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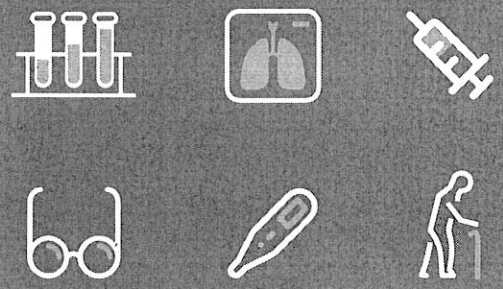
主旨：檢送歐盟執委會因歐盟新版醫療器材法規MDR(2017/745/EU)即將實施，近期更新之製造商應注意事項文件，及駐歐盟兼駐比利時代表處經濟組摘譯資料（如附件），請卓參。

說明：依據駐歐盟兼駐比利時代表處110年3月5日比貿字第1100000145號函辦理。

正本：台灣醫療暨生技器材工業同業公會
副本：中華民國全國工業總會（含附件）、駐歐盟兼駐比利時代表處經濟組

局長 江文若

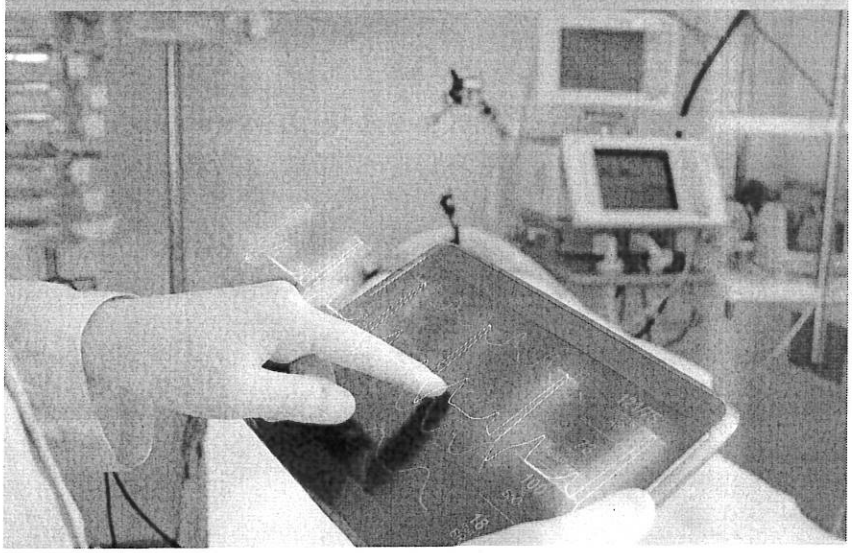
European Commission



Factsheet for Manufacturers of medical devices

MEDICAL DEVICES CHANGE OF LEGISLATION

What you need to know!



This Factsheet is aimed at manufacturers of medical devices. For a general overview of the impact of the in vitro diagnostic medical devices Regulation (IVDR) on manufacturers see the Factsheet for manufacturers of in vitro diagnostic medical devices. References to Annexes and Articles in this factsheet refer to the MDR (2017/745/EU).

The new medical devices Regulation (2017/745/EU) (MDR) and the *in vitro* diagnostic medical devices Regulation (2017/746/EU) (IVDR) bring EU legislation into line with technical advances, changes in medical science, and progress in law making.

The new Regulations create a robust, transparent, and sustainable regulatory framework, recognised internationally, that improves clinical safety and creates fair market access for manufacturers.

In contrast to Directives, Regulations do not need to be transposed into national law. The MDR and the IVDR will therefore reduce the risks of discrepancies in interpretation across the EU market.

Transitional periods are planned to smooth the application of the new Regulations. However, you should bear in mind that consultants, in-house professionals, and Notified Bodies will all get busier as the deadline draws closer.

Act now to be ready on time!

Medical devices Regulation (MDR) background

The MDR will replace the existing medical devices Directive (93/42/EEC) (MDD) and the active implantable medical devices Directive (90/385/EEC) (AIMDD). The MDR was published in May 2017, marking the start of a four year period of transition from the MDD and the AIMDD.

