衛生福利部食品藥物管理署

108年度「推動建立醫療器材來源流向管理機制計畫」

歐盟醫療器材法規(MDR)與單一識別系統要求

工業技術研究院 量測技術發展中心
醫療器材驗證室

中華民國108年

大綱

一、歐盟醫療器材法規(MDR)

二、歐盟醫療器材單一識別系統管理要求(EU UDI)

三、美國與歐盟UDI異同分析

一、歐盟醫療器材法規(MDR)

歐盟醫療器材法規

Current before 2020/5/26	Coming after 2020/5/26*
Active Implantable Medical Devices (AIMDD) Council Directive 90/385/EEC on (1990)	Regulation (EU) 2017/745 (MDR), April 5, 2017
Medical Devices (MDD) Council Directive 93/42/EEC on (1993)	
on in vitro Diagnostic Medical Devices (IVDMD)Council Directive 98/79/EC (1998)	Regulation (EU) 2017/746 (IVDR), April 5, 2017

*Extension.

[1]AIMDD/MDD certificates will generally remain valid until their indicated expiry dates

[2]All certificates issued after May 25, 2017 will be void at the latest by May 27, 2024.

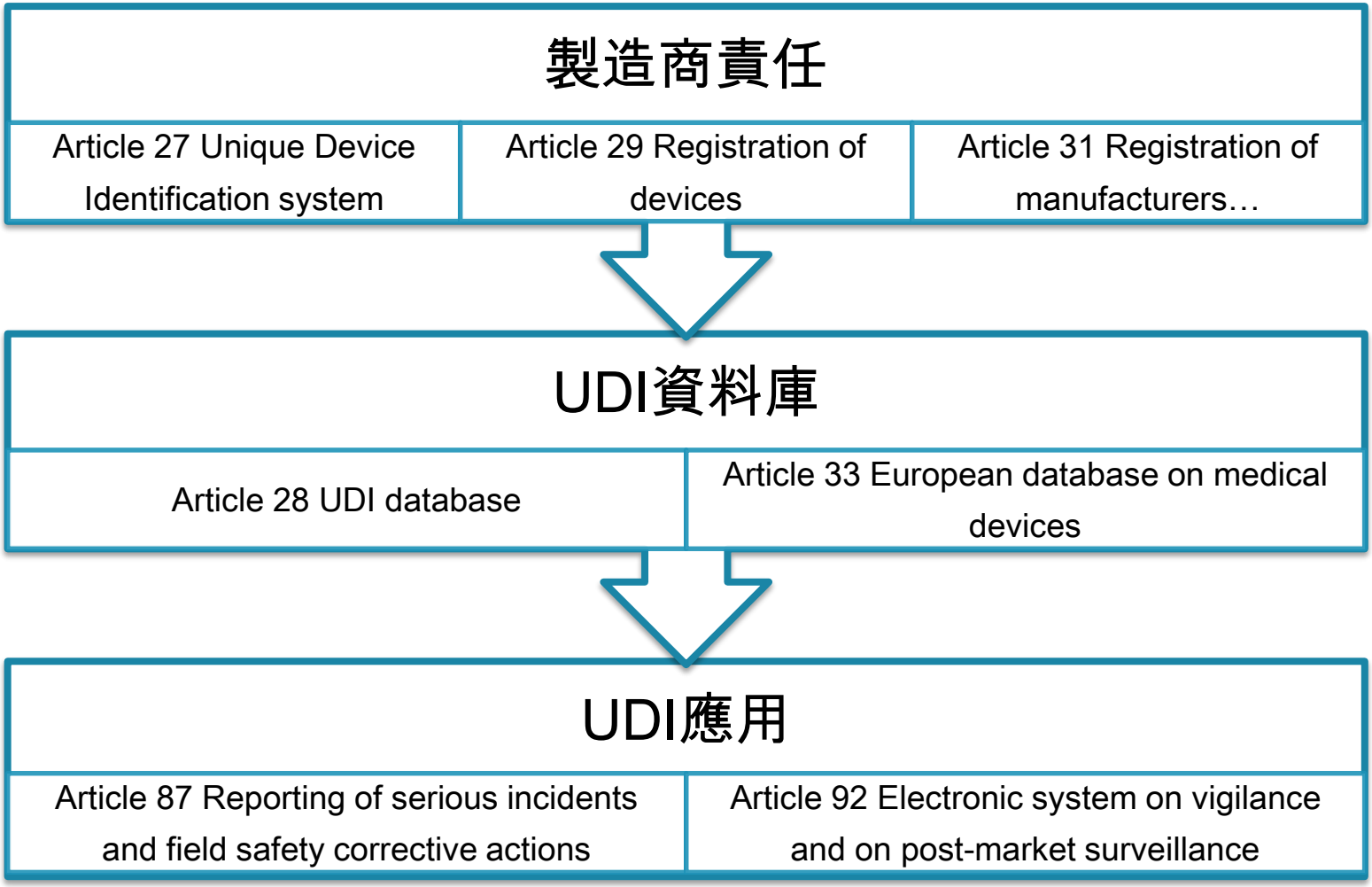
歐盟醫療器材法規(Highlights, Manufacturer)

