

# The new European Medical Device Regulation and the Unique Device Identification





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# The new European Medical Device Regulation and the Unique Device Identification

The most predominant topic spoken about by manufacturers of medical devices in the European Union is currently the implementation of the new Medical Device Regulation (MDR), the In Vitro Diagnostic Regulation (IVDR) and the Unique Device Identification (UDI), eclipsing even challenges like growing cost pressure and a higher demand for innovation. The ultimate goal of the new regulation is a stronger focus on patients' safety and needs. Given that the transitional period will end in May 2021\*, the implementation time frame is tight and manufacturers are forced to act now. Otherwise they risk losing market access and approval of their products.

This paper reveals the relevance of the new regulations for the Life Sciences Industry and especially the Medical Technology industry. We will discuss the importance of effectively integrating MDR and UDI into daily business and opportunities provided by Capgemini to implement a beneficial solution. Therefore, you can discover some of the core solutions developed by Capgemini to give the best support to overcome the given challenges, to stay competitive and even to generate growth.



**Do you feel sufficiently informed about the implementation of the MDR?**

Only **15%** of manufacturers feel sufficiently informed

**Do you think that products or product lines will have to be discontinued due to the increased requirements?**

**50%** of manufacturers say yes

**Do you expect any impact on the research budget?**

More than **65%** of manufacturers are already reducing their research budgets

Source: <https://www.item.fraunhofer.de/de/leuchtturm-projekte/leistungszentrum-translazionale-medizintechnik/doku-mdr-veranstaltung-2018.html>

1 \*The European Parliament has decided to postpone the new approval rules by one year. Dates have been updated. European Parliament: <https://www.europarl.europa.eu/news/en/press-room/20200415IPR77113/parliament-decides-to-postpone-new-requirements-for-medical-devices> (access on 17.06.2020)

# 1.0 Introduction

Currently, there are over 500,000 different medical devices and in vitro diagnostic devices in use in the European Union (EU). While medical devices encompass instruments as diverse as MRI scanners, insulin pens and surgical masks, in vitro diagnostic devices are used to perform tests on samples (e.g. blood samples and HIV or pregnancy tests).

They represent an important economic factor, accounting for an annual revenue of 110 billion euros in sales and 675,000 jobs<sup>1</sup> within the EU. Medical technology is also a highly innovative sector, with almost 14,000 patents filed at the EPO in 2018<sup>2</sup>.

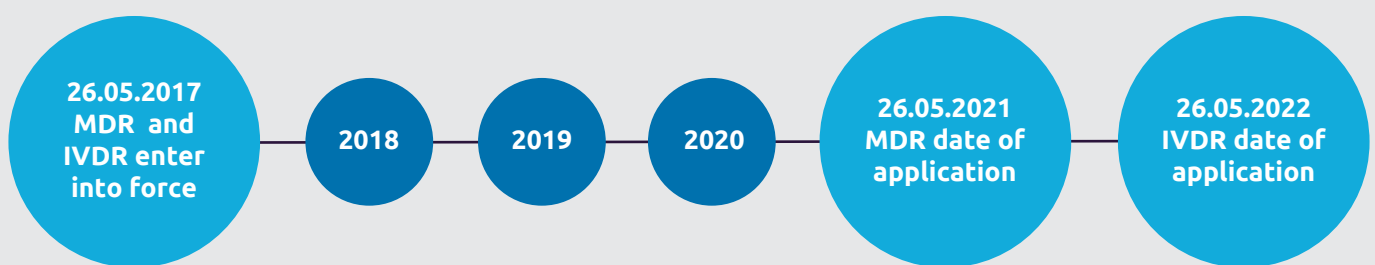
Not surprisingly, this high innovation pace entails rapid advances in technology and medical sciences. As a consequence, the existing legislative EU framework, consisting of three directives from the 1990s, has been replaced with two new regulations: the Medical Device Regulation (MDR, 017/745/EU) and the In Vitro Diagnostic Medical Device Regulation (IVDR, 017/746/EU). They both became effective

in May 2017 and include a plethora of new measures aimed to improve reliability, safety and quality of medical devices. After a transition period until May 2021 (MDR) and May 2022 (IVDR), the new regulations will officially be applied (see Fig. 1).

Given their broadened scope and increased complexity, the new MDR regulations pose a significant compliance challenge to medical device companies. Among the most complex are:

- focus on life cycle management
- more extensive requirements for clinical evidence before product release
- classification of certain devices broadened, which leads to reclassifications
- introduction of a Unique Device Identifier (UDI) system
- submission of legal information to the new European Database for Medical Information (EUDAMED)

