General information:

Computer readable information requires two types of structures:

1. Data structure
   A data structure is needed that defines the sequence of all information. For example, to understand a calendar date it has to be clear if the day is written before the month or vice versa. For the information that our customers require GKE decided to use the HIBC ("Health Care Bar Code") barcode that contains vital information like a batch number and an expiry date.

2. Code system
   The barcode lines are understandable for digital systems but not Latin characters and Arabic numbers which are designed for human use. Therefore, a barcode is used that can be read and interpreted very fast and error free from a scanner that is the input interface of the computer. The barcode information is decoded by software and the contained data (in our case HIBC) can be processed by a software like an inventory control system. GKE uses the barcode structure EAN 128 (B) on the packages.

1. HIBC-Barcode (Data Structure)

The following table describes the information contained inside.

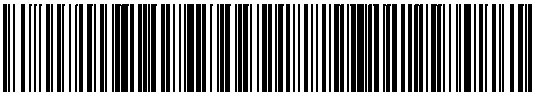
*	+	EGKE	211255	ED	S	0	/	$$	0425	123456789101112131415	W	*
1	2	3	4	5	6	7	8	9	10	11	12	13

1. HIBC Supplier Labeling Flag Character. It starts and identifies the data structure for the software that decodes the information (added since 04-2022).
2. HIBC Supplier Labeling Flag Character.
3. Labeler Identification Code of GKE: 4 Characters (Our international Code is "EGKE")
4. Article number without a dash.
5. The language version, i.e. "ED" stands for English/German or other language versions.
6. Additional product information. "S" means "standard", alternative "M" for "sample".
7. Unit package information. "0" is the standard package size that is always provided on all GKE packages.
8. Separator between primary and secondary part of the code.
9. Format for the date.
10. Expiry date. 4 digits are used for the expiry date. The first two digits stand for the month and the last two digits for the year. The example "0425" means that the expiry date is April 2025. To process the bar code in our ERP system the indication of the expiry is absolutely mandatory. For products without expiry date (e.g. technical equipment) an imaginary date (1299) has to be used.

11. Lot number that can consist of up to 15 digits.
12. Automatically generated check sum character.
13. HIBC Supplier Labeling Flag Character. It finishes the data structure for the software.

Printed in the EAN 128 (B) barcode structure

The EAN HIBC LIC 128 barcode system is used, smaller systems cannot contain all required information.



The character, the digit 0, is executed in plain writing with a slash to ensure better differentiation from the letter O.

2. Other code systems

2.1 Two-dimensional Codes (2D-Codes)
There are several 2D code versions which GKE does not use, since most GKE customers require barcode. On customer request, 2D codes can also be supplied if sufficient quantities are ordered.

2.2 Other data structures, e.g.

GMDN	Global Medical Device Nomenclature
UDI	Unique Device Identification
UMDNS	Universal Medical Device Nomenclature System
UNSPSC	United Nations Standard Products and Services Code

These data structures are also partly used in the medical devices area. However, HIBC is the most commonly used data structure.

Due to international agreements, all **medical devices** should be marked according to a clear procedure in order to improve the safety of medical devices (including market surveillance and simplification of product recalls.

This will be done using a special **Unique Device Identification (UDI)** and a **database for medical devices (UDID).**

UDI is a worldwide system for uniform product marking of medical devices. UDI is intended to be applied to the product as a machine-readable mark (e.g. barcode) and in plain text. It serves as the key to UDID, which will contain a wide range of information about the products.

The UDI are issued by so-called issuing agencies (currently GS1, HIBCC, ICCBBA. IFA-GmbH).

Currently there are at least two such databases worldwide.

1. GUDID (USA), is already actively used and
2. EUDAMED (EU). The European Commission officially declared that the introduction of EUDAMED as the EU's UDI database was postponed by two years. Therefore, right now it is not possible to deposit UDI in EUDAMED.

Unfortunately, both databases are not identical.

In the EU GKE products are no medical devices according to the MDR. Entries in the EUDAMED are therefore not intended as long as indicators are not medical devices.

GKE is labelling all products with the UDI-compatible HIBC code of HIBCC, which is one of the official issuing agencies, already for several years.