- Scope (Article 1)
- Obligations of manufacturers (Article 10, 11, 13, 14, 15, 18, 20)
- Risk classes of devices (Annex VIII)
- Device identification, UDI (Article 25, 27)
- Conformity assessment(Article 52)
- Summary of safety and clinical performance (Article 32)

Factsheet for Manufacturers of Medical Devices, EU commission, 2018

二、歐盟醫療器材單一識別系統管理要求(EU UDI)

EU UDI法規相關條文



EU UDI法規剖析

1 編碼

UDI組成 (Part C of Annex VI)

- 器材識別 UDI device identifier (UDI-DI) + 生產識別UDI production identifier (UDI-PI)

HeRO graft, Merit medical Inc.

2 貼印

UDI貼印 (Article 27, 123)

- 器材標籤、最小包裝以上各層級包裝
- 本體標示(direct marking) 可重覆使用器材

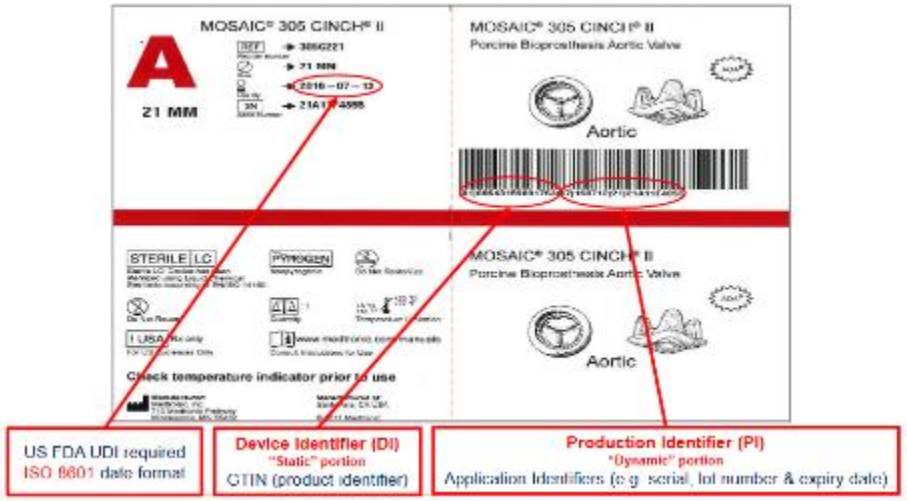
3 登錄

歐盟UDI資料庫 (Article 28 UDI database)

- 產品資料登錄欄位
- 產品資料登錄方式

1 UDI組成

- UDI Carrier：人眼可讀(HRI)及自動識別(AIDC)
  - In a plain-text version/human readable information (HRI) and in a form that uses AIDC technology.
- UDI Carrier：器材識別(UDI-DI)及生產識別(UDI-PI)
  - UDI = UDI device identifier (UDI-DI) + 生產識別UDI production identifier (UDI-PI)



UDI-DI UDI-PI

AIDC

HRI

(01)09504000059101
(21)19067811811
(10)563GS1
(17)200331

1 UDI組成

- 歐盟核准UDI發碼機構 (UDI issuing entities)：
  - GS1 AISBL
  - Health Industry Business Communications Council (HIBCC)
  - International Council for Commonality in Blood Banking Automation (ICCBBA)
  - Informationsstelle für Arzneispezialitäten (IFA) GmbH

