本期企劃

體外診斷醫療器材之風險分級與監管架構：以歐盟、美國與台灣為例

Risk-based Classification and Regulatory Frameworks for In Vitro Diagnostic Devices: A Comparative Study of the EU, the United States, and Taiwan

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摘 要

隨著COVID-19疫情爆發及檢測技術快速發展，體外診斷醫療器材的監管議題日益受到各國關注。風險分級管理有助於依器材風險程度設計適當的監理強度，以兼顧安全與創新。本文比較歐盟、美國與我國在體外診斷醫療器材風險分級及監管架構之異同，分析各國於分類原則、監管要求及實驗室自行研發檢驗方法相關規範差異，以供我國建構更完備的監管架構，並強化產業國際競爭力。

With the global outbreak of COVID-19 and the rapid

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advancement of diagnostic technologies, the regulation of in vitro diagnostic medical devices (IVDs) has become an issue of growing concern worldwide. Risk-based classification systems are essential for aligning the level of regulatory oversight with the potential risks of each device, thereby striking a balance between ensuring safety and promoting innovation. This article compares the IVD risk classification and regulatory frameworks of the European Union, the United States, and Taiwan. It analyzes the differences in classification principles, regulatory requirements, and the oversight of laboratory-developed tests (LDTs) across these jurisdictions, with the aim of supporting the development of a more robust regulatory framework in Taiwan and strengthening the international competitiveness of its IVD industry.

壹、前言

體外診斷醫療器材（In Vitro Diagnostic Device, IVD）係指蒐集、處理或檢查取自人體之檢體，作為診斷疾病、決定健康狀態或其他狀況，而使用之診斷試劑、儀器、軟體或系統[1]。其應用範圍涵蓋傳染病檢測、遺傳疾病篩檢、治療監控、精準醫療與公共健康等多元領域。

近年來，隨著次世代定序（next-generation sequencing, NGS）等基因定序技術迅速發展，以及COVID-19疫情帶動全球對大規模、快速檢測工具之高度需求，IVD不僅在疾病控制與精準醫療領域中扮演關鍵角色，亦促使各國監管機關加速調整相關法制架構，以回應科技演進與社會急迫需求。

1 「醫療器材許可證核發與登錄及年度申報準則」第2條第3款。