



Global Model Number management guidance regarding mergers and acquisitions – Position paper

Background

In the framework of the [EU Medical Devices Regulation \(MDR\)](#) and [In-vitro Diagnostics Medical Devices Regulation \(IVDR\) and in regard to mergers and acquisitions \(M&A\)](#), this position paper will focus on providing guidance on the relationship between the GS1 Company Prefix (GCP) in the Global Model Number (GMN) and the GCP in the Global Trade Item Number (GTIN).

Though, presently a standalone document, this position paper may in the future be included in other documents related to implementation of GTIN and/or GMN for healthcare.

Disclaimer

The upcoming EU MDR and IVDR requirements to be released by the European Commission will in any case prevail over this position paper guidance.

Audience

Medical device manufacturers using GS1 standards to identify products supplied to the EU market under the EU MDR and IVDR.

Scope

Regulated medical devices in the EU covered by the EU MDR and IVDR requirements for Basic UDI-DI. The guidance defined here will not apply to other industry sectors using the GMN.

The scope of this document is the GMN only. In particular, potential guidance on the consequences of M&A on the Single Registration Number (SRN) are not covered as GS1 does not have the authority to define such requirements.

Definitions

Mergers & Acquisitions (M&A)

Mergers and acquisitions (abbreviated M&A) refers to transactions where the ownership or assets of a company or business are sold or consolidated. Commonly, a merger occurs when two legal entities are consolidated to one and an acquisitions occurs when one company purchases the shares of another company.

GS1 Company Prefix (GCP)

A GS1 Company Prefix is a unique string of four to twelve digits used to issue GS1 identification keys. The first digits are a valid GS1 Prefix and the length of the GCP must be at least one longer than the length of the GS1 Prefix. The GS1 Company Prefix is issued by a GS1 Member Organisation or by GS1 Global Office, is based on a GS1 Prefix allocated to the issuer, and is allocated either to a GS1 user company or to the issuer itself (e.g., for issuing individual identification keys).

The GCP is part of the GTIN (Global Trade Item Number) as well as of the GMN (Global Model Number).

The GMN and its related GTINs can be based on different GCPs.

Global Trade Item Number (GTIN)

Upon joining a GS1 Member Organisation companies receive a GS1 Company Prefix and full documentation on how to allocate GTINs to their products. The four methods to construct a GTIN are explained in detail on the web site:

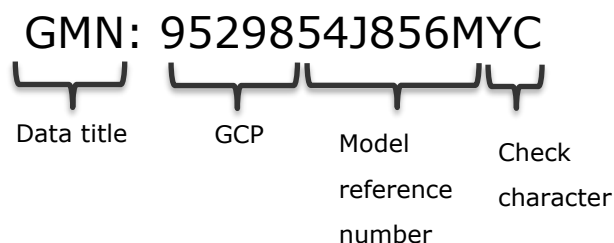
https://www.gs1.org/docs/idkeys/GS1_GTIN_Executive_Summary.pdf.

Global Model Number (GMN), or Basic UDI-DI under the EU Medical Device Regulation

A product model is a base product design or specification from which a trade item is derived. The trade item inherits major features/functions from the base model. The GS1 Global Model Number (GMN) is the GS1 identification key used to identify product models from which trade items are derived. The GMN comprises the GS1 Company Prefix and a model reference. The model reference is alphanumeric and its structure is left to the discretion of the brand owner who assigns it. The GMN is an up-to-25 length character key (23 characters plus 2 check digits). This element string, once assigned to one product model, SHALL NOT be reissued to another. The GMN SHALL NOT be used to identify a trade item.

