U.S. FDA UDI使用規範聲明書
Declaration of U.S. FDA UDI Policy for the Use of GS1 Standards

採用GS1國際條碼（GTIN）為醫療器材單一識別時，應遵循U.S. FDA UDI Rule規範條文之重要注意事項和原則。GS1前置碼申請廠商理解及認可下列事項：

Use of GS1 barcode numbers (GTINs) to identify MEDICAL DEVICES under U.S. FDA Rules – important & urgent action needed. The following rules shall apply:

1.GS1國際條碼(GTIN)由財團法人中華民國商品條碼策進會[GS1 Taiwan] 授權核發，除了其原本商品條碼相關用途與功能外，亦在美國、歐盟等數個國家核定准許其成為醫療器材單一識別 (unique device identifier, UDI)，GS1國際組織為U.S. FDA合法認可的UDI核發機構。

1.GS1 barcode number issued by GS1 Taiwan can be used as an UDI in several jurisdictions (e.g. U.S., EU). GS1 is accredited as an issuing agency for UDI by the U.S. FDA.

2.依據U.S. UDI Rule法規規定，GS1國際組織每年必須向U.S. FDA申報，所有使用GS1國際條碼作為其醫療器材產品出口至美國時產品標識之企業名單。

2.In that capacity, GS1 is required by law to declare to the U.S. FDA on an annual basis which companies use GS1 barcode numbers to identify medical devices that they (or their affiliates) are putting on the U.S. market under their label.

3.GS1前置碼申請廠商完全理解，當使用GS1標準做為醫療器材單一識別 (unique device identifier, UDI)時，應符合U.S. UDI Rule法規規定進行醫療器材產品標識。

3.The GS1 company Prefix member understands that when it uses [GS1 Key] to identify a product that may be characterised as a medical device under the U.S. UDI Rule where such product is marketed (a “Medical Device”).

如果GS1前置碼申請廠商未完成上述聲明事項，使用GS1國際條碼作為醫療器材單一識別在美國銷售醫療器材產品，GS1國際組織向U.S. FDA遞交的年度報告名單中將不會包含未簽署本聲明事項之GS1前置碼申請廠商。GS1對由此可能導致的任何後果（例如額外成本支出、行政程序、監管機構的要求）不需承擔任何法律責任。

If you do not report the use of GS1 barcode numbers to identify medical devices marketed in the U.S. under your label , your company will not be identified in our annual report to the U.S. FDA. GS1 disclaims any liability for any consequences (e.g. costs, administrative processes, requests from regulators) that may result thereof.

☐ 已閱讀及充份理解及同意上述聲明事項，醫療器材產品標識符合U.S. FDA UDI rule 規範

By signing below, I hereby acknowledge that I have completely read, fully understand and totally agree to the above policy and relevant statements,so as to use GS1 standards to implement the U.S. FDA Rule on Unique Identification of medical devices.

☐ 未出口任何產品至美國市場

None of our products being exported to U.S. market

廠商名稱：_____ 簽署日期：_____ 年 _____ 月 _____ 日

公司大小章：