During the transitional period the MDR will come into force gradually, starting with the provisions related to the designation of Notified Bodies and the ability of manufacturers to apply for new certificates under the MDR.

The transitional period will end on 26 May 2021, the "Date of Application" (DoA) of the Regulation. From that date the MDR will apply fully.

To avoid market disruption and allow a smooth transition from the Directives to the Regulation, several transitional provisions are in place (Article 120). Some devices with certificates issued under the Directives (AIMDD/MDD certificates) may continue to be placed on the market until 26 May 2024[1], and made available until 26 May 2025[2].

During the transition phase, products certified under the Directives and products certified under the Regulation will coexist on the market. Both will have equal status under the law, and no discrimination on eligibility criteria in public tenders may take place.

What has changed?

In terms of their impacts on manufacturers and products, the Directives and the MDR largely share the same basic regulatory requirements. No existing requirements have been removed, but the MDR adds new requirements.

Compared to the current Directives, the MDR places more emphasis on a life-cycle approach to safety, backed up by clinical data.

The MDR brings more stringent requirements for the designation of Notified Bodies, with increased control and monitoring by the national competent authorities and the Commission.

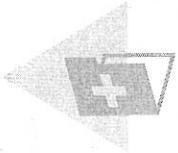
The MDR reclassifies certain devices and has a wider scope. For instance, the MDR explicitly covers all devices for cleaning, sterilising or disinfecting other medical devices (Article 2.1); reprocessed single-use medical devices (Article 17)[3]; and certain devices with no intended medical purpose (Annex XVI).

The MDR also covers internet sales of medical devices and medical devices used for diagnostic or therapeutic services offered at a distance (Article 6).

The MDR introduces a clinical evaluation consultation procedure for some Class IIb devices and for implantable Class III devices by an independent expert panel (Article 54).

A new Unique Device Identification system (Article 27) will significantly enhance the traceability and the effectiveness of post-market safety-related activities.

The MDR will also provide increased transparency, with information on devices and studies being made public. The new European Database for Medical Devices – EUDAMED – will play a central role in making data available and increasing both the quantity and quality of data (Article 33).



What does this mean in practice?

Scope (Article 1)

The scope of the MDR has broadened, so as a manufacturer you must check your product portfolios to find out whether more of your devices fall within the scope of the Regulation compared to the Directives. Pay attention to products listed in Annex XVI, which will be covered by the Regulation once the respective Implementing Regulation setting out common specifications has been adopted. The list of products excluded from the scope can be found in paragraph 6. Some products that combined a medical device and an *in vitro* diagnostic device or a medicinal product follow specific rules (see paragraphs 7, 8, 9).

It is now explicit that devices and services sold online fall under the scope of this Regulation (Article 6).

Definitions (Article 2)

The definition of a medical device has been slightly modified and there are more definitions of terms in the Regulation than in the Directives, in order to ensure a common understanding at EU level. Examples include: Unique Device Identifier (Definition 15), clinical data (Definition 48), clinical evidence (Definition 51), and serious incident (Definition 65).

Obligations of manufacturers

The obligations of the different actors and their relations are now clearly stated in the Regulation.

According to Article 10, manufacturers shall have systems for risk management (paragraph 2) and quality management (paragraph 9); conduct clinical evaluations (paragraph 3); compile technical documentation (paragraph 4); and apply a conformity assessment procedure (paragraph 6). Manufacturers are also responsible for their devices once they are on the market (paragraphs 12, 13, 14). They must have systems in place to cover their financial responsibility for harm caused by defective devices (paragraph 16).

Every manufacturer shall have a named person responsible for regulatory compliance (Article 15).

Manufacturers of some implantable devices will have to provide an implant card for the patient (Article 18).

Once they have completed all these obligations, manufacturers shall draw up a declaration of conformity (Article 19) and apply CE marking to their devices (Article 20).

Manufacturers outside the EU/EEA shall have a contract with an authorised representative inside the EU/EEA[4] (Article 11).

