

	Technical Information	730-090-EN		V06
	Databases for Medical Devices and Barcode on GKE-packages	Created	06.06.2008	KP
		Changed	02.09.2021	KP
		Checked	02.09.2021	UK
		Released	02.09.2021	UK
File no.: 0.0				

1. 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 barcode that contains vital information like a batch number and an expiry date. HIBC stands for "Health Care Bar Code". (Details see point 2)

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. We use as the barcode structure EAN 128 (B) on our packages.

2. HIBC-Barcode (Data Structure)

The following table describes the information contained inside.

+	EGKE	211260	EN	S	0	/	\$\$	1019	123456789101112131415	W
1	2	3	4	5	6	7	8	9	10	11

1. HIBC Supplier Labeling Flag Character. It identifies the data structure for the software that decodes the information.
2. Labeler Identification Code: 4 Characters (Our international Code is "EGKE")
3. Article number without a dash.
4. The language version, i.e. "ED" stands for English/German version.
5. Additional product information. "S" means "standard", alternative "M" for "sample".
6. Unit package information. "0" is the standard package size that is always provided on all GKE packages.
7. Separator between primary and secondary part of the code.
8. Format for the date.
9. 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 "1019" means that the expiry date is October 2019. 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.
10. Lot number that can consist of up to 15 digits.
11. Automatically generated check sum character.

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3. Barcode (Printed in the EAN 128 (B) barcode structure)

The EAN 128 (B) barcode system is used, smaller systems cannot contain all required information.



4. Other code systems

4.1 2-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.

4.2 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 will be postponed by two years to May 2022. Therefore, right now it is not possible to deposit UDI in EUDAMED.

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Unfortunately, both databases are not identical.

In the EU GKE products are no medical devices, neither according to the MDD nor the MDR. Entries in the EUDAMED are therefore not intended.

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.