

Application for the use of the GS1 Germany country prefix for medicinal products for the National Trade Item Number (NTIN)

We hereby apply for the use of the GS1 Germany country prefix for medicinal products, which enables us to convert pharmaceutical central numbers (PCN) for our products into a unique article number, the National Trade Item Number (NTIN).

We are a company in the pharmaceutical industry.

The headquarters of our company is located outside the Federal Republic of Germany.

We already have a current contract for participation in GS1 System with the
GS1 member organization _____ (country).

Our GLN is _____ (Global location number).

We have taken note of and accepted the price conditions listed below as well as the terms and conditions of business and participation (Annex1).

For the country prefix for pharmaceuticals, GS1 Germany charges a **one-time provision fee of EUR 350. and an annual usage fee of EUR 2,000 (both plus VAT).**

The annual fee is incurred regardless of when the contract is signed.

Customers who use the GS1 Complete service package from GS1 Germany can use the country prefix as an included component of the contract.

Data protection for direct advertising

In order for you to be able to use our range of services in the best possible way in your company in the future and for us to be able to fulfill our legitimate interest in direct advertising pursuant to Article 6 (1) lit. f DSGVO, we reserve the right to regularly send you offers and information on our products and services by e-mail if we receive your e-mail address in the course of concluding a contract and providing our products and services and you have not objected to this. In doing so, the offers and information will only relate to products and services that are similar to those you have purchased from us. The offers are designed to help you best integrate the GS1 Standards included in the service offering into your business processes so that you can take maximum advantage of all the opportunities and benefits that the GS1 Standards offer you. For more information on how we use your personal information, please see our Privacy Policy.

You may opt out of this use of your name and email address at any time by sending a message to widerspruch@gs1-germany.de or via a link provided for this purpose in the newsletter e-mail, without incurring any costs other than the transmission costs according to the basic rates.

GS1 Complete service package

We **agree** that the address and contact information belonging to our service package will be made available on **www.gepir.de** in order to be found in the worldwide company database via our Global Location Number (GLN) or our company name. (If not applicable, please delete).

For fast processing, you are welcome to send us your request in advance by fax to +49 (0)221 94714-7290 or scanned to antrag@gs1-germany.de.

Company name

E-mail

Street, No

E-mail for e-invoice

Zip code, city

Managing director (surname, first name)

Country

VAT No

Place, date

Technical contact (name, first name)

Phone/Fax

Company stamp and legally binding signature

GS1 Germany GmbH

Maarweg 133, 50825 Köln

T +49 221 947 14-567 | **F** +49 221 947 14-7567

E service@gs1.de

www.gs1.de

Connect With Us



General terms and conditions of participation

of GS1 Germany GmbH (hereinafter referred to as "GS1 Germany") for participation in the GS1 Complete service package with the GS1 identification numbers including, for example, the global location number (GLN), the global trade item number (GTIN), the serial shipping container code (SSCC; NVE in Germany), the title number (VDZ in Germany) and the electronic product code (EPC) in the Federal Republic of Germany.

GS1 Germany is a limited liability company (GmbH) registered in the Commercial Register. The Company's registered office is in Cologne, Germany (District Court of Cologne No. 6276). GS1 Germany is a member of the International Global Standards Organisation GS1 headquartered in Brussels, Belgium.

The following hold equal shares in the limited liability company (GmbH):

- Markenverband e. V., Berlin, Germany
- EHI-Verwaltungsgesellschaft mbH, Cologne, Germany

The corporate bodies of the Company are:

- the shareholders' meeting
- the supervisory board
- the managing board

The supervisory board appointed by the users of the identification numbers is responsible for defining the principles and guidelines for the Company's work. The supervisory board monitors compliance with the orderly process pursuant to the relevant "directives" and is the decision-making body.