Fig. 1. MDR and IVDR timeline



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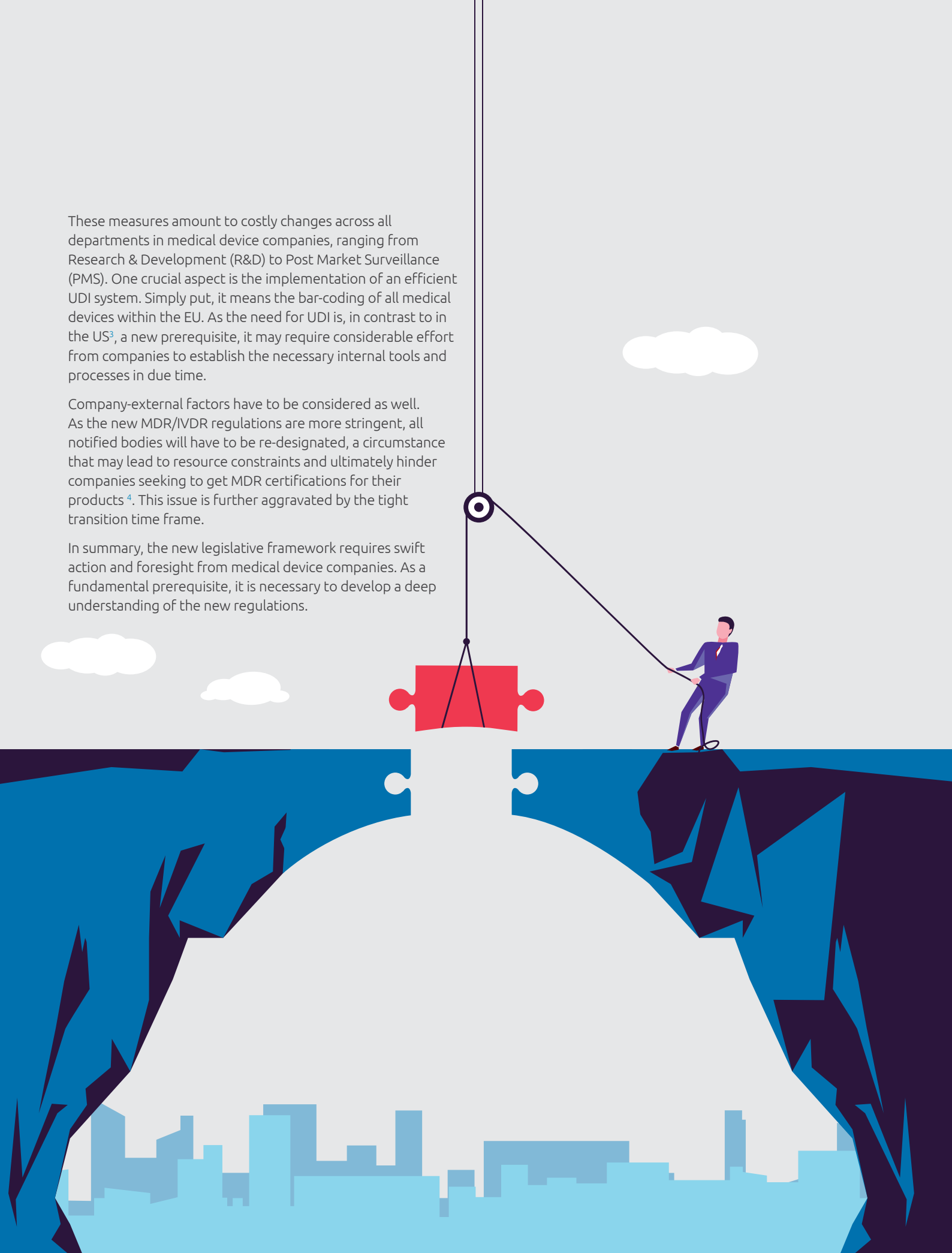
<sup>1</sup>MedTech Europe a (12.01.2018): [https://www.medtecheurope.org/wp-content/uploads/2018/06/MedTech-Europe\\_FactsFigures2018\\_FINAL\\_1.pdf](https://www.medtecheurope.org/wp-content/uploads/2018/06/MedTech-Europe_FactsFigures2018_FINAL_1.pdf) (access on 10.07.2019)

<sup>2</sup>European Patent Office (21.1.2019): Annual Report 2018. <https://www.epo.org/about-us/annual-reports-statistics/annual-report/2018/statistics/patent-applications.html#tab3> (access on 10.07.2019)

These measures amount to costly changes across all departments in medical device companies, ranging from Research & Development (R&D) to Post Market Surveillance (PMS). One crucial aspect is the implementation of an efficient UDI system. Simply put, it means the bar-coding of all medical devices within the EU. As the need for UDI is, in contrast to in the US<sup>3</sup>, a new prerequisite, it may require considerable effort from companies to establish the necessary internal tools and processes in due time.

Company-external factors have to be considered as well. As the new MDR/IVDR regulations are more stringent, all notified bodies will have to be re-designated, a circumstance that may lead to resource constraints and ultimately hinder companies seeking to get MDR certifications for their products<sup>4</sup>. This issue is further aggravated by the tight transition time frame.

In summary, the new legislative framework requires swift action and foresight from medical device companies. As a fundamental prerequisite, it is necessary to develop a deep understanding of the new regulations.



3 U.S. Food and Drug Administration (05.06.2019): <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system> (access on 10.07.2019)

4 Zimmer, Christina (18.04.2018): <https://www.bvmed.de/de/recht/rechtsrahmen/eu-medizinprodukte-verordnung/eu-mdr-einfuehrung> (access on 10.07.2019)

## 2.0 The Medical Device Regulation and the In Vitro Diagnostic Medical Device Regulation

On 26 May 2021, manufacturers of medical devices will have had four years to comply with the new regulation. Exceptions in the form of a soft transition apply only to class IIb and III medical devices with an AIMDD/MDD certificate issued before the date of application and only without modification of the intended purpose<sup>4</sup>. The former and at present still valid Medical Devices Directive (93/42/EEC) and the Active Implantable Medical Devices Directive (90/385/EEC) will then be replaced entirely by the new MDR. This will happen in order to align EU legislation with new technical developments, the legal environment and progress in medical sciences. During the transitional phase (May 2017 – May 2021) both the directives and the regulation are valid. Nevertheless, the new MDR does not apply to in vitro medical devices, which will be dealt with in the new IVDR<sup>5</sup>.

