

The purpose of this document is to clarify the role of a GS1 Company Prefix and provide guidance on its use in the creation of GS1 identification keys, in particular in the context of implementation of Unique Device Identification (UDI) in the EU.

GS1 Company Prefix overview:

A GS1 Company Prefix¹ (GCP) is a licensed number of **four** to **twelve** digits issued by GS1 Member Organisations to a user company to entitle that user company to create any of the GS1 identification keys (i.e., Global Trade Item Number, Global Location Number, Serial Shipping Container Code, etc.). These GS1 identification keys are what is used throughout GS1 systems of standards to identify products, companies, locations, etc - not the GS1 Company Prefix itself.

The GS1 Company Prefix can be used to determine which GS1 Member Organisation (MO) allocated the prefix. However, it cannot be used to determine where an item was produced or distributed. For example, while a GCP may have been issued to a company headquartered in Belgium, the product may have been produced in another country. Country of origin, for example, is often communicated via master data about the product or labelled on the product itself.

Examples of EAN-13 and GS1 DataMatrix with a 7-digit GCP





Although a GCP is a licence to create GS1 identification keys it is not an identifier of the company to whom it has been issued and cannot be used as an identifier of a company (i.e., manufacturer, distributor, hospital, health system, clinic etc.). The Global Location Number (GLN) identifies a company within the GS1 system of standards.

The GCP is simply a licence number issued to companies who need to create GS1 identification keys such as a Global Trade Item Number (GTIN) and Global Location Number (GLN), among many others.

For more information refer to the GS1 General Specifications.

GCPs and internal company policies:

Below are two common examples for managing GCPs. Each company will determine the best method of managing their GCP based on how their business operates.

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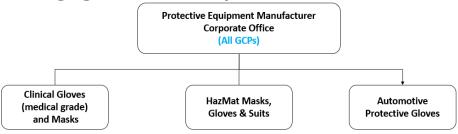
¹ According to the GS1 General Specifications: a GS1 Company Prefix is "a unique string of four to twelve digits used to issue GS1 identification keys. The first digits are a valid GS1 Prefix and the length must be at least one longer than the length of the GS1 Prefix. The GS1 Company Prefix is issued by a GS1 Member Organisation. As the GS1 Company Prefix varies in length, the issuance of a GS1 Company Prefix excludes all longer strings that start with the same digits from being issued as GS1 Company Prefixes."



When taking into consideration the two approaches below, a company should consider its business structure and rules for managing GCPs.

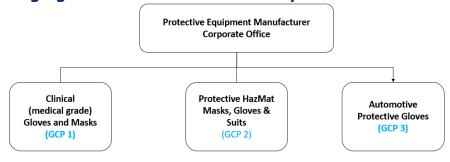
• The centralised approach: the parent company (or one subsidiary of the company) identifies the entire range of products, locations, and other items that need identification using GCP(s) licensed to the parent company and according to the GS1 General Specifications and potential specific rules of the country in which the company is located. This approach offers the advantages of centralisation and consistency in managing identifiers for product, locations, etc., but does not always offer the necessary flexibility for the allocation of GS1 identification keys across large, complex organisations.

Managing GCPs at the corporate office level



• The decentralised approach: every subsidiary company identifies its products, locations, and other items that need identification at the national level using relevant GCP(s) licensed to each subsidiary company. This approach offers flexibility but may lead to the same product, location, etc., being identified internationally with different GS1 identification numbers, including different GS1 Company Prefixes.

Managing GCPs at a business unit or product level



In addition, the parent company and its subsidiaries consult together to decide which products, locations, and other items that need identification will be identified in a centralised way (e.g., when production units located in different countries manufacture the same product) and which products will be numbered on a decentralised way (i.e., national, regional or global basis).

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Consulting across the organisation is intended to help improve internal alignment and create a more consistent and harmonised approach on how GCPs are managed and how GS1 identification keys are created and allocated.

It's also possible that a company may adopt a hybrid approach. For example, the general approach could be as described in the centralised method above, but they may choose to dedicate a specific GCP to a particular product category or perhaps to a specific country.

Below are a few steps to consider when developing internal practices and policies in the management GS1 Company Prefixes.

Step 1: Identify the GCP manager

- Determine which function will be responsible for the management of GS1 Company Prefix(es) within the organisation.
- This can be either an individual, department or by division depending on the structure that best suits the business. In a small organisation it is most likely that an individual person can perform this role. In larger organisations the responsibility may be assigned to a specific department.
- Refer to the roles and responsibilities step for additional information.