I. General

The purpose of GS1 Germany is to compile and publish recommendations or other work results which serve to rationalise the transfer of data and products and the organisational processes between users (industry, retail, service providers, etc.) and facilitate the implementation of these results (coorganisation). The general terms and conditions of participation apply only in respect of entrepreneurs as defined in section 14 of the German Civil Code (BGB). They regulate the application of GS1 identification numbers such as, for example:

- global location number (GLN)
- global trade item number (GTIN)
- serial shipping container code (SSCC; NVE in Germany)
- electronic product code (EPC)
- title number (VDZ in Germany)

hereinafter referred to as "GS1 Complete".

The identification numbers are defined in the publications issued by GS1 Germany. All interested parties, e.g. economic enterprises and their commercial combinations, may participate. Users who apply these coorganisation processes are obliged to do so in a manner that is system-compatible; in particular, the defined implementation regulations are binding.

II. Participation

1. All users named in Section I and their combinations are entitled to participate.

2. Registration is made in writing using the GS1 Germany form. This is considered an application for the provision of the GS1 Complete service package and for participation in the respective system. By registration, the user accepts these terms and conditions of participation.
3. GS1 Germany will decide whether to approve the application for provision of the GS1 identification numbers.
4. If the application is approved, participation in the registered system is deemed to be justified and identifies the full company name, possibly also the business establishment name, and the address. A contract is thereby established between GS1 Germany and the applicant. Unless the user objects in the application, it consents to the rationalisation of the inter-business exchange of information by the submission of its data. Any changes to these data must be notified to GS1 Germany without delay.
5. Users of the GS1 identification system are obliged to check the application confirmation immediately upon receipt and notify GS1 Germany of any corrections that may be necessary.
6. Users of the GS1 Complete service package may receive more than one GLN if this is necessary for organisational reasons.

III. Obligations of participants

1. The user undertakes to pay GS1 Germany the annual fees defined in the price list. These are payable in advance on January 1 each year. The first fees are payable on submission of the application.
2. Calculation of the annual usage price is based on the total reported sales of the participant's company. Each year, the user will be asked to notify GS1 Germany of their total sales for the previous year and present suitable verification thereof if required to do so. GS1 Germany reserves the right to perform a review and possible reclassification, coupled with a recalculation of the annual usage price.
3. All users of the GS1 Complete service package should use their GLN (incl. check digit) with the prefix "GLN" for an appropriate period, usually twelve months from provision, on correspondence with other participants, especially on order forms, invoices, invoice lists, etc.
4. A user may only create individually assigned GLNs, GTINs for numbering articles, SSCCs (NVEs) for identifying logistic units, EPCs and other identification numbers from GS1 Germany for its own business on the basis of a Type 2 GLN.
5. All GS1 identification numbers (incl. GLNs, GTINs) may only be used in accordance with the currently applicable

implementation regulations, especially in respect of the rules on non-reuse.

6. Misuse of GS1 identification numbers may result in termination of participation without notice (see Section IX.5) and claims for damages by GS1 Germany. Misuse exists in particular if the numbers are passed on to third parties without the written consent of GS1 Germany.

IV. Participants' obligation to provide information in respect of medical devices; liability disclaimer

1. In order to comply with the UDI requirements of the US Food and Drug Administration (FDA), the participant shall notify GS1 Germany when applying for a license if a GS1 key is to be used to identify a medical device.
2. If a GS1 key is to be used to comply with FDA UDI requirements, the participant shall notify GS1 Germany of this fact within five working days of applying for the license. If the participant does not meet its aforementioned obligation to provide information within the due time, its data cannot be reported in the annual report submitted by GS1 Germany to the FDA. GS1 Germany does not accept any liability for consequences arising therefrom (e.g. costs, administrative processes, queries from regulatory authorities).
3. The participant is and remains at all times responsible for the information in respect of medical devices that it provides to GS1 Germany and for compliance with all applicable legal and regulatory obligations and shall ensure that all information provided to GS1 Germany is at all times correct and up to date.

