out more than 400 unannounced audits worldwide since March 2014. Under the new MDR such inspections must be performed at least once every five years. Manufacturers should put in place procedures to deal with these, should they not already have done so, and always be prepared for an audit.
Delegating Acts

The harmonising standards and Delegating Acts that will make the MDR operational are still under active discussion and development at the EU level. It is important that manufacturers closely follow these developments by actively engaging with their Trade Associations, and where possible, lobbying to influence their final form.

ISO 13485 Quality System

In addition to needing to comply with Regulation 2017/745 requirements, the medical device industry is currently transitioning to the newly revised ISO 13485:2016 standard required for medical device QMS which is itself a de facto requirement for medical devices placed on the EU market. This new standard has a transition period that ends 1st March 2019, overlapping closely with the MDR transition period. In practise, manufacturers must phase in these two transitions together, further complicating the implementation of the MDR.

Steps Manufacturers Should Take Now

It is evident that conformance with the MDR is a significant business issue; all products on the market must be phased into the new system no later than the end of the grace period following the three-year transition period. All new products being placed on the market after the transition period must be compliant with the MDR. Furthermore, regulatory control over conformance with the requirements of the MDR is ever-increasing.

Additional Costs and Resource Requirements

MDR conformance will place a considerable additional administrative burden on manufacturers. Both staffing and external cost budgets should be carefully considered and adjusted to ensure that timely access to the EU market is not compromised and that regulatory compliance is maintained in the face of significantly enhanced regulatory scrutiny.

Many manufacturers will rely on additional resources to assist with the workload at a time when there is a shortage of skilled professionals. Manufacturers who plan and implement sooner rather than later will have the best access to limited resources and will be able to cherry pick the best personnel. Whenever there is demand and a lack of resources, prices increase, so there is also likely to be an increase in labour costs over the next few years. When budgeting, manufacturers must allow for this fluctuation and also be aware that it is a candidate’s market so they will need to act fast to secure top professionals.

Programmatic Approach

It is imperative that medical device manufacturers and other economic operators be proactive and adopt a programmatic approach to conformance. It is recommended that a cross-functional project team be formed to manage this Program. This Program should ensure that the following are addressed:
MAETRICS MDR PROGRAMMATIC APPROACH

+ Brief Executive Management to ensure they gain a clear understanding of the importance and business implications of the MDR;
+ Ensure that overall responsibility for MDR implementation has been established and that a Cross-functional programme team is formed in order to cover all aspects;
+ Study the detailed requirements of the MDR;
+ Perform a detailed gap analysis for products and the whole organization against the MDR requirements;
+ Give special consideration to certification expiry dates versus transition period and enforcement date;
+ Review the MDR Implementation plan, identifying and addressing key areas of risk;
+ Consider organizational challenges: management awareness, staffing capability and availability, budget implications;
+ Continue to actively monitor the still-developing European Regulatory environment;
+ Check classification rules and confirm conformity assessment routes for existing and future products and take steps to address any changes;
+ Contact the selected Notified Body and determine their capacity and availability to service the implementation plan;
+ Review the changes needed in existing Technical Documentation (Technical File);
+ Determine the adequacy of Clinical evidence and address any gaps (CERs);
+ Review the adequacy of Quality Management System (QMS) processes and plans to transition to ISO 13485:2016 and build in the new regulatory requirements into the QMS;
+ Identify Person Responsible for Regulatory Compliance (PRRC) and be sure they are adequately qualified and trained and plan their training, if applicable, as early as possible;
+ Review product labelling;
+ Ensure Product Liability provisions are adequate;
+ Ensure PMS arrangements are adequate;
+ Review Supply Chain provisions and clarify roles and responsibilities of business partners;
+ Prepare for unannounced inspections from Notified Bodies;
+ Ensure regular review of progress versus the MDR Implementation program plan are held and included in the Management Review process.
Summary

Conformance with the MDR is a significant business challenge that must be overcome in order to enjoy continued access to the EU market. To meet this challenge manufacturers must be proactive and begin preparing now.

Some of the underlying details of the MDR implementation process are not yet fully defined. Manufacturers must closely follow the emerging regulatory landscape, keeping alert for the detailed Implementing and Delegating Acts that are required in order to make the MDR operational.

In this challenging and competitive environment, the availability of resources, both internal and external, are likely to prove rate limiting. Executive support and proactive programme management of MDR implementation is a prerequisite for a manufacturer’s success in this regard.

Sources

2. Emergo, Global Medical Device Industry Outlook for 2017