衛生署 Department of Health
醫療器械科 Medical Device Division

InstruMedica @DH

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「創新通道」優先審批創新醫療器械，市民更快受惠先進技術

By Fast-tracking Novel Medical Devices, "Novo Lane" Ensures Citizens' Access to Advanced Technologies

衞生署醫療器械科 特設「創新通道」，加快***合資格創新醫療器械**的表列審批，讓市民更快受惠於先進技術。此外，我們亦透過持續對產品進行上市後監察，確保產品的安全性及性能，守護市民健康。

The Department of Health's Medical Device Division has established the "Novo Lane" to accelerate the approval of ***eligible innovative medical devices**, facilitating citizens to access advanced technologies sooner. In addition, we also continuously conduct post-market monitoring to ensure product safety and performance, safeguarding public health.

NovoLane @DH

截至2026年7月9日，衞生署醫療器械行政管理制度(MDACS)下的創新醫療器械表列數目:

As at 9 July 2026, no. of innovative MD listings under MDACS:

101

***合資格創新醫療器械**應符合以下任何一項：

*Eligible Innovative Medical Devices should possess any of the following:

獨特功能且市場上沒有同等產品（「首創」）

Unique feature without existing equivalence on the market ("First-of-its-kind")

過去五年內曾於參考司法管轄區透過創新審批通道獲得銷售核准

Referenced marketing approval under innovation channel from referencing jurisdictions within past 5 years

（例如：國家藥品監督管理局的「創新器械名錄」或美國食品藥物管理局的「De Novo 許可」）

(e.g. "創新器械名錄" in NMPA or "De Novo Approval" in FDA)

具備人工智能功能，且於過去五年內獲准於參考司法管轄區上市

Artificial intelligence features approved to be marketed in referencing jurisdictions in past 5 years

核心技術於過去五年內取得專利

Core technology patented within past 5 years

就相關表列申請的詳細要求，請參閱最新版本的指南文件GN-02及GN-06。

For detailed requirements of listing application, please refer to the latest Guidance Documents GN-02 and GN-06.

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