GS1

HIBCC

ICCBBA-ISBT 128

2 UDI貼印

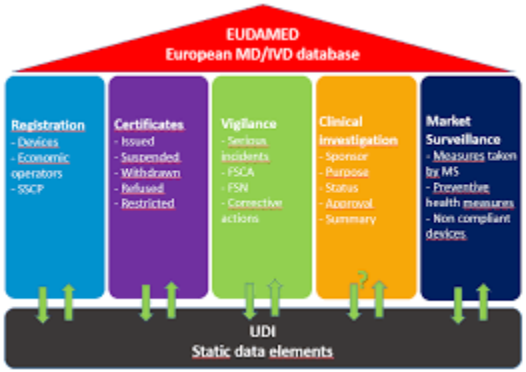
- 器材標籤與包裝貼印要求
  - 器材標籤、最小包裝以上各層級包裝
    The UDI Carrier shall be on the label or on the device itself and on all higher levels of device packaging.
- 排除條款(當空間受限(significant space constrain))
  - 可貼印於下一個層級包裝
  - 醫院使用器材優先標示自動識別(AIDC)
  - 非醫院用器材(如家用器材)優先標示人眼可識別標示(HRI)
- OTC特別條款
  - OTC販售器材，販售包裝層級標籤可免除生產識別(UDI-PI)標示要求
    For devices exclusively intended for retail point of sale(OTC), the UDI-Pis in AIDC shall not be required to appear on the point of sale packaging.

2 UDI貼印

- 本體標示(direct marking)
  - 適用對象：可重覆使用器材 (reusable devices)
  - 耐用性要求：產品生命週期內皆能被讀取
    Be readable during normal use and throughout the intended lifetime of the device.
  - 排除條款：當會影響產品安全與功效或技術不可行，可免除本體標示要求
    Interfere with the safety or performance of the device or not technologically feasible.

3 歐盟UDI資料庫

- UDI Database (EUDAMED)
  - 產品資料登錄欄位：
    MDR/IVDR UDI device data sets
  - 產品資料登錄方式：
    網頁登錄(EUDAMED)、資料交換(Machine-to-machine (M2M) data exchange)



EUDAMED public site:
https://ec.europa.eu/tools/eudamed

EU UDI 法規時限

- 法規符合時限：
  - 完成UDI編碼 (UDI assignment)：2020-5-26
  - 完成UDI資料登錄(Submission of EUDAMED/UDI Database)：2021-11
  - 完成UDI貼印 ：

	Implantable devices and Class III devices	Class IIa and Class IIb devices	Class I devices
器材標籤、最小及各層級包裝	2021-5-26	2023-5-26	2025-5-26
本體標示(Direct marking)	2023-5-26	2025-5-26	2027-5-26

EU UDI法規指引文件

Title	Publication	Date
MDCG 2019-1	MDCG guiding principles for issuing entities rules on basic UDI-DI	January 2019
MDCG 2019-2	Guidance on application of UDI rules to device-part of products referred to in article 1(8), 1(9) and 1(10) of Regulation 745/2017	February 2019
MDCG 2018-1 v2	Guidance on basic UDI-DI and changes to UDI-DI	February 2019
MDCG 2018-2	Future EU medical device nomenclature - Description of requirements	March 2018
MDCG 2018-3	Guidance on UDI for systems and procedure packs	October 2018
MDCG 2018-4	Definitions/descriptions and formats of the UDI core elements for systems or procedure packs	October 2018
MDCG 2018-5	UDI assignment to medical device software	October 2018
MDCG 2018-6	Clarifications of UDI related responsibilities in relation to article 16	October 2018
MDCG 2018-7	Provisional considerations regarding language issues associated with the UDI database	October 2018

三、美國與歐盟UDI異同

美國與歐盟UDI法規比較(摘要)

相似

- UDI法規依據IMDRF UDI Guidance建立(2013)
- UDI = HRI + AIDC
- UDI貼印：器材標籤及最小包裝與各層級包裝
- 採認之編碼機構(GS1, HIBCC, ICCBBA)
- 運輸用外箱、客製品、研究用器材免除UDI法規要求
- 提供部分排除/例外條款
- 可重覆使用器材之直接貼印(direct mark)要求

相異

- UDI法規職責(US FDA標籤貼印者labeler、EU法定製造商legal manufacturer)
- 醫療器材組件貼印要求(procedure packs)
- 部分排除/例外條款適用範圍(例如對於PI貼印要求)
- UDI-DI產品資訊登錄欄位(data elements)
- UDI-DI資料登錄/上傳方式

Jay Crowly, 2019 UDI Conference, 2019-6-11

FY108食品藥物管理署
「醫療器材單一識別系統法規諮詢服務」

「UDI產品資料彙整與登錄訓練」

UDI資訊平台-智慧資料彙整工具(AI-UDI)

UDI Help Desk諮詢服務

謝謝聆聽，敬請指導