1 For definition see Article 2 paragraph 282
2 For definition see Article 2 paragraph 27
3 Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this Article.
4 EEA: European Economic Area

The obligations of authorised representatives (Article 11), importers (Article 13) and distributors (Article 14) are also clearly described.

Risk classes of devices

As a manufacturer you must check your portfolio of products to determine whether some of your devices will be reclassified or will need to be scrutinised by a Notified Body. Determining the risk class of a medical device is essential in specifying the steps required for CE marking (Article 51), especially in terms of the choice of conformity assessment procedure and clinical requirements.

The MDR sets out 22 rules for determining risk classes (Annex VIII), compared to 18 rules under the Directive. You should pay special attention to rules regarding: invasive devices, surgically invasive devices and implantable devices (Section 5: Rules 5 to 8); active devices (Section 6: Rules 9 to 13, for example, software now falls under Rule 11); devices utilising tissues and cells (Rule 18); devices incorporating nanomaterials (Rule 19); and devices composed of substances (Rule 21).

Notified Bodies (Chapter IV)

Notified Bodies have to be designated under the new Regulation. They will be required to meet more stringent criteria, particularly in terms of clinical competence. Notified Bodies can apply to be designated from 26 November 2017. The process of designation, which might take 12 months or more, involves assessors from both national and European authorities. This means that the first Notified Bodies designated under the new Regulation might be available by the beginning of 2019.

The database of Notified Bodies (NANDO) can be found *here*.

As a manufacturer you must verify whether your Notified Body will be designated under the new Regulation and whether the scope of its designation will cover all your products. You must also start working with your Notified Body to plan the timing of certification for your product portfolio, taking into account the availability of your Notified Body, the need for additional data on devices and the transitional provisions in the new Regulation.

Device identification

A system of unique device identifiers (UDIs) will enhance the identification (Article 27) and traceability (Article 25) of MDs. This is a completely new feature of the Regulation.

Each MD – and as applicable, each package – will have a UDI composed of two parts: a device identifier (UDI-DI) specific to a device, and a production identifier (UDI-PI) to identify the unit producing the device.

Manufacturers are responsible for entering the necessary data on the European database (EUDAMED), which includes the UDI database, and for keeping it up to date.

Conformity assessment (Chapter V Section 2)

The assessment of the conformity of a device for CE marking varies according to the risk class and specific features of certain devices (Article 52). The intervention of a Notified Body is needed for all Class IIa, IIb and III devices, as well as some specific Class I devices (see paragraphs 7a[5], b[6], and c[7]). The different routes of assessment according to the class of the device are described in Article 52 and the Annexes IX, X, XI. In some cases manufacturers have some choice regarding the conformity assessment route.

For certain Class III and Class IIb devices there is a new clinical evaluation consultation procedure to be carried out by an independent expert panel, based on the clinical evaluation assessment report of the Notified Body (Article 54).

Annex I specifies the general safety and performance requirements, while Annexes II and III specify the makeup of the technical documentation.

The scope of the Quality Management System (Article 10 paragraph 9) now includes clinical evaluation and post-marketing clinical follow-up (PMCF). A clinical evaluation plan must precede the clinical evaluation itself (Annex XIV, Part A).

Common specifications defining additional requirements may be put in place for certain devices (Article 9).

Clinical requirements (Chapter VI)

The new Regulation reinforces the requirements for clinical evaluation (Article 61), introducing some of the biggest changes compared to the previous regime.

As under the Directives, it includes the collection of clinical data already available in the literature as well as the setting up of any necessary clinical investigations. The concept of equivalence with other devices for which clinical data already exists can still be used, but only in a limited number of situations, and the new rules are tighter (Article 61 paragraphs 4, 5, 6).

Article 62 and Annex XV set out the new and more precise requirements for clinical investigations. With only certain exceptions, implantable and Class III medical devices must now go through clinical investigations.

For all Class III devices, and for Class IIb devices intended to administer a medicinal product (or remove it from the body), the manufacturer has the option to consult a group of European experts to obtain an upstream review of its intended clinical development strategy (Article 61 paragraph 2).

5 "Devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions".
6 "Devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements".
7 "Reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use".