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<sup>4</sup>Zimmer, Christina (18.04.2018): <https://www.bvmed.de/de/recht/rechtsrahmen/eu-medizinprodukte-verordnung/eu-mdr-einfuehrung> (access on 10.07.2021)

<sup>5</sup>European Commission a (09/08/2018): Factsheet for manufacturers of medical devices. <https://ec.europa.eu/docsroom/documents/31201> (access on 10.07.2021)

## 2.1 Background of the MDR

The new regulation will ensure fair market access for medical device manufacturers based on the following three main changes:

1. higher safety, quality and reliability of medical devices
2. higher transparency for customers
3. enhanced vigilance and market surveillance<sup>7</sup>

The new regulations do not need to be transposed into national law because they are already binding. This will lead to a higher conformity in the understanding of the law across the EU market. However, extensive adaptations of existing national law will be required to be compliant with the new EU regulations. In order to create a consistent understanding between the EU and individual nations, the definition of a medical device has been slightly changed and associated terms were defined in a more detailed way (e.g. UDI, clinical evidence). To ensure a smooth transition, several transitional provisions are formulated and defined (article 120).



<sup>7</sup>European Commission b (05.04.2017): New EU rules on medical devices to enhance patient safety and modernise public health.

[http://ec.europa.eu/growth/content/new-eu-rules-medical-devices-enhance-patient-safety-and-modernise-public-health-0\\_en](http://ec.europa.eu/growth/content/new-eu-rules-medical-devices-enhance-patient-safety-and-modernise-public-health-0_en) (access on 10.07.2019)



## 2.2 Changes Made by the New MDR

The former directive and the new regulation share the same regulatory basis and therefore no existing requirements have been removed, but new requirements were added, i.e. there are about 100 new articles and 16 instead of 12 annexes<sup>4</sup>. The new regulation also includes certain aesthetic devices since they present the same characteristics and risk profiles as medical devices<sup>8</sup>. In the following, the major changes are pointed out.

To increase quality and quantity of data the new EUDAMED database has been published. The database will increase transparency, since information on devices and studies are made available for public access (article 33). Part of the EUDAMED database is also the new UDI (article 27). The UDI accompanied by shorter reporting deadlines and new labeling requirements will increase effectiveness of post-market safety-related activities significantly. Article 54 of the MDR describes a clinical evaluation consultation procedure also known as pre-market scrutiny mechanism for highly safety relevant devices (drug dispensing class IIb and implantable class III devices).

The procedure is used to advise notified bodies through an independent expert panel. A second group of experts called Medical Device Coordination Group (MDCG), composed of member state experts is also introduced to give advice and support to the commission. More clinical requirements regarding clinical data and clinical investigations are defined in chapter VI. Also, internet sales of medical devices and services are now regulated (article 6). The MDR broadened the regulatory scope regarding the classification of medical devices. That means manufacturers now have to check their product portfolio for necessary new- or reclassification of devices including sterilizing devices (article 2.1) and reprocessed single-use medical devices (article 17) as well as software, among others. The national competent authorities and the commission receive more control and monitoring authorizations regarding the designation of the notified bodies, especially in terms of the clinical competence. The MDR increases the significance of the life cycle of products and their technical documentation due to safety aspects. As a consequence, new reports and documented plans must be generated by the manufacturers, e.g. the post-market surveillance plan/report and the post-market clinical follow-up report.<sup>4,8</sup>

## Key changes in MDR



Wider scope of regulated medical devices



More stringent clinical evidence and documentation



Increased focus on identification and traceability



Definition of common specifications



Unannounced factory audits



Increased notified body authority and/or involvement



More rigorous vigilance and market surveillance



At least one person responsible for regulatory compliance



<sup>4</sup>Zimmer, Christina (18.04.2018): <https://www.bvmed.de/de/recht/rechtsrahmen/eu-medizinprodukte-verordnung/eu-mdr-einfuehrung> (access on 10.07.2019)

<sup>8</sup>European Commission c: New regulations. [https://ec.europa.eu/growth/sectors/medical-devices/new-regulations\\_en](https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en) (access on 10.07.2019)

## 2.3 General Obligations of Manufacturers and other Actors

Based on article 10, manufacturers of medical devices shall have systems in place for quality (paragraph 2) and risk management (paragraph 9) as well as systems to cover financial responsibility for harm which might be caused by defective devices (paragraph 16). Manufacturers should also apply a conformity assessment procedure (paragraph 6) and conduct clinical evaluations (paragraph 3). The MDR also redefines the requirements for the technical documentation

(paragraphs 4 and 8) including the manufacture of custom-built devices (paragraph 5) and the manufacturer's responsibilities for devices in the field (paragraphs 12-14). Necessary information for the identification of suppliers shall also be stated (paragraph 15). In further paragraphs of article 10, additional obligations are defined, like the commitments concerning the UDI- (paragraph 7) or market surveillance system (paragraph 10). Also, the need for information availability in different languages (paragraph 11) as well as the compensation in case of damage (paragraph 16) are mentioned.<sup>6</sup>



Essential legal acts and documents for the implementation of the MDR are still missing.



To date, there is no sufficient number of notified bodies that have successfully completed the necessary accreditation.



To date, there are no harmonised European standards against which notified bodies can check the conformity of medical devices.

