Policy Brief – UDI first-batch implementation

Global Project Quality Infrastructure, Country Component China, GIZ

Summary

On 17 September 2019, the National Medical Products Administration (NMPA) circulated a call for comments on the "Notice to matters related to the first batch implementation of UDI for medical devices"[1]. The deadline for comments is 25 September 2019.

Following the publication of the regulations for the UDI-system on 27 August 2019, the draft notice specifies the first step in the step-by-step implementation plan for UDI in China. It includes a product catalogue for the first batch of products requiring UDI, covering certain high-risk, class III devices.

It also outlines the following timeline requirements for products in the catalogue:

- UDI labels must be issued / applied for products manufactured from 1 August 2020;
- UDI-DI must be provided to the registration management system from 1 August 2020 for first-time registration; before 1 August 2020, for products already registered, UDI-DI must be provided to the registration management system for registration extension or change of products already registered;
- relevant data must be uploaded to the UDI data base for products manufactured from 1 August 2020.

Main contents

Scope

The first batch of products, for which UDI is implemented, includes certain high-risk, third class devices. Specific products are named in the product catalogue for first batch implementation of UDI included in the notice. The catalogue specifies first- and second-level product categories according to the "Medical Device Classification Catalogue". Certain products from the following types of class III products are listed:

1. Active surgical instruments;
2. Passive surgical instruments;
3. Neurovascular surgical instruments;
4. Medical imaging devices;
5. Devices for blood transfusion, dialysis and cardiopulmonary bypass;
6. Active implants;
7. Passive implants;
8. Infusion, recovery and protective devices;
9. Ophthalmic instruments.

[1] http://www.nmpa.gov.cn/WS04/CL2138/358442.html

Timeline

Registrants for products specified in the product catalogue are to implement UDI as follows:

1. UDI issuing / labelling
   - Products manufactured from 1 August 2020 onwards must have a UDI label;
   - Products already manufactured before 1 August 2020 do not need a UDI label (manufacturing date on the label is taken as reference).
2. Providing UDI to the registration management system
   - From 1 August 2020 onwards, registrants must provide UDI-DI of the smallest sales unit to the registration management system when applying for first-time product registration;
   - Before 1 August 2020, for products already registered, registrants must provide UDI-DI for the smallest sales unit to the registration management system when applying for registration extension or change registration.
   - UDI-DI is not evaluated in the registration process; a single change in UDI-DI does not require a change registration.
3. Uploading UDI data to the UDI data base
   - For products manufactured from 1 August 2020 onwards, registrants shall – before the product enters the market – upload the UDI-DI of the smallest sales unit and the higher-level packing as well as relevant data to the UDI database according to relevant standards or regulations.
   - In case of changes to relevant data of the UDI-DI of the smallest sales unit, the registrant shall – before the product enters the market – submit a change request to the UDI database, and implement the data update after passing relevant checks.
   - In case of changes to the UDI-DI of the smallest sales unit itself, the registrant shall upload the new UDI-DI to the UDI data base.