Summary of safety and clinical performance (Article 32)

For Class III and implantable devices, manufacturers shall draw up a summary of their safety and clinical performance in a form that intended users (and patients, if relevant) can understand. This summary will form part of the technical documentation sent to the Notified Body.

Timing your transition to the new Regulation

As a manufacturer, the timing of your transition to the MDR is up to you.

From 26 May 2021, all new certificates will have to be delivered according to the Regulation. The certificates delivered under the Directives can be valid until their date of validity for a maximum of four years (27 May 2024[8] at the latest). However, in the latter case, the requirements of the new Regulation relating to post-market surveillance, market surveillance, vigilance, and the registration of economic operators and devices shall apply from the Date of Application (Article 120 paragraph 3).

Class I devices (other than those that have a valid certificate under the Directive) will have to conform to the new Regulation from 26 May 2021.

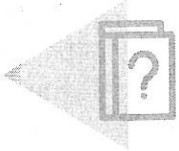
Class I (except sterile devices, devices with a measuring function and reusable surgical instruments) and Class IIa might be easiest to start with. Classes IIb and III will be more challenging because of the more stringent requirements for clinical data.

As a manufacturer, you can start now by making sure that:

1. all your products are classified appropriately;
2. all product documentation and evidence of compliance will be available in a timely fashion and conforms with the MDR; and
3. you have the necessary systems in place to handle clinical evaluation, quality management, post-market surveillance, and liability for defective devices.

More information

For more information on any of the above topics, please refer to the Medical Devices section on the *European Commission website*.



Frequently asked questions

Below you can find an extract from the FAQs of the Competent Authorities for Medical Devices. For a complete list, see:

https://www.camd-europe.eu/regulatory/available-now-mdr-ivdr-transitional-faqs/

When does the medical devices Regulation (MDR) apply?

The MDR (EU) 2017/745 will apply from 26 May 2021 – the "Date of Application" (DoA).

Some provisions of the MDR will come into force earlier (e.g. regarding Notified Bodies and the Medical Device Coordination Group). Some will apply later (e.g. regarding UDI labelling).

When do the existing Directives cease to apply?

In general, Directives 90/385/EEC and 93/42/EEC will be repealed on 26 May 2021 (the DoA). However, there are some exceptions, such as:

- for the continued marketing of devices that comply with the Directives (see below); and
- to serve as a backup in case EUDAMED is not fully functional by the DoA.

What is the applicable legislation up to 26 May 2021?

Until the Date of Application, the laws and regulations adopted by Member States in accordance with the Directives will continue to apply. However, there are some exceptions.

Is it possible to place devices on the market that are compliant with the MDR prior to the DoA?

Yes, you may certainly place MDR-compliant devices on the market before the end of the transitional period. This applies to devices in all risk classes, and includes, for example, custom-made devices, systems and procedure packs.

However, devices subject to the "clinical evaluation consultation procedure", which covers certain devices in Classes IIb and III, may not be placed on the market before the Medical Device Coordination Group (MDCG) and the expert panels have been established.

Depending on the risk class of the device, conformity assessment may involve an appropriate Notified Body. This requirement may create further delays before such devices can be marketed due to the delays in the availability of appropriate Notified Bodies for all technologies.

8 There are some exceptions described in Article 120 paragraph 2

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As a manufacturer, which obligations of the Regulation do I need to fulfil in order to place compliant devices on the market before the DoA?

You should meet as many obligations as possible, bearing in mind that the complete MDR infrastructure, including EUDAMED, may not be fully functional before the Date of Application.

Both the device and the manufacturer must comply with the MDR. You should assess the conformity of your device – a process that may require the involvement of a Notified Body. Other important points include:

- Clinical evaluation
- Risk management
- Quality Management System (QMS)
- Post-market surveillance
- Technical documentation and other reports
- Liability for defective devices.

Until EUDAMED is fully operational, some parts of the Directives will have to substitute for the corresponding requirements of the Regulation. These include the registration of devices and economic operators.

A person responsible for regulatory compliance needs to be available but not necessarily registered until EUDAMED is operational.