Source: <https://www.zvei.org/themen/gesundheit/medtech-telegram/>

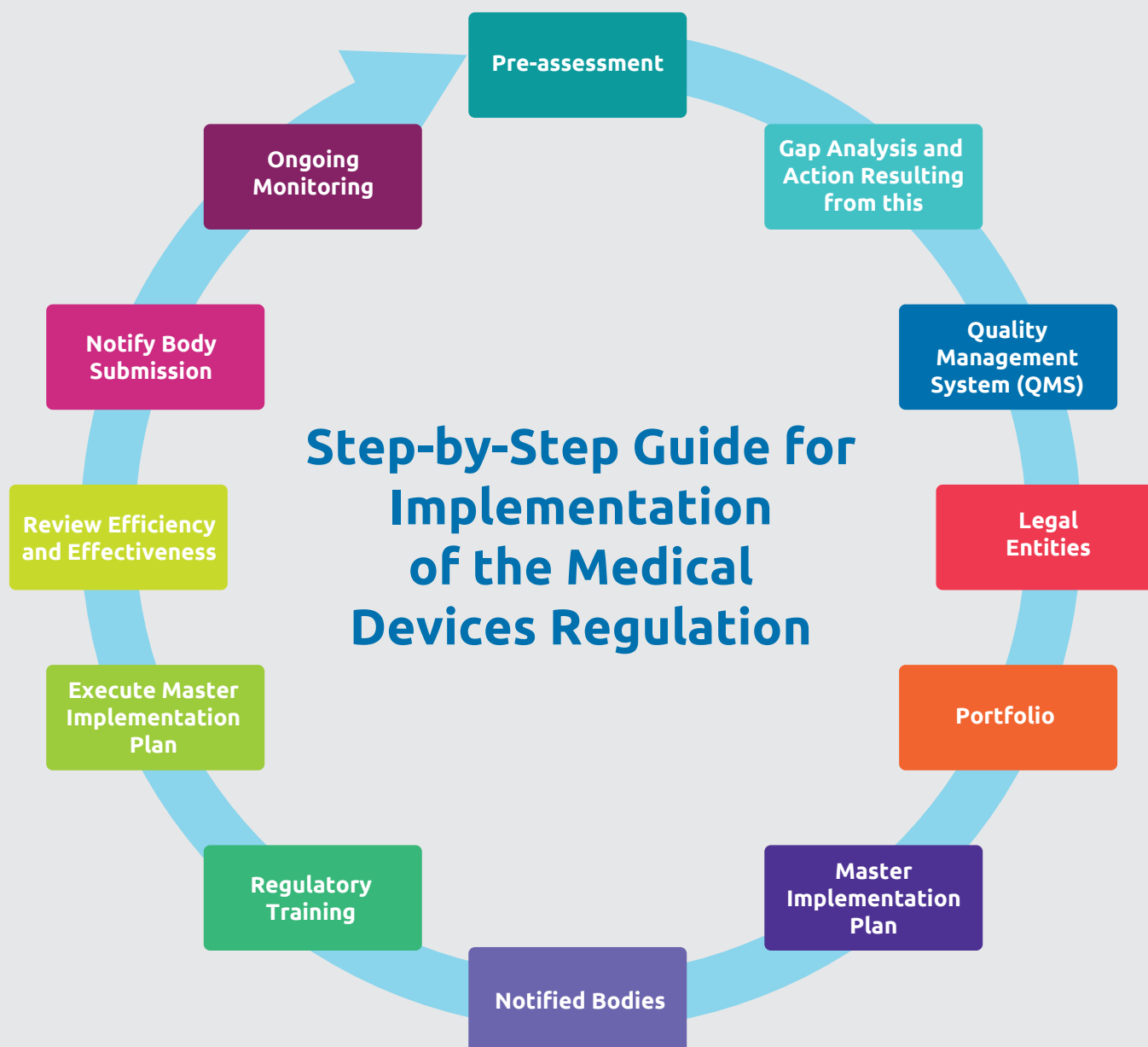
<sup>6</sup>EUR-Lex (05.05.2017): Verordnung (EU) 2017/745. [https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=uriserv:OJ.L\\_.2017.117.01.0001.01.DEU](https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=uriserv:OJ.L_.2017.117.01.0001.01.DEU) (access on 10.07.2019)

Beyond the obligations listed in article 10, further commitments are defined, like the need to assign responsibility for regulatory compliance to one person (article 15). Manufacturers of implantable devices shall also provide an implant card to patients, containing information about implanted medical devices (article 18). Obligations of third parties like authorized representatives (article 11), importers (article 13) and distributors (article 14) are also defined in detail.

After fulfilling all the obligations, a declaration of conformity shall be provided by the manufacturer (article 19) and the devices need to be marked with a CE label (article 20).<sup>6</sup>

As assistance, the European Commission published an implementation model for the medical device regulation. It serves as a step-by-step guide including 12 steps (see Fig. 2) with further underlying actions.

