



26 April 2021

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

Dear GS1 Thailand's members,

More and more countries are adopting laws that require companies that manufacture, label or distribute medical devices to identify these with a “unique device identifier” (UDI). As you may know, in addition to its many other uses, a GS1 barcode number issued by GS1 Thailand can be used as an UDI in several jurisdictions (e.g. U.S., EU).

Specifically, GS1 is accredited as an issuing agency for UDI by the U.S. FDA. 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.

Therefore, if your company uses GS1 barcode numbers to identify medical devices that are currently on the U.S. market for UDI purposes, we kindly ask you to fill in the “UDI Declaration form for GS1 Thailand's members” at <https://forms.gle/cHbwDMJzPXEDJMrw8> or in the attached form by 30 September 2021.



Please also note that we are updating our own terms and conditions to make it compulsory to keep this information up to date (see attached terms and conditions).



สถาบันรหัสสากล GS1 THAILAND

สภาอุตสาหกรรมแห่งประเทศไทย THE FEDERATION OF THAI INDUSTRIES

If you do not report the use of GS1 barcode numbers to identify medical devices marketed in the U.S. under your label by 30 September 2021, your company will not be identified in our annual report to the U.S. FDA. GS1 and GS1 Thailand disclaim any liability for any consequences (e.g. costs, administrative processes, requests from regulators) that may result thereof.

If you do not use GS1 barcode numbers to identify medical devices that are currently on the U.S. market, you can disregard this letter.

We thank you for your kind co-operation and remain available for any questions. Please send your questions to jirapornc@gs1thailand.org and metineew@gs1thailand.org.

Yours sincerely,



(Mr. Sinchai Thiensiri)

CEO of GS1 Thailand

The Federation of Thai Industries

GS1 Thailand Healthcare & AIDC

Email: jirapornc@gs1thailand.org and metineew@gs1thailand.org.

Section 1 : Rules of Membership

(1) Member who applies for membership type of 1,500 Baht and 3,000 Baht must be an entrepreneur registering not over 1 year, an authorized capital less than or equal to 5 million Baht OR registering more than 1 year, an income before expenses less than or equal to 5 million Baht.

(2) The member will receive registered numbers based on a particular type of structure as approved by GS1 Thailand as follows:

2.1 A membership 1,500 Baht/year will get 9 codes. In case the next year income before expenses is **more than 5 million Baht**. We will modulate the annual membership fee higher with the **specified rate***.

Member remains the same structure 9 codes of initial registration.

2.2 A membership 3,000 Baht/year will get 99 codes. In case the next year income before expenses is **more than 5 million Baht**. We will modulate the annual membership fee higher with the **specified rate***.

Member remains the same structure 99 codes of initial registration.

(3) If the member under 2.1 and 2.2 wishes to apply more barcodes:

3.1 In case the income before expenses is **more than 5 million Baht**.

The member must apply for 9999 codes and pay an entrance fee at 7,000 Baht and the annual membership fee at the **specified rate***. (considered from the income before expenses)

3.2 If the member who registers to 9 codes (1,500 Baht/year) for the initial registration and has the income before expenses less than or equal to 5 million Baht requests the additional numbers, the member can apply for 99 codes. In case of asking for 9999 codes, the member will have to pay the entrance fee at 7,000 Baht and the annual membership fee at the **specified rate***. (cannot apply for 9 codes in the second structure)

3.3 If the member who registers to 99 codes (3,000 Baht/year) for the initial registration and has the income before expenses less than or equal to 5 million Baht requests the additional numbers, the member can apply for 99 codes. In case of asking for 9999 codes, the member will have to pay the entrance fee at 7,000 Baht and the annual membership fee at the **specified rate***.

(4) A collection of next year annual membership fee for 9999 codes is based on the ~~income before~~ expenses of the member.

(5) In case the member does not wish to continue using the GS1 Standard Barcode. The member must write an advanced cancellation notice to GS1 Thailand by registered mail or e-mail before **30th June of that year**. If it is overdue, the member will have to pay the membership fee for that year.

(6) The member is willing to follow the rules and regulations of GS1 Thailand in all aspects and the member has no right to sell the number(s) to others whether it has a compensation or not. The transfer case must be complied with the rules and regulations of GS1 Thailand.

(7) The member allows GS1 Thailand to reserve the right to change or add any rules or regulations as GS1 Thailand deems appropriate. The rules and regulations will take effect immediately once the member has been approved as the GS1 Thailand member.

(8) The member will cooperate with GS1 Thailand to update information and fill in the details requested by GS1 Thailand, also carefully read and understand the rules and regulations as well as agree to comply with all aspects.

*** Specified rate**

(Considered from the income before expenses.)

Income over 5 million Baht - 50 million Baht, the rate is 8,000 Baht

Income over 50 million Baht - 100 million Baht, the rate is 10,000 Baht.

Income over 100 million Baht, the rate is 12,000 Baht.

Section 2 : GTIN used for unique identification of medical devices (“Unique Device Identifiers” or “UDI”)

- (1) The member understands that GS1 Thailand 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) The 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:
 - 2.1. Upon applying for a license, the member must inform GS1 Thailand if a GTIN will be used to identify a Medical Device and in which country the related product will be marketed;
 - 2.2. The member is and shall at all times remain responsible for the information about the Medical Device provided by it to GS1 Thailand and for compliance with any applicable regulatory obligations and shall ensure any information provided to GS1 Thailand is accurate and up to date at all times;
 - 2.3. GS1 Thailand may monitor correct implementation of the GS1 Standards by the member;
 - 2.4. In case GS1 Thailand identifies a Deficiency (as defined in section 3 below), GS1 Thailand may inform the member in writing (addressed to the member’s usual contact person) of such Deficiency, suggesting a way to correct the Deficiency and requiring the member to correct such Deficiency within 90 calendar days from the date of the notification (the “**Correction Period**”).
 - 2.5. GS1 Thailand may monitor whether the member has corrected a Deficiency within the Correction Period. Failing such correction, at the latest eight (8) calendar days after expiry of the Correction Period, GS1 Thailand may contact the member again and seek to amicably resolve the Deficiency.
 - 2.6. 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 Thailand, 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.
 - 2.7. The member acknowledges and agrees that GS1 Thailand 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 the member uses the GTIN to identify Medical Devices marketed in the regulator’s country, the GTIN, the name of the member’s company, as well as any identified and uncorrected Deficiencies. The member understands that neither GS1 Thailand nor GS1 Global Office may be held liable for any direct or indirect consequences, losses or damages resulting of GS1 Thailand and/or GS1 Global Office providing such information to a regulator.
- (3) For the purpose of this section, 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



Rules and Regulations of GS1 Thailand Membership

Signature _____ Authorized person/company seal (if applicable)

(_____) (Elaborate handwriting)

Position _____

Date ___ Month _____ Year _____

(Effective April 8, 2021)