Do certificates issued by Notified Bodies under the existing Directives remain valid after the DoA?

Yes, AIMDD/MDD certificates will generally remain valid until their indicated expiry dates. This applies to all the certificates commonly issued by Notified Bodies, including the EC Design-Examination Certificates, Certificates of Conformity, EC Type Examination Certificates, the EC Certificate Full Quality Assurance System, and the EC Certificate Production Quality Assurance.

However, all certificates issued after 25 May 2017 will be void at the latest on 27 May 2024. By this date there will be no more valid AIMDD/MDD certificates.

Is it possible to have valid MDR and AIMDD/MDD certificates in parallel until 26 May 2024?

Yes.

Can manufacturers still place on the market/put into service Directive-compliant devices after the end of the transition period?

Yes, under certain conditions there will be an option to continue placing on the market/putting into service devices that comply with the Directives until their existing certificates expire. This may avoid the immediate need for a new certificate under the MDR.

To use this option, all the existing certificates will have to be valid (including, for example, the QMS), the purpose and nature of the device must not change, and you must follow the new MDR rules for registration, surveillance and vigilance.

What is the "sell-off" provision about?

The "sell-off" provision is intended to limit the time during which devices that are compliant with the Directives and have already been placed on the market may be made available.

Any devices that are still within the supply chain and that have not reached their final user as being ready for use, for example a hospital, on 27 May 2025 are no longer marketable and must be withdrawn.

Once a Directive-compliant device has been made available to the final user by the deadline, the further making available of this device is not subject to/covered by the Regulation.

01/08/2020

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https://ec.europa.eu/health/md_newregulations/overview_en

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歐盟新醫療器材法(MDR)簡介

駐歐盟經濟組編譯
110.03.05

一、 立法背景

為因應醫療科技演進及立法趨勢，歐盟於 2017 年 5 月公布新醫療器材法(Medical devices Regulation, MDR)[1]，將取代現行歐盟醫療器材指令(MDD)[2]及主動植入式醫療器材指令(AIMDD)[3]，且過渡期達 4 年，以利新舊法銜接運作。

歐盟 MDR 法規於過渡期內逐步生效，包括核定代施查核機構(Notified Bodies, NBs)相關條款，及製造商得依新法申請新許可證等。前述過渡期將於 2021 年 5 月 26 日結束，自當日起歐盟 MDR 將完全適用。

相較於現行歐盟醫材指令，歐盟新醫療器材法為歐盟層級規章，爰歐盟會員國無須再轉換為國內法，有助歐盟醫材市場之法律確定性。為避免對市場可能造成的干擾，確保自指令轉換為規章之順利運作，爰於第 120 條訂定若干過渡條款，另部分依據現行歐盟醫材指令核發許可證(AIMDD/MDD certificates) 之醫療器材，至 2024 年 5 月 26 日前仍可上市[4]，並可至 2025 年 5 月 26 日前於歐盟市場供應該等產品[5]。

在過渡期間依新、舊法獲許之醫療器材可於市場併存，

1 Regulation (EU) 2017/745
2 Council Directive 93/42/EEC
3 Council Directive 90/385/EEC
4 For definition see Article 2 paragraph 28
5 For definition see Article 2 paragraph 27

兩者具同等法律效力，且於公共招標之適格標準方面不具歧視性。

二、新法變革重點

(一) 在對醫材製造商及其產品的影響方面，歐盟 MDR 新法與現行歐盟醫材指令之基本規範大致相似，既有要求並未遭刪除，惟新法增訂若干新規定。

(二) 相較於現行指令，歐盟 MDR 強調產品生命週期的安全性，且須以臨床數據佐證。

(三) 歐盟 MDR 對驗證機構的要求較為嚴格，會員國主管機關及歐盟執委會均將加強管控與監視。

(四) 歐盟 MDR 對部分醫療器材重新分級及擴大範圍，如將涵蓋所有用以清潔、消毒其他醫材之器材(第 2.1 條)，及特定無預設醫療目的器材等(Annex XVI)。

