本期企劃

歐盟醫材法規監管簡化要點暨臺灣廠商市場准入機會

Highlights on EU Medical Device Regulatory Simplification and Market Access Opportunities for Taiwanese Manufacturers

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摘 要

歐盟於2025年12月提出「簡化醫療器材及體外診斷醫療器材相關規則的法規提案」，包括醫療器材法規在流程簡化、減輕行政負擔、認證的可預測性與成本效益、專家小組的協調等面向之調整。本文從歐盟醫療器材法規調整之主要內容進行重點摘錄，並據此討論臺灣廠商前進歐盟市場的准入建議做法，包括從打破臨床資料轉化與資料治理瓶頸、提供諮詢小組預擬風險等級與監管框架、銜接全生命週期的場域驗證這三

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關鍵詞：場域驗證（field validation）、智慧醫材（smart medical device）、監管框架（regulatory framework）、臨床資料轉化（translation of clinical data）、體外診斷醫療器材（in vitro diagnostic medical devices）

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個面向提出技術面、法規面及市場面之因應建議。
The European Union put forward a legislative proposal to simplify rules concerning medical devices and in vitro diagnostic medical devices in December 2025; the proposal includes adjustments such as procedural simplifications, a reduction in administrative burdens, improved predictability and cost-effectiveness of certification, and enhanced coordination among expert panels. This article highlights the regulatory adjustments for medical devices in the European Union and discusses recommended strategies for Taiwanese manufacturers seeking to enter the European Union market. It offers response recommendations—covering technical, regulatory, and market dimensions—focused on three suggestions: overcoming bottlenecks in clinical data translation and data governance; utilizing advisory groups to determine preliminary risk classifications and regulatory frameworks; and integrating real-world validation across the product lifecycle.

壹、緒論

近10年來的醫療器材（下稱醫材）產業發展隨著資通訊科技的賦能，已然開始轉向接軌全球高齡化與數位醫療等高附加價值的創新應用。值此機會之窗，我國政府在近10年來亦從法規基礎建設開始，結合產學研成果，將醫材轉譯為臨床需求導向的產品，協助產業跨越商品化障礙，強化國產醫材在國際市場的競爭力。例如，2021年底修正通過之《生技醫藥產業發展條例》，已將精準醫療、數位醫療及專用於生技醫藥產業之創新技術平臺等納入適用範疇；同年施行之《醫療器材管理法》，逐步回應智慧醫材與數位醫療興起所帶來的監管需