Fig. 2. Implementation model for the medical device regulation<sup>9</sup>



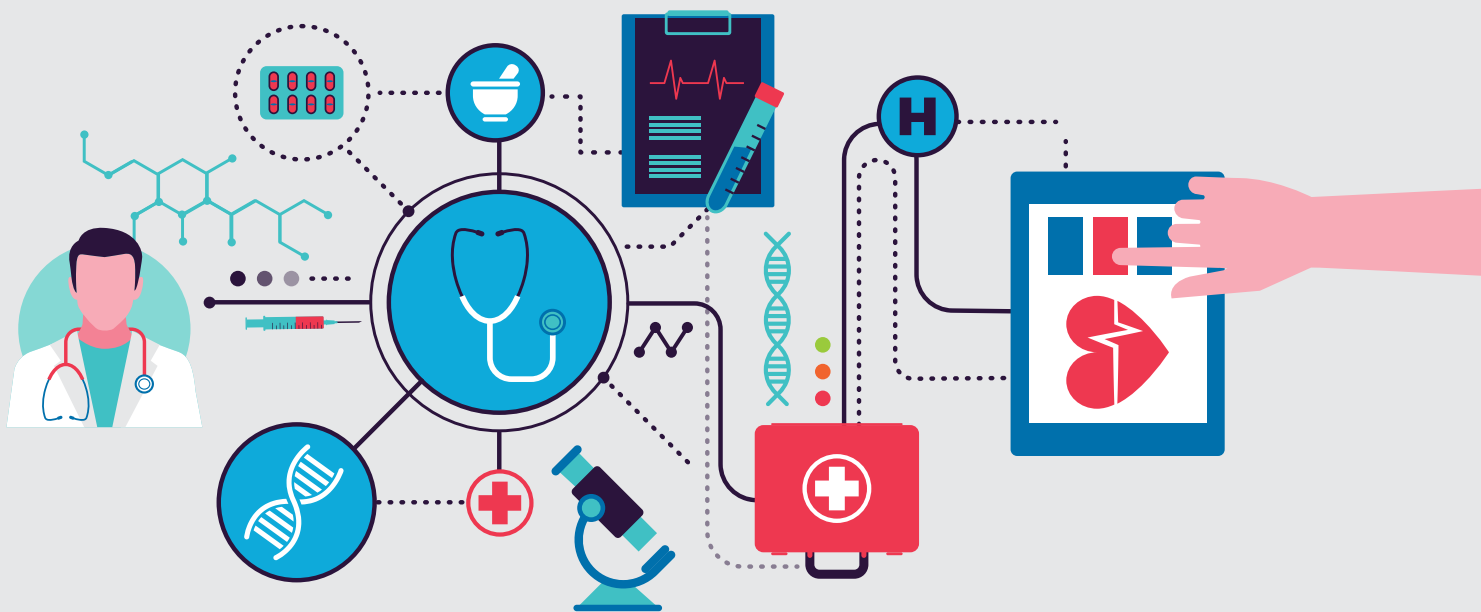
<sup>6</sup>EUR-Lex (05.05.2017): Verordnung (EU) 2017/745. [https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=uriserv:OJ.L\\_.2017.117.01.0001.01.DEU](https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=uriserv:OJ.L_.2017.117.01.0001.01.DEU) (access on 10.07.2019)

<sup>9</sup>European Commission d (20.07.2018): Step-by-step implementation model for Medical Devices Regulation. <https://ec.europa.eu/docsroom/documents/30905> (access on 10.07.2019)

## 2.4 Changes Made by the New IVDR

Most of the requirements listed above also apply to in vitro diagnostic medical devices e.g. more stringent requirements for the designation of notified bodies, involvement of an independent expert panel for highest risk devices, introduction of UDI or the increased transparency due to usage of the EUDAMED. But there are also regulations that only apply to

in vitro devices. Firstly, IVDR defines rules to assign each in vitro device to one risk class between A (lowest risk) and D (highest risk). As a result, more than 85% of all devices have to be tested by a notified body in future, instead of 15%. The new regulations bring more stringent requirements for conformity assessment and clinical evidence. Devices classified as class D (high risk devices) will require the involvement of an EU reference laboratory (if available for that type of device).<sup>10</sup>



<sup>10</sup>European Commission e (09.08.2018): Factsheet for manufacturers of in vitro diagnostic medical devices. <https://ec.europa.eu/docsroom/documents/31202> (access on 10.07.2019)

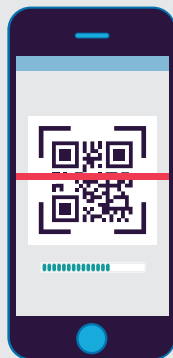


### 3.1 Background of Unique Device Identification

In 2013, the International Medical Device Regulators Forum (IMDRF) released a guide intended to globally harmonize device identification<sup>12</sup>. The regulatory frameworks of the US and the EU, two of the biggest markets for medical devices, follow these guidelines, although there are some discrepancies between the two systems regarding UDI data submission requirements/terminology as well as UDI labeling.

As for the US UDI system, it is currently in the final phase of implementation. According to the UDI Rule, the device labelers - typically the manufacturers - are required to:

- include a UDI on device labels and packages (except where exceptions or alternatives are allowed); in the case that a device is intended to be used more than once and intended to be reprocessed before each use, the device labeler is also required to mark the UDI directly on the device.
- submit device information to the Global Unique Device Identification Database (GUDID).



MDR and IVDR determine the legal requirements for the European UDI system. The UDI data must be provided on the EUDAMED database. The European UDI system will be phased in successively as scheduled (see Fig.3), in a similar way to the US approach. Depending on the medical risk class, all marketed devices shall have a unique identifier by 26 May 2027.

Contrary to the US FDA regulation, a new identifier – the Basic UDI-DI - has been introduced by the EU regulations. This new

identifier allows the grouping of medical devices with similar features within the EU regulatory database. The submission of a product for market registration and/or approval to the competent authority assumes that the assignment was done by the medical device manufacturer or authorized representative.

### 3.2 UDI Format

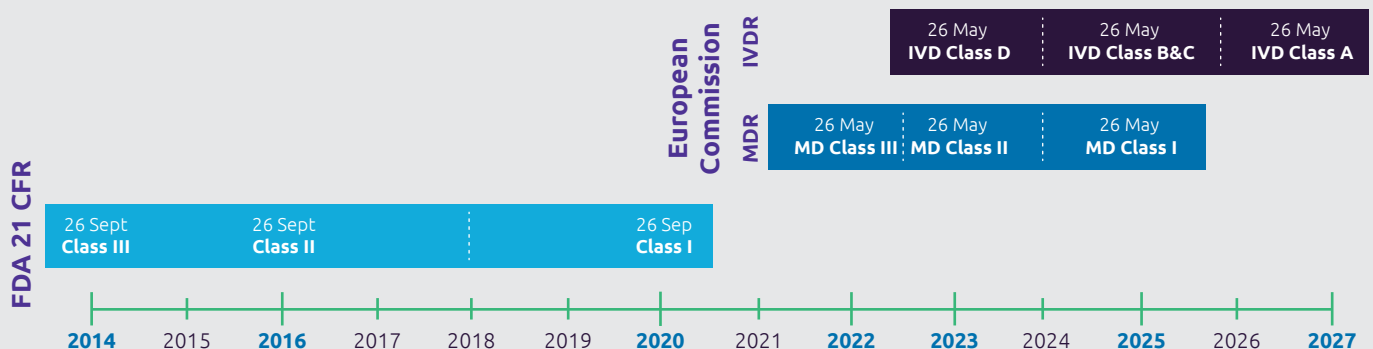
In order to develop a UDI, device labelers need to contact one of the issuing agencies accredited by the FDA or the European Union. The accredited agencies are GS1, HIBCC (Health Industry Business Communications Council) and ICCBBA (International Council for Commonality in Blood Banking Automation).

