

Quick Guide For NMPA UDID GDSN Implementation

Quick Guide For Medical Device License Holders/General Agents To Conduct NMPA UDID GDSN Implementation.

Release 1.1, Draft, drafted by Hua Wang, Sep. 2021







1. Submit the Authorization Statement for Production to GS1 China.

1.1 Log into the <u>website of Authorization Statement for Production System</u>, click "Agree", complete the form, and click "Submit" to trigger the data subscription.



Note: when the sign " appears, it means the submission is successful.

1.2 E-mail to GS1 China contact (Wei Bo, <u>bow@ancc.org.cn</u>) to indicate the completion of step 1.1 and confirm the request for GDSN implementation.

2. Complete the Authorization process on the NMPA UDID portal.

2.1 Log into the <u>Production system of NMPA UDID</u>, select "中国物品编码中心"(GS1 China) as the authorized agency, upload the Authorization Letter, and complete the authorization.



3. Make sure relevant medical device license information has been maintained in the UDID Production system.

3.1 Log into the <u>Production system of NMPA UDID</u> to view or maintain license information.

4. Upload UDI data into local data pools based on NMPA UDID data requirements.

- 4.1 Please find the latest version of the NMPA UDID to GDSN Attribute Mapping document at the top of the webpage \underline{here} .
- 5. Publish UDI data to NMPA UDID's Production GLN (6907777443952).
- 6. Manage CIC messages.
 - Take correction actions based on the CIC messages of "Review" (if any) resulting from data validations. Please find the NMPA UDID CIC Message Mapping document at the top of the webpage <u>here</u>.
- 7. Check UDI data in the Production system of NMPA UDID.
 - 7.1 Log into the *Production system of NMPA UDID* and check UDI data, if necessary.



FAQs

Q1: How can I obtain a NMPA UDID account?

- A1: There are two steps as follows:
 - First, register and login NMPA's Online Service Website.



• Second, conduct NMPA UDID system account authorization to create your NMPA UDID account. (For detailed instructions, please visit <u>here</u>.)





Q2: Why do I receive a CIC errorCode-7 saying "无权限维护非自身数据(The data provider has not been authorized to register/modify this data)"?

A2: This error usually happens due to one of the following reasons:

- You have no account in the NMPA UDID; or
- You have not confirmed the M2M connection authorization on the UDID portal as Step 2.1; or
- The M2M connection authorization expires, and you need to extend the M2M connection authorization period on the UDID portal as Step 2.1.

Q3: What are the implications for using GDSN to publish data that has already been submitted manually to NMPA? Will it override the record or be rejected? Does the data provider need to delete the manual record prior to GDSN publication?

A3: The data provider will receive a CIC message of "Review" with the errorCode-6 saying "数据重复 提交" (The data is duplicate.) because the data has been uploaded into the UDID manually and in such case the M2M method is not allowed. The data provider needs to delete the manual record in NMPA UDID prior to GDSN publication.