(五) 歐盟醫材新法涵蓋於網路銷售之醫療器材，及作為遠端診斷及治療服務之器材等(第 6 條)。

(六) 歐盟 MDR 就部分第 IIb 級醫材及第 III 級植入性醫材，訂定由獨立專家小組進行臨床評估諮商程序規定(第 54 條)。

(七) 新的單一醫療器材識別系統(Unique Device Identification System) 將顯著強化可追溯性，及與後市場安全性相關活動之有效性(第 27 條)。

(八) 歐盟 MDR 將提升透明化，有關醫療器材及研究資訊將公開於新的歐盟醫療器材資料庫(European Database for Medical Devices, EUDAMED)，並將增進

其資料質量(第 33 條)。

三、 實務層面意涵

(一) 規範範圍(第 1 條)

1. 由於歐盟 MDR 規範範圍擴大，爰製造商應檢視其產品組合，確認是否有更多產品適用新法，並須留意 Annex XVI 產品清單，蓋因有關該等產品通用規格之執行規章通過後，將被納入新法規範範圍。

2. 排除適用之醫材產品清單係規範於第 6 段，至第 7、8、9 段則有關部分結合醫材、體外診斷器材或醫藥品等產品規範範圍。

3. 另根據第 6 條，線上銷售之醫材及服務亦涵括於歐盟 MDR 規範範圍。

(二) 定義(第 2 條)

新法對醫療器材定義微調，並較現行醫材指令擴增定義內容，以確保歐盟層級所達成之共識，如：第 9 項之單一器材識別碼(Unique Device Identifier)、第 48 項之臨床資料(clinical data)、第 51 項之臨床證據(clinical evidence)，及第 65 項之嚴重事故(serious incident)等。

(三) 製造商的義務

1. 根據第 10 條第 2 段及第 9 段，製造商應建立風險管理及品質管理系統、進行臨床評估(第 3 段)、彙整技術文件(第 4 段)、進行適用之符合性評估

程序(第 6 段)等。另製造商於產品上市後亦負有責任(第 12, 13,14 段)，且須建立因醫材瑕疵造成損害之財務責任系統(第 16 段)。

2. 根據第 15 條，製造商須設專人負責法遵業務。

3. 根據第 18 條，部分植入性醫材製造商，須提供病患植入資訊卡。

4. 依據第 19 及 20 條，製造商於完成所有相關義務後，應草擬符合性聲明書，及標示 CE Marking 於其醫材產品。

5. 根據第 11 條，歐盟或歐洲經濟區(EU/EEA)以外的製造商，應與 EU/EEA 之授權代表(authorized representative)簽訂合約，後者應盡義務亦規範於第 11 條；另有關進口商及經銷商之義務則明訂於第 13 及 14 條。

(四) 醫療器材風險分級

1. 製造商應檢視其產品組合，以確認醫材產品是否被重新分類，或須經代施查核機構驗證，爰先確定醫材風險分級，對於確認取得 CE 標示之步驟至為重要(第 51 條)，特別是在擇選符合性評估程序及臨床要求方面。

2. 歐盟 MDR 訂定 22 項醫療器材風險分級規則(Annex VIII)，較現行醫材指令之 18 項新增 4 項。須特別留意之處包括：侵入性器材、手術用侵入型器材、植入性器材(Section 5: Rule 5 to 8)、主動器材(Section 6: Rule 9 to 13，如：軟體)、使用組

織及細胞器材(Rule 18)、奈米材料器材(Rule 19)及由物質組成器材(Rule 21)等。

(五) 代施查核機構(第 IV 章)

1. 歐盟代施查核機構之核定將採更嚴格要求，尤以在臨床能力方面。代施查核機構於 2017 年 11 月 26 日起可申請核可，相關程序約歷時 12 個月，爰首批依新法獲核可之代施查核機構係自 2019 年公布，名單可於驗證機構資料庫(NANDO)[6]查詢(按：目前計核可 19 家)。