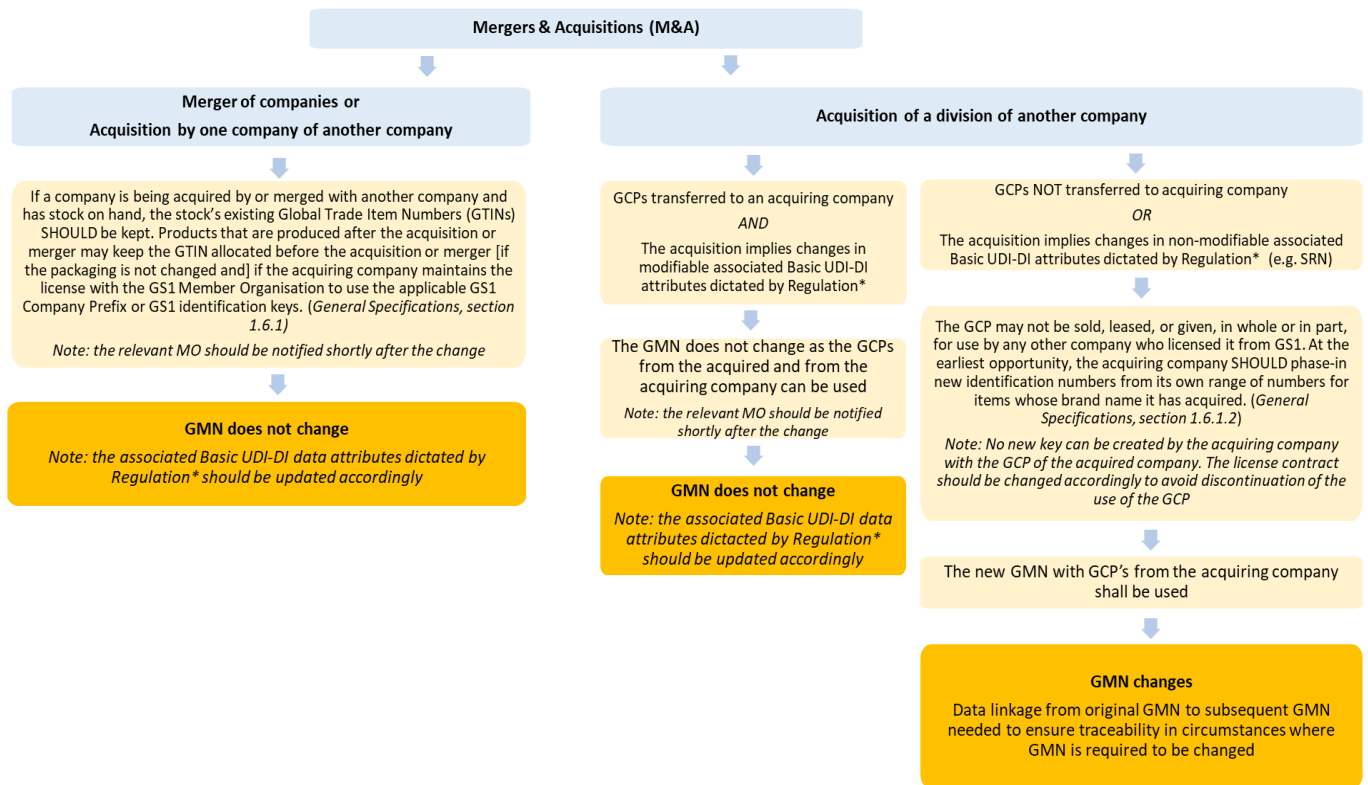
The manufacturer assigns the GMN.

Example of basic UDI-DI on regulated documentation:



M&A and GMNs – Decision tree

It is important to note that a change of GMN will imply a change in the documentation in which the Basic UDI-DI is required, as well as in EUDAMED.



*See below in "Reference documents and links" the links to the Basic UDI-DI data attributes under MDR and IVDR

Examples

	Company A	Company B
GCP	9523572	9529465
Sample product GTIN	Product A : 19523572332174	Product B : 19529465753217
GMN associated to sample product	9523572563A25C6WH	952946589GM752AM9

Company A and company B are both members of GS1 and their GCPs start with 952.

Case 1: Company A fully acquired company B

Company A acquired Company B GCP as an asset and can therefore use company B GCP too.
Company A GCPs: 9523572 and 9529465

Product A1 GTIN: 19523572332174
GMN 9523572563A25C6WH

Product A2 (former Product B) GTIN: 19529465753217
GMN 952946589GM752AM9

→ GMN does not change



Case 2: Company A acquired a division of company B

Division of Company B's GCPs are transferred to Company A. The M&A implies a change in a *modifiable* associated Basic UDI-DI attribute dictated by the EU MDR and/or IVDR. Company A notifies its GS1 Member Organisation that it acquired a division of company B.

Product A1 GTIN: 19523572332174
GMN 9523572563A25C6WH

Product A2 (former Product B) GTIN: 19523572753214
GMN 952946589GM752AM9

→ GMN does not change

Case 3: Company A acquired a division of company B

The M&A implies a change in a non-modifiable associated Basic UDI-DI attribute dictated by the EU MDR and/or IVDR (e.g. SRN). Company A notifies to its GS1 Member Organisation that it acquired a division of company B. Company B will therefore not use this GCP in the future.

Product A1 GTIN: 19523572332174
GMN 9523572563A25C6WH

Product A2 (former Product B) GTIN: 19523572286491
GMN 952357248Y56K325G9

→ GMN changes

Reference documents and links

- [Final EUDAMED UDI Device Data Dictionary](#)
- [Basic-UDI-DI and UDI-DI attributes for the MDR](#)
- [Basic UDI-DI and UDI-DI attributes for the IVDR](#)
- [GS1 Global Model Number - GMN \(Basic UDI-DI\) generator webpage](#)

