

Option 1

Step by Step guide for machine to machine data submission to the Chinese NMPA UDI Database

This document provides general guidance for data submission to the NMPA. For further information refer to <https://udi.nmpa.gov.cn/showListInterr.html>. The manufacturer is responsible for this process.

This document aims at presenting possible options for machine to machine submissions of regulated UDI data to Chinese NMPA Database. This document has been developed in collaboration with GS1 China to support global healthcare stakeholders.



Steps

1

Complete and submit the form

of Machine-to-Machine (M2M) Connection Application (about 1-2 weekdays). Relevant form and instructions are available at : <https://udi.nmpa.gov.cn/showListInterr.html>

2

Confirm the authorization on NMPA UDID portal.

Upon receiving the request to confirm authorization from GS1 China contact via E-mail, log into the Production system of NMPA UDID and confirm your authorization.

Note: the Authorization Confirmation in the UDID Production system will be auto-synced into the UDID Pre-production system the next day and work for data testing.

3

Develop M2M connection functionality

according to the NMPA APIs standards (no predefined timeframe)

4

Provide relevant information

about the company and its device registration/fill certificates on the NMPA UDID portal (no predefined timeframe)

5

Register directly UDI data

to the NMPA UDI Database using the relevant APIs (no predefined timeframe)

➔ Visit the NMPA UDID portal:
<https://udi.nmpa.gov.cn/showListInterr.html>

Please refer to this page for further information on how to connect to the NMPA UDID using API



Option 2

Machine to machine data submission to the Chinese NMPA UDI database via a GDSN Data Pool

This document provides general guidance for data submission to the NMPA. For further information refer to <http://gmd.gds.org.cn:8080/index.php?doc-view-43601>. The manufacturer is responsible for this process.

For UDI data submission to NMPA using a Data Pool (possible with GS1 China Data Pool), Global manufacturers are advised by GS1 China to follow these steps:



Steps

- 1** **Submit the Authorization Statement to GS1 China.**
 - 1.1** Log into the website of Authorization Statement, click "Agree", complete the form, and click "Submit";
 - !** Note: when the sign "✓" appears, it means the submission is successful.
 - 1.2** E-mail to GS1 China contact (Yingxi Yang, yangyx@ancc.org.cn) to indicate the completion of step 1.1, then the authorization information will be uploaded into NMPA UDID.
- 2** **Confirm the authorization on NMPA UDID portal.**
 - 2.1** Upon receiving the request to confirm authorization from GS1 China contact via E-mail, log into the Production system of NMPA UDID and confirm your authorization.
 - !** Note: the Authorization Confirmation in the UDID Production system will be auto-synced into the UDID Pre-production system the next day and work for data testing.
- 3** **Make sure relevant medical device license information has been maintained in the UDID Pre-production system.**
 - 3.1** Log into the Pre-production system 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 here.
- 5** **Publish UDI data to NMPA UDID's Pre-production GLN (6907777445543).**
- 6** **Manage CIC messages.**
 - 6.1** Take correction actions based on the CIC messages of "Review" (if any) resulting from data validations.
- 7** **Check UDI data in the Pre-production system of NMPA UDID.**
 - 7.1** Log into the Pre-production system. The medical device license holder/general agent's user account in NMPA UDID's Production system also works in the Pre-production system.



Find here GS1 China Implementation Guide (Chinese and English versions available):
<http://gmd.gds.org.cn:8080/index.php?doc-view-43601>

