The Global Language of Business

Unique Device Identification (UDI) Declaration Guide

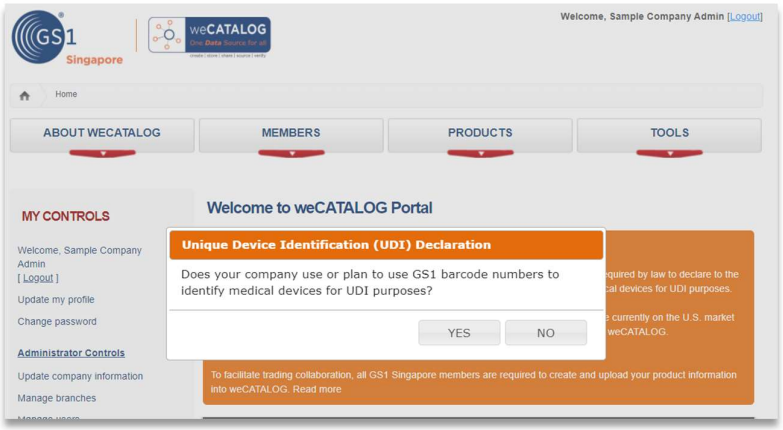
GS1 is accredited as an UDI issuing agency based on regulations worldwide, in particular US, EU, China, South Korea and Saudi Arabia. In that capacity, GS1 is required by law to declare to the U.S. FDA on an annual basis which companies use GS1 barcode numbers to identify medical devices for UDI purposes. To enable this, GS1 members must submit their declaration in weCATALOG:

1. Login to GS1 weCATALOG

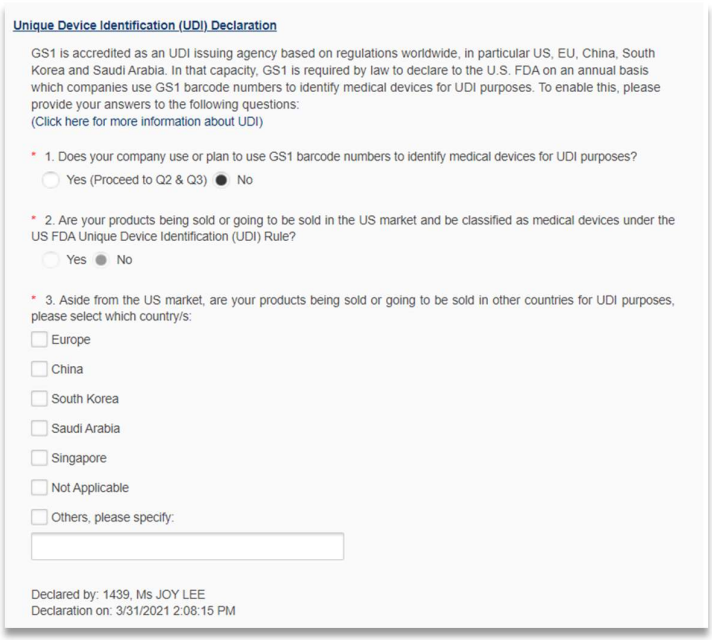
   https://wecatalog.gs1.org.sg/Home.aspx

For companies without declaration yet, a pop-up window will be prompted upon login:

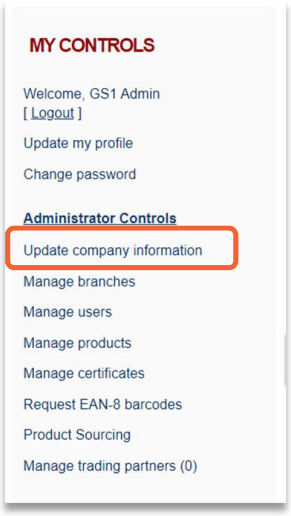
If the answer is **YES**, the system will direct to the UDI Declaration panel:



If the answer is **NO**, the system will update the UDI Declaration automatically as per the screenshot below:

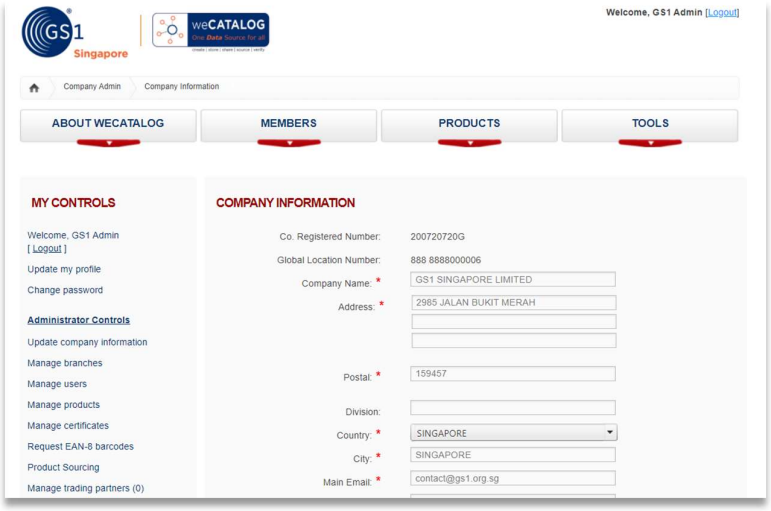


2. To update the declaration: In Administrator Controls panel, click on 'Update Company Information':



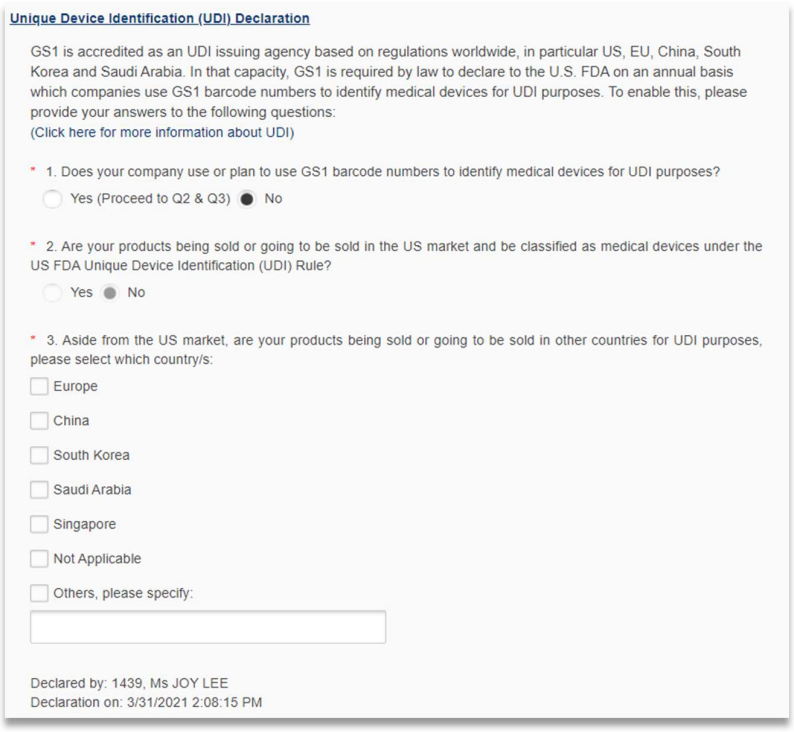
3. Under Company Information, scroll down to the UDI declaration and then click Update button at the bottom:

First View:



Scroll Down to UDI Declaration:

In this panel, please select the answers appropriate to your company.



Click 'Update' button at the bottom of the page to save your changes:

GS1 Singapore ID Keys used for unique identification of medical devices ("Unique Device Identifiers" or "UDI"

1. Licensee understands that GS1 Singapore 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. Licensee understands that when it uses GS1 Singapore ID Key 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, a licensee must inform GS1 Singapore if a GS1 Singapore ID Key will be used to identify a Medical Device and in which country the related product is or will be marketed;

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

(c) GS1 Singapore may monitor correct implementation of the GS1 Standards by Licensee;

(d) In case GS1 Singapore identifies a Deficiency (as defined in section 3 below), GS1 Singapore may inform Licensee in writing (addressed to Licensee usual contact person) of such Deficiency, suggesting a way to correct the Deficiency and requiring Licensee to correct such Deficiency within 90 calendar days from the date of the notification (the "Correction Period").

(e) GS1 Singapore may monitor whether Licensee 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 Singapore may contact Licensee 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 GS1 Singapore, 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) Licensee acknowledges and agrees that GS1 Singapore 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 Licensee uses the GS1 Singapore Identification Key to identify Medical Devices marketed in the regulator's country, the GS1 Singapore ID Key, the name of Licensee company, as well as any identified and uncorrected Deficiencies. Licensee understands that neither GS1 Singapore nor GS1 Global Office may be held liable for any direct or indirect consequences, losses or damages resulting of GS1 Singapore 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.