2. 製造商須確認往來之代施查核機構是否依歐盟新法獲核可，及其驗證範圍是否涵蓋擬銷售之醫療器材。製造商亦應與代施查核機構規劃其各項產品之查核時程，須考量因素包括代施查核機構之可用性、是否須補充提供其他醫材資訊，及新法轉換條款等。

(六) 醫療器材識別

1. 醫療器材單一識別系統(UDIs)將有助強化醫材識別及可追溯性(第 27、25 條)，此為歐盟 MDR 新特色之一。每項醫療器材及其包裝，均有 UDI 碼，其係由一器材識別碼(UDI-DI)，及一生產識別碼(UDI-PI)等兩部份所組成。

2. 製造商須負責於 EUDAMED 系統登錄必要醫材資訊（包括 UDI 資料庫），及應負責資料之更新。

(七) 符合性評估(第 V 章第 2 節)

6 https://ec.europa.eu/growth/tools-databases/nando/

1. 獲取 CE 標示之符合性評估程序，將依醫療器材風險等級，及部分醫材特徵而有差異(第 52 條)。

2. 針對第 IIa、IIb、III 級，及若干第 I 級醫療器材，須代施查核機構的介入；另依不同風險等級之符合性評估途徑，係規範於第 52 條及 Annex IX、X 及 XI，且在部分情況下製造商可進行擇選。

3. 針對部分第 III 級及第 IIb 級醫材，歐盟新法訂定由獨立專家小組(independent expert panel)基於代施查核機構之臨床評估報告，進行臨床評估諮商程序之規範(第 54 條) 。

4. 有關一般安全性及效能要求，係規範於 Annex I，另 Annex II、III 則與技術文件要求相關。

5. 根據第 10 條第 9 段規定，有關品質管理體系將納入臨床評估及後市場臨床追蹤(PMCF)；另臨床評估計畫須早於臨床評估(Annex XIV, Part A)。

6. 根據第 9 條，歐盟可針對特定醫療器材新增通用規格。

(八) 臨床要求(第 VI 章)

1. 歐盟新法強化對臨床評估的要求(第 61 條)，包括臨床文獻資料，及進行必要臨床調查(clinical investigations)等。

2. 另僅在有限情況下得使用其他同等醫療器材之臨床資料，並訂定較為嚴格規定(第 61 條第 4-6 段)。

3. 第 62 條及 Annex XV 規範對臨床調查之明確要求，

且除部分例外情況，植入性及第 III 級醫材須進行臨床調查。

4. 針對所有第 III 級醫材，及用於藥品注射或移除體外之第 IIb 級醫材，製造商可選擇諮詢歐洲專家團體，獲取有關其臨床開發之上游評估(第 61 條第 2 段)。

(九) 安全及臨床表現摘要(第 32 條)

針對第 III 級及植入性醫材，製造商須以使用者可瞭解形式，研擬其安全性及臨床表現摘要資訊，作為提送代施查核機構之技術文件的一部分。

四、 轉換至新法時程

自 2021 年 5 月 26 日起，所有上市許可須依歐盟醫材新法核發，依原歐盟醫材指令核發之上市許可，至多仍有 4 年效期(最遲至 2024 年 5 月 27 日[7])，惟後者自新法生效日起，即適用有關後市場監視、市場監視、警示，及業者與醫材註冊等規定。

除依現行醫材指令仍持有效上市許可外，第 I 級醫材應自 2021 年 5 月 26 日符合新法規範。

第 I 級醫材(除用於消毒、具測量功能及可重複使用手術工具以外)，及第 IIa 級醫材適法轉換相對較易，至第 IIb 級、第 III 級醫材較具挑戰性，主因係歐盟醫材新法對該類產品之臨床資料要求較為嚴格。

7 There are some exceptions described in Article 120 paragraph 2.

製造商須確認事項包括：

- 所有產品均已適當分級；
- 所有產品文件及符合性證明將及時符合新法規範；
- 建立必要系統處理臨床評估、品質管理、後市場監視及瑕疵醫材之責任等。

製造商倘擬瞭解進一步資訊，可逕至歐盟執委會官網 https://ec.europa.eu/health/md_newregulations/overview_en 查詢參閱。