Step 2: Perform an internal audit to determine how many GCP Licences your organisation has acquired

- It is common for multinational organisations to have applied for different GCP licences. For example a local division acquires a GCP licence from local GS1 Member Organisations in addition to a GCP licence acquired by another division in a different country. Another example is provided by data registered in the U.S. FDA UDI Database, where a company has registered devices using 101 GCPs and several other companies more than 40. It is not uncommon for companies that operate in multiple industries, countries or have diverse and extensive product lines to have licensed more than one GCP.
- The advent of mergers and acquisitions is another source of additional GCP licences. A full acquisition of an entire company would include GCPs they acquired previously. Alternatively, partial acquisitions and/or product line acquisitions may come with the GTINs for the impacted products but not the GCP from which they were created by the previous owner. In this case the impacted trade items will require new GTINs, usually with updates to labelling. The GTIN change is usually coordinated between the seller and the buyer in order to minimize trading partner and supply chain disruptions.

Note: Changes in GCP ownership due to mergers and acquisitions must be reported to the GS1 Member Organisation (MO) who issued the GCP license. However, GCPs may not be moved from one GS1 Member Organisation (MO) to another. The GCP will remain with the MO who issued it.

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Action:

- Take inventory of the GCP licences your organisation has acquired, especially if you are a multinational organisation.
- Ensure your GCPs are stored in a central database or platform where they can be managed properly and in accordance with relevance regulations.
- Contact the local <u>GS1 Member Organisation</u> for support, which can be instrumental in determining how many GCPs have been assigned to your company.

Step 3: Develop a GCP management and governance plan

- A GCP license is an asset of the organisation to whom it has been issued.
- Establish a database where all GCPs are stored including proper staff access credentials.
- Develop internal governance, policies, roles and responsibilities and an operations manual which includes your company's business structure and policies regarding the way GS1 identifiers are created and managed.
- Ensure your internal policies are consistent with the specifications and rules of the GS1 standard.

Note: Organisations that sell products through multiple channels such as regulated healthcare, consumer products and other channels may want to consider, in the event of a future split or sale of a division, the impact of GTINs for multiple channels based on the same GCP. For example, new GTINs must be created and assigned due to a company changing its legal status because of an acquisition, merger, partial purchase, split, or "spin-off".

Action:

- Develop appropriate policies, procedures and an operational manual that best suits your organisation's needs and business management model. This should include when all GS1 identification keys will be issued from the same GCP or from multiple GCPs. See note above.
- Ensure your internal policies are consistent with GS1 specifications and rules.
- Refer to the <u>GS1 General Specifications</u>, the <u>GS1 Healthcare GTIN</u> <u>Allocation Rules</u> and <u>GLN Standard Allocation Rules</u> for further information.

Step 4: Roles and responsibilities

• Identify the function that has the responsibility of creating, allocating and managing GS1 identification keys such as GTIN, GLNs, SSCCs and others. This may be a different person or department.

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- Assignment of a GTIN may be the responsibility of one person or department while assignment and management of a GLN may be the responsibility of a different person or department. This is entirely dependent on which practice best fits your organisational business practices.
- Action: Define and document the roles and responsibilities that best suit your organisational model and business needs.

For more information about GCPs contact your local GS1 Member Organisation.

Frequently Asked Questions

1. What happens when the GCP is no longer valid due to a company going out of business, for example.

GS1 Member Organisations are prohibited from re-assigning GS1 Company Prefixes which have been issued to users that have identified themselves as offering regulated healthcare items (e.g., pharmaceuticals or medical devices sold or dispensed in a controlled environment).

Once GS1 identification keys have been assigned to this category of products, they should never be reassigned under any circumstances to avoid any potential duplication and to support the long-term needs of the healthcare industry.

2. Can GCPs be re-assigned?

No, a GCP cannot be reassigned from the original company to whom it was issued. The GS1 Company Prefix may not be sold, leased, or given, in whole or in part, for use by any other company. Companies should notify their GS1 Member Organisation of any legal status change within one year of that change to facilitate a smooth transition.

3. When two companies merge how and where do they record the new ownership of all GCP under the new company?

Companies should contact the GS1 Member Organisation from whom the GCP was acquired to report a merger so that that can updated their records.

Refer to the <u>Contact Us</u> section of the GS1 Website for contact information for all GS1 Member Organisations.

Refer to the <u>GS1 General Specifications</u> for more information about Mergers and Acquisitions.

4. What is the role of a GCP relative to the location where the product manufactured?

There is no correlation between the GCP and the location where the product is manufactured. The GCP does not identify the product nor the location where it is manufactured. For example, a GCP may be issued to the corporate office of company located in country A, but the products may be manufactured in country B or in many locations located in separate countries.

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