



Q&As in the context of implementation of NMPA UDI requirements

China Filing Procedures of GS1 Company Prefix (GCP) / Global Trade Item Numbers (GTINs)

1. China Filing Procedure

Who needs to do filing?

The GTIN filing procedure is only applicable for the Chinese Domestic Company whose products are marked using a GTIN allocated with a GS1 Company Prefix or individually assigned GTIN not licensed by GS1 China:

- a. manufactured or distributed by the Chinese Domestic Company and sold directly in Chinese mainland market;
- b. and marked with the name of the Chinese Domestic Company on its labels or packages;

Note: There is no GTIN filing requirement for products imported into or exported from Chinese mainland.

How to do filing?

The Chinese Domestic Company needs to call 400-7000-690 (The language is Chinese), there is an automatic information broadcast, that will help company finish GTIN Filing.

The detail of the process:

- **The Chinese Domestic Company** needs to provide the following documents (Chinese language documents are acceptable) when it applies to do filing with GS1 China.
 - 1) One copy of Chinese Domestic Company's Business License.
 - 2) A photo of the packaging of one item that includes the name of the Chinese Domestic Company (this is only required for a GTIN level Filing, not Filing at a GCP Level).
 - 3) A single application form will be used by Chinese Domestic Company to file for the GTIN or GCP Filing by listing multiple prefixes on the same form.For GTIN filing renewal in the subsequent year, filing documents can be exchanged in electronic copies.
- **GS1 Company Prefix Licensee** needs to decide to do the filing either at the GCP level or at the GTIN level according to actual needs, and provides the MO where the GCP is

registered with the electronic document of the Authorization Declaration with an official seal or signature (see Attachment).

- The MO where the GCP/or individually assigned GTINs is registered needs to forward the electronic document of the Authorization Declaration to the contact person at GS1 China office through email.

The contact persons at GS1 China:

Ms. Zhang Yuan zhangy@ancc.org.cn

Ms. Hao Yuan haoy@ancc.org.cn

- GS1 China will complete the filing within two working days after receiving and checking the required documents as described in item one and item three above.
- GS1 China will issue the original Notice of Filing Approval to the applicant (Chinese Domestic Company) and inform the result to the MO where the GCP is registered by email after the final approval.

The Notice of Filing Approval is valid for two years. Chinese Domestic Company needs to renew the registration within three months before the expiring date.

If the validity of the License of overseas GCP/or individually assigned GTINs or Authorization Declaration is less than two years, then the valid date of the Notice of Filing Approval will be equal to the date of whichever expires earlier.

There is no charge for the filing.

Online reference materials in Chinese:

Online registration: <http://ancc.org.cn/Business/Barcode/Register.aspx>

Procedure: <http://glb.ancc.org.cn/WSBA/help.pdf>

Attachment:

To: GS1 China

Authorization Declaration

Licensee's Name: XXXXX

Licensee's GS1 Company Prefix/es (for Prefix level Filing): XXXXX

OR Individually assigned GTINs (for GTIN level Filing) : XXXXX

The GS1 Company Prefix/es is valid until: XXXX/XX/XX (year/month/day)

Being the GS1 Company Prefix Licensee or Individually assigned GTINs of XXXXX (Name of the company who licensed the GS1 Company Prefix or Individually assigned GTINs), we fully understand the GS1 GTIN Management Standard. Herein, I declare to authorize the Chinese Domestic Company XXX (Company Name of Chinese Domestic Company) to use my Company Prefix or Individually assigned GTINs XXXXX (list of licensed Company Prefixes or Individually assigned GTINs).

The authorized GTIN List is in appendix (optional).

This authorization is valid until: XXXX/XX/XX (year/month/day)

Signature of the GS1 Company Prefix
or Individually assigned GTINs Licensee

Print Name (in English) of the GS1
Company Prefix
or Individually assigned GTINs Licensee Executive
(This form should be signed by a duly authorised Executive of the company)

Date: XXXX/XX/XX (year/month/day)

Appendix (to fill in the form if you want to do filing at GTIN level):

No.	GTINs	Product Name	Brand Name (Optional)	Specification	Packaging Type
1					
2					
3					
4					
5					
6					
7					
...					

2. Questions and Answers in the context of implementation of NMPA UDI requirements

The overall objective of this filing procedure is to fight counterfeiting products manufactured and sold in China.

Domestic companies are required to register GTIN's to ensure the legitimate use of foreign GCPs, should the device bear the labelling of a foreign company.

Q: Does the GS1 Member Organisation (MO) that issued the GCP or individual GTIN need to forward to GS1 China the Authorisation Declaration in order to use the "non-GS1 China GCP or individual GTIN" in China for applicable devices?

A: Yes, an authorisation from the relevant GS1 MO licencing the GCP or individual GTIN must be provided to GS1 China for our GTIN to be entered into the China UDID. Please contact the relevant GS1 MO and use the Authorisation Declaration provided in that document. The authorisation issued by the non-Chinese GS1 MO will ensure that the domestic company registering the GTIN is a legitimate user of the GS1 system.

Q: What are the consequences of not registering all applicable GTINs in this GS1 China site?

A: For the retail market, regulations already exist and might result in market withdrawal. However, we do not yet know the consequences for devices that are sold outside the retail environment, in healthcare in particular.

Q: Is there an English translation of the registration process described on the following page: <http://glb.ancc.org.cn/WSBA/help.pdf>

A: The translation will be provided later by GS1 China

Q: What does it mean to be a 'temporary procedure'? Is this filing an interim step so we can avoid having to issue new GTINs for products manufactured and sold in China?

A: The procedure mentions that "this is a temporary procedure". However, this refers to the regulation used as the legal basis for that procedure, not the filing authorisation itself. There is NO need for new GTINs, licensed from GS1 China, to be needed.

Q: If this is temporary – will this have to be done again in another system?

A: The current procedure states that the authorisation will be valid for 2 years. The exact date will be on the authorisation declaration. Please note that this may be subject to revision in the future.

**Q: Are all Medical Devices concerned which we place on the Chinese market, regardless where they are produced?
Or only the Medical Devices placed on the Chinese market and produced outside of China?
Or only the Medical Devices placed on the Chinese market and produced in China?**
A: Only medical devices produced and sold in China and bearing the name of a Chinese domestic company.

Q: What exactly does GS1 China need as documents? Is there a certain form which need to be filled?
A: Please see the list of documents in the Procedure above and the specific declaration and form provided above.

Decision tree