A UDI itself is a unique alphanumeric or numeric code (see Fig. 4) that consists of a:

- device identifier (DI): a mandatory, fixed segment that identifies the labeler and the specific model or version of a device, following an identification standard such as GTIN
- production identifier (PI): a conditional, variable segment that identifies one or more of the following pieces of information when part of the label of a device:
  - lot or batch number
  - serial number
  - expiration date
  - manufacturing date
  - distinct identification code (for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device)

It is the device labeler’s duty to provide the UDI in two forms on packages and labels. It consists of an easily readable plain text format and a machine-readable format that uses Automatic Identification and Data Capture (AIDC) technology.

Fig.3: Timetable of UDI application dates



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<sup>12</sup>MedTech Europe b (01.2019): UDI System in the US and in the EU – Mapping of Differences.

### 3.3 Capturing of UDI Related Data

UDI-related information can be captured in different ways. For small and medium-sized companies with limited numbers of devices that need to be registered, a lightweight solution might be sufficient. However, with an increasing number of items, software support is advisable. By using a workflow management software, users can be guided through the data capturing process which usually results in increased efficiency and productivity. At the same time, software solutions can help to avoid false data entries by validating the user's input.

### 3.4 Submission of Device Information

In the US, device information needs to be submitted to the GUDID. For that, the FDA provides two options:

- manual data entry by using the web application
- HL7 SPL file submission using the FDA Electronic Submissions Gateway

The first option offers the possibility to submit single DI records manually by using the GUDID web application online. The latter enables the submission of DI records in bulk as XML files that are compliant with Health Level 7 (HL7) Structured Product Labeling (SPL).

The GUDID does not include the PI but rather the DI as the key to obtaining device information from the database, together with a standard set of basic identifying attributes for each device with a UDI.

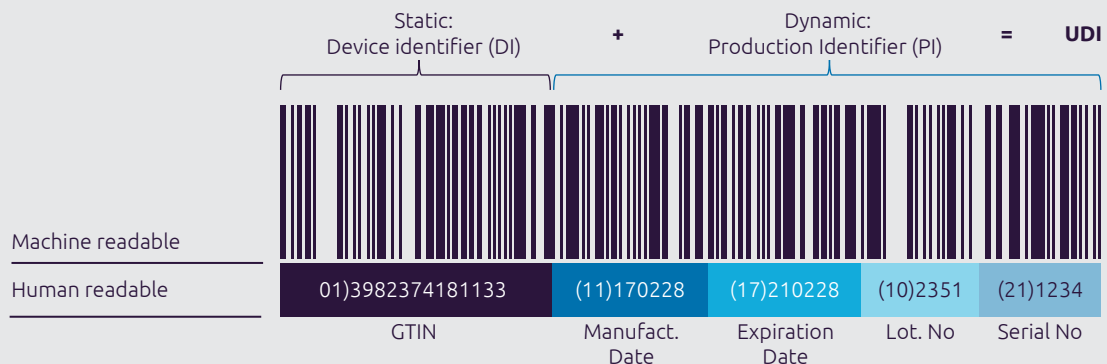
As for EUDAMED, there are three ways planned to enter and download data:

- manual data entry through the application
- semiautomatic XML upload/download
- machine2machine

The last option signifies that data will automatically be transmitted between an external system and EUDAMED. Regarding the most appropriate way to transmit data, the European Commission provides a guideline to consider relevant parameters such as volume of data, frequency of transmission etc.<sup>13</sup>



Fig. 4 UDI Labeling (Adapted from GS1)<sup>14</sup>



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<sup>13</sup>European Commission f (29/05/2019): Eudamed Data Exchange Guidelines. <https://ec.europa.eu/docsroom/documents/35684> (access on 10.07.2019)

<sup>14</sup>GS1 b: Unique Device Identification (UDI). <https://www.gs1-germany.de/gs1-complete/branchenangebote/udi-umsetzung-mit-gs1-standards/#c269953> (access on 10.07.2019)

## 4.0 Capgemini's Approach

Capgemini helps companies to adhere to the stringent regulations of the European Union and the FDA, to stay competitive and relevant in the market. Capgemini's MDR and UDI structured approach encompasses a strategy for end-to-end MDR & UDI compliance and predefined roadmap execution.



## 4.1 Service Portfolio

Capgemini offers a unique and diversified service portfolio consisting of the following (see Fig. 5):

Our approach delivers profound sector expertise combining depth of knowledge and comprehension of the areas affected by MDR to provide customers with extensive benefits.

With the support of more than 200 regulatory submissions and after having aided more than 30 product categories in their development, Capgemini has been gaining experience with medical devices and in health care for more than 17 years. Hence, Capgemini is accurate in identifying the changes of device classifications, can enable product compliance and certification by partner ecosystems and is able to reduce time consumption by achieving compliance with templates for MDR impact assessment and process maps.