V. Obligations of GS1 Germany

1. In accordance with the implementation regulations and immediately upon receipt of application, GS1 Germany shall provide the contractual partner with the required number of Global Location Numbers including check digits or with access to already available EPCglobal specifications. In general, the numbers are provided in the sequence in which applications are received.
2. GS1 Germany will allocate the location numbers it issues to just one participant and will ensure that there are no overlaps in allocation (avoidance of collision). If there is not sufficient capacity in the systems, GS1 Germany is obliged to provide remedy without delay.
3. If necessary, the GS1 Germany implementation regulations shall be supplemented. Participants shall be notified of such supplements at least six months before they come into effect.
4. GS1 Germany shall deploy working groups in the development and promotion of rationalisation projects and of EPCglobal to ensure the appropriate involvement of the affected business groups.

VI. Liability

1. GS1 Germany shall be liable under statutory provisions if the user seeks to assert claims for damages on the basis of wilful intent or gross negligence, including wilful intent or gross negligence by a representative or agent of GS1 Germany. Unless GS1 Germany is accused of a wilful breach of contract,

its liability shall be restricted to foreseeable and typically occurring damages.

2. GS1 Germany shall be liable under statutory provisions if it has culpably breached a material contractual obligation. In such case too, however, its liability shall be restricted to foreseeable and typically occurring damages.
3. This shall be without prejudice to liability for culpable injury to life, limb or health, which shall apply to mandatory liability in accordance with product liability legislation.
4. Unless otherwise regulated in the foregoing, liability shall be excluded.

VII. Joint liability

1. Any further liability for damages other than that set forth in Section VI. shall be excluded, irrespective of the legal nature of the claim being asserted. This applies in particular to claims for damages arising from culpa in contrahendo, other breaches of obligations or claims in tort for the indemnification of material damages as defined by section 823 of the German Civil Code (BGB).
2. The limitation pursuant to paragraph 1 shall apply mutatis mutandis to a claim for compensation for damage instead of a claim for reimbursement of wasted expenses.
3. To the extent that the liability of GS1 Germany for claims for damages has been excluded or restricted, this shall apply mutatis mutandis to personal claims for damages from employees, representatives and agents of GS1 Germany.

VIII. Contributions

Users shall pay the fees shown in a price list. These fees may be utilised solely for the purposes specified in the statutes of GS1 Germany. In accordance with section 315 of the German Civil Code (BGB), any changes to the contractual considerations of users for implementing the purpose of GS1 Germany shall be decided by the supervisory board.

IX. Termination

1. Each user may terminate its participation with notice of three months to the end of a year. Notice of termination must be made in textform and becomes effective upon receipt by GS1 Germany.
2. Individual location numbers may be returned at any time with written notification to GS1 Germany and without the need for termination of participation in the system as a whole.
3. With notice of termination, the user undertakes to cease using the GS1 identification numbers and manager numbers provided by GS1 Germany at the end of the period of notice. In the case of Type 2 GLNs, this shall apply irrespective of the granting of appropriate use-by periods for materials. In the case of improper further use, i.e. if the former user deliberately ignores the foregoing provision, it shall be liable for all damages incurred by GS1 Germany, including those asserted against GS1 Germany by other system participants.
4. Termination of participation by GS1 Germany is only possible for good cause, especially but not restricted to the non-

payment of fees, a sustained breach of these terms and conditions of participation or a threat to the functioning of the systems.

X. Use of data and transfer of data to authorities

1. GS1 Germany is entitled to use the user's data – especially the electronic mail address – for the direct promotion of its own similar products or services. The user may make an objection to the use of its data at any time to GS1 Germany GmbH, Stolberger Str. 108a, 50933 Cologne, Germany, phone: +49 221 94714-0, fax: +49 221 94714-990, e-mail: widerspruch@gs1-germany.de. Only the applicable standard rates will apply for the means of communication used.
2. If required to do so by law or due to a decision by a court or administrative authority, GS1 Germany reserves the right to

transmit the user's data to the respective administrative authority, also outside the European Economic Area.

XI. Place of jurisdiction and place of performance

Provided the user is a business person, the place of jurisdiction and place of performance will be the registered office of GS1 Germany. Substantive German law shall apply with the exclusion of the United Nations Convention on Contracts for the International Sale of Goods.

Cologne, June 2023

GS1 Germany GmbH

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