< Appendix > Unique Device Identifiers (UDI)

Global Trade Item (GTIN) is used for unique identification of medical devices ("Unique Device Identifiers" or "UDI")

1. Member understands that GS1 Hong Kong is a member of the global GS1 organisation ("**GS1 Global Office**"), which has been accredited by certain regulatory agencies as an issuer of UDIs and, in that capacity, both are subject to certain regulatory obligations (e.g. reporting of companies that use the GS1 standards for unique identification of medical devices).

2. Member understands that when it uses GTIN to identify a product that may be characterised as a medical device under the laws of the country where such product is marketed (a "**Medical Device**"), the following rules shall apply:

   (a) Upon applying for a license, customer must inform GS1 Hong Kong if a GTIN will be used to identify a Medical Device which will be marketed in U.S.;

   (b) Member is and shall at all times remain responsible for the information about the Medical Device provided by it to GS1 Hong Kong and for compliance with any applicable regulatory obligations and shall ensure any information provided is accurate and up to date at all times;

   (c) GS1 Hong Kong may monitor correct implementation of the GS1 Standards by GS1 Hong Kong member;

   (d) In case GS1 Hong Kong identifies a **Deficiency** (as defined in point 3), GS1 Hong Kong may inform Member in writing of such Deficiency and requiring Member to correct such Deficiency within 90 calendar days from the date of the notification (the "**Correction Period**").

   (e) GS1 Hong Kong may monitor whether Member has corrected a Deficiency within the Correction Period. Failing such correction, at the latest 8 calendar days after expiry of the Correction Period, GS1 Hong Kong may contact Member again and seek to amicably resolve the Deficiency.

   (f) If the Deficiency is not corrected within an additional period of 90 days from the expiry of the Correction Period and pertains to a repeated and/or deliberate misuse of the GS1 Standards related to UDI, GS1 Global Office, working with the GS1 Hong Kong, may inform the regulator and modify the use (incl. suspension and revocation) of the GS1 Company Prefix for UDI implementation in the relevant jurisdiction, as a follow-up action taken in cooperation with the relevant regulator.

   (g) Member acknowledges and agrees that GS1 Hong Kong must, in the context of its regulatory obligations, share certain information with the relevant regulators either directly or via GS1 Global Office, including without limitation: the fact that Member uses the GTIN to identify Medical Devices marketed in U.S., the GTIN, the name of Member's company, as well as any identified and uncorrected Deficiencies. Member understands that neither GS1 Hong Kong nor GS1 Global Office may be held liable for any direct or indirect consequences, losses or damages resulting of GS1 Hong Kong and/or GS1 Global Office providing such information to a regulator.

3. For the purpose of this point, a "**Deficiency**" means any of the following: a misconstruction of the identifier, a mismatch between the name of the company holding the license for the GS1 Key and the company using the GS1 Key or any other inaccurate, incomplete or outdated information.

< 附件 > 醫療器材產品標籤 (UDI)

全球貿易貨品編碼 (GTIN) 是用於醫療器材產品的獨一無二識別碼 (醫療器材標籤 或 UDI)。

1. 會員明白香港貨品編碼協會是全球 GS1 組織 ("GS1 全球總辦事處") 的成員，已被有關監管機構認可發 UDI 行人，並同時承擔監管義務 (例如: 報告正使用 GS1 標準之醫療器材標籤的公司)。

2. 會員明白，當使用 GTIN 識別產品時，而該產品被銷售國家/地區的法律歸納為醫療器材產品 ("醫療器材產品") 時，應遵守以下規則：

    a. 會員必須於申請時告知香港貨品編碼協會，是否會使用 GTIN 作識別醫療器材產品並在美國銷售。

    b. 會員有責任在任何時間向香港貨品編碼協會提供最準確及最新的醫療器材產品資訊，以及遵守任何適用的監管規則。

    c. 香港貨品編碼協會可監察會員是否正確執行 GS1 標準。

    d. 若香港貨品編碼協會發現會員所提供的產品資訊有誤 (如第 3 點所定義)，我們會以書面通知會員在發出通知後 90 天內(修正期限)完成修正。

    e. 香港貨品編碼協會可監察會員在修正期限內是否已完成修正，否則，我們可於修正期限後最快 8 天內再次聯絡會員以尋求完滿解決方法。

    f. 如會員仍未能於修正期限後 90 天內完成修正，並發現其故意和/或重複不適當地執行與 UDI 相關的 GS1 標準，GS1 全球總辦事處聯同香港貨品編碼協會，通知有關監管機構共同採取跟進行動，修改其 GS1 公司字首在相關司法管轄區使用 UDI 的權利 (包括暫停和撤銷) 。

    g. 會員知悉並同意，香港貨品編碼協會必須在其監管義務的範圍內直接或通過 GS1 全球辦事處與相關監管機構共享部份資訊，包括但不限於，會員使用 GTIN 識別在監管機構所在國家/地區銷售的醫療器材產品上、全球貿易貨品編碼、會員企業名稱、以及所有已識別及未修正的產品資訊。會員明白香港貨品編碼協會和/或 GS1 全球辦事處向監管機構提供相關資訊所導致的任何直接或間接後果、損失或損害，香港貨品編碼協會和 GS1 全球辦事處概不負責。

3. "產品資訊有誤" 是指以下任何一種情況：識別碼結構出錯、GS1 識別碼的公司名稱與使用 GS1 識別碼的公司名稱不符合或其他任何不準確、不完整或過時的資訊。