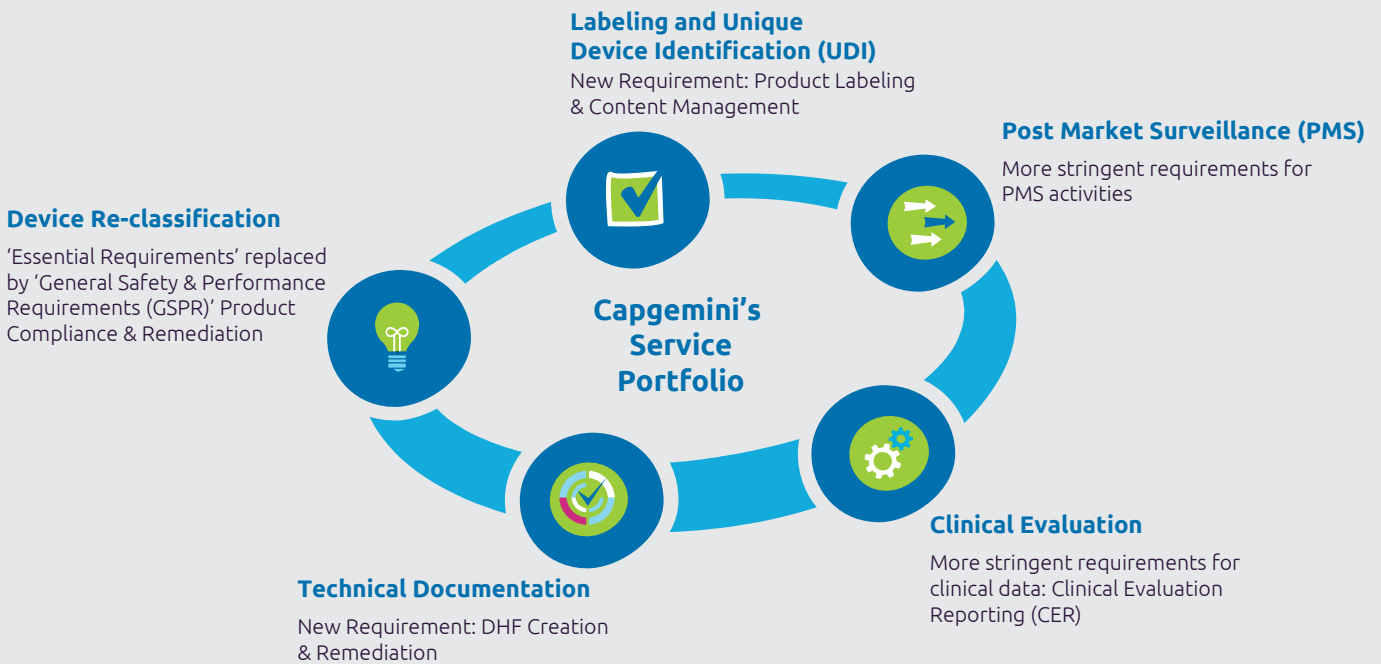
Capgemini brings together deep domain and technology expertise for the digital as well as the physical world of products and is ready to support the medical device industry in achieving compliance effectively and efficiently. Capgemini ensures that medical device companies launch their products in accordance with the new guidelines of the European Union.

Capgemini also offers business accelerators like the “Accelerated Solution Environment” (ASE) or the global platform “Applied Innovation Exchange” (AIE) for exchange, networking and execution. Their major advantage is to facilitate the quick development of business solutions and the alignment of stakeholders to solve even complex business problems. Methods like rapid ideation, design thinking and hackathons support the solution-finding process and generation of results. In general, the working culture and particularly the working methods between different functional areas are improved.

As a part of Capgemini, idean – our global strategic design arm – best embodies Design Thinking capabilities to rapidly innovate in a customer-centric way. They are able to create high-value digital products and services to unlock customer value and market opportunity for medical device and healthcare companies.



Fig. 5 Capgemini’s Service Portfolio



## 4.2 Case Studies UDI

The following outlines challenges facing the customer and Capgemini's solution approach as well as issues already tackled and benefits. Capgemini supports the reinforcement of procedures regarding UDI management for internal collaborators and external partners.

### 4.2.1 Brief Description of the Project

In this project, Capgemini ensured that regulatory relevant data printed on product labels was also included in the customer's product master data and transferred to governmental databases.

The cross-functional data gathering affected various departments and processes. Workflow management software with BPM functionality to prepare, document and facilitate the publication of medical device data was used to create the Unique Device ID Management for the customer. To ensure compliance and transparency, the customer reinforced its procedures regarding UDI management for internal collaborators and external partners.

### 4.2.2 Issues Faced during the Project

In 2021, the customer needs to transmit the basic UDI-DI and related product data to regulatory agencies. But knowledge within the company about required information for submission was scarce and no electronic process for capturing UDI related information was established. In addition, the infrastructure to save the relevant information was not available.

### 4.2.3 Solution Provided

Capgemini introduced a browser-based solution integrated into the customer's material master creation process. A three-step approach for UDI record creation was provided:

1. initiation of the creation of a legislation-based UDI manually, process triggered or automatically
2. data capture by different data owners
3. record approval incl. digital signature

The UDI record was automatically saved in SAP MDG and the UDI was embedded into the product re-launch process with bulk creation.

### 4.2.4 Benefits

The solution increased the process efficiency and productivity of the customer's company. It also improved the control over process executions, response time and process delivery. Furthermore, the process visibility was enhanced, and human effort reduced, resulting in time and cost savings. The result was a more scalable, flexible, consistent and reliable UDI creation system.

## 4.3. 1<sup>st</sup> Case Study MDR

Capgemini developed a roadmap for the implementation of MDR at a medical device company in Europe.

### 4.3.1 Brief Description of the Project

For this project, Capgemini facilitated the communication between the different workstreams at the customer's site and the MDR program manager. Capgemini provided guidance on the project plan and ensured that the workstreams were activated and engaged. Work stream integration and coordination ensured meeting the deadlines and achieving the milestones. The workstreams involved included:

- the clinical & post market clinical follow-up
- vigilance & Post Market Surveillance (PMS)
- labeling
- introduction for use of hazardous substances
- UDI and EUDAMED
- portfolio and technical documentation
- organization
- communication
- change management

Within the scope of project monitoring, reporting and control, Capgemini:

- conducted a comprehensive gap assessment of the current process and technical documentation affected by the new MDR requirements
- formed an understanding of the business impact including project execution, remediation, and potential organizational and operating model changes
- developed a pragmatic 3-year roadmap to enable the customer to achieve and maintain long-term regulatory compliance with the MDR.

### 4.3.2 Issues Faced during the Project

Since different business units were responsible for different parts of the workflows, the exchange of information was hindered. Further issues were the prioritization of tasks and milestones which led to deadlines not being met. The customer also struggled with a lack of robust Standard Operating Procedures (SOPs).

### 4.3.3 Solution Provided

Capgemini identified a point of contact for all business units involved to facilitate communication and exchange of information between different workstreams. Regular weekly follow-ups and touchpoint meetings were introduced to review open tasks and deliverables. The meetings were prepared by workstream owners ensuring project deliverables were completed and on time.

The repository for MDR project documents was updated regularly with meeting minutes, MDR guidance and project related documents. Various project management tracking and estimation tools specific to different work streams were developed, including the following:

1. Tracking tools:
  - for workstream roadmaps to track the milestones, activities and deliverables
  - to track action items of each workstream, enabling a quick understanding of project activities, to identify risks and to mitigate them
  - for identifying the status of Clinical Evaluation Reports (CER) to track the CER frequency, the existing number of CERs, the compliance with MEDDEV 2.7/1 rev4 and the type of clinical data available
  - for identifying PMS status to track existing PMS plans and reports with their frequency, compliance status with MDR, the PSUR frequency, the PMCF frequency and the PMCF Plan

- for gap assessments on labels and Instructions for Use (IFUs) to track the coverage of various items indicated as per the new MDR from a process perspective
  - for MDR product classifications to track the progress of product classification changes as per MDR
  - for technical file documentations to track product wise technical file sections tracked against their existing format (electrical/physical)
2. Resource estimation tools:
    - for clinical affairs to estimate resources based on priority of CER completion, kick-off meeting, literature search/review, compilation of source data activities
    - for PMS to estimate resources based on planning and reporting hours of a PMS, PSUR and PMCF report
  3. Communication plan templates to update the different communication activities

### 4.3.4 Benefits

The solution enabled the client to identify risks early and develop a strategy to mitigate them. Workstream activities are now prioritized based on the bandwidth, the expertise and the experience of their leaders. Finally, workstream charters, milestones and activities with deliverables were developed.



## **4.4 2<sup>nd</sup> Case Study MDR**

During the product design process, a customer used a third-party flushing device that was not compliant with the medical device design control process. With the introduction of the new MDR, the customer decided not to use the third-party component anymore and commissioned Capgemini with developing the product with all the design control, verification and validation processes required to meet regulatory compliance.

### **4.4.1 Brief Description of the Project**

Capgemini designed and improved the next generation endoscope flushing device, increasing performance and enriching the features. The necessary regulatory requirements for medical devices were met.

### **4.4.2 Issues Faced during the Project**

The new device as well as the design and manufacturing documentation and system validation had to comply with the new regulatory requirements of the design control process for product development.

### **4.4.3 Solution Provided**

Capgemini designed and developed the next generation device in different stages and developed the mechanical-, hardware-, firmware- and software subsystems. In addition, Capgemini developed the detailed design of enclosure components, the assembly, the production of prototypes to validate functional requirements, the execution of pre-compliance/compliance tests and commercial off-the-shelf validation. In parallel, all design and manufacturing artefact for regulatory submission requirements were created. The final validation was carried out by the customer.

### **4.4.4 Benefits**

The result was a compliant medical device meeting the general safety and performance requirements with all documentation for technical file submission in place. This made the customer less dependent on equipment from one supplier.

## 5.0 Outlook

The new MDR/IVDR regulations and the associated UDI have considerable potential to improve traceability of medical devices, transparency of related data and ultimately, the safety of patients. In this regard, meeting the regulations is a prerequisite for further business growth. Therefore, all stakeholders must develop a deep understanding of the underlying changes to ensure continued compliance with EU regulations.

During the entire journey towards MDR compliance and UDI implementation, Capgemini enables its customers to implement the necessary changes. By combining sector knowledge, practical expertise and a broad partner network, Capgemini ensures that today's technology reaches tomorrow's patients.



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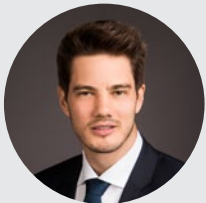
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## About Capgemini

Capgemini is a global leader in consulting, digital transformation, technology and engineering services. The Group is at the forefront of innovation to address the entire breadth of clients' opportunities in the evolving world of cloud, digital and platforms. Building on its strong 50-year+ heritage and deep industry-specific expertise, Capgemini enables organizations to realize their business ambitions through an array of services from strategy to operations. Capgemini is driven by the conviction that the business value of technology comes from and through people. Today, it is a multicultural company of 270,000 team members in almost 50 countries. With Altran, the Group reported 2019 combined revenues of €17billion.

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