

Dear Ladies and Gentlemen.

The Medical Device Regulation (MDR), which came into force in May 2017, increases the regulatory requirements for the registration and labeling of medical devices.

For this reason and the increasing demand of our customers, we are changing step-by-step the labeling of our products from October 1st on to a Data Matrix Code with GS1 data structure. (GS1: Global Standard One)

Since 2009, Medicoplast has been using the HIBC code (Health Industry Bar Code) in the form of a Data Matrix Code for secondary and transport packaging.

GS1, with the Global Trade Item Number (GTIN) is globally established in all industries with more than 90% market share. This GS1-compliant coding is fully suitable to UDI-regulation under MDR.

UDI is a system that assigns a unique number to each product in each packaging unit.

Unique Device Identification has been required for years due to the FDA regulations (Food and Drug Administration) and has to be implemented as well to the MDR in Europe.

Starting October 1, with monthly batch 1810, Medicoplast will switch the coding of the products to a GTIN code. Thus all requirements for the mandatory UDI identifier and registration in the EUDAMED database as of May 2020 have already been met.

The coding will be continued in a Data Matrix code. This code can save a lot of information by its structure. In addition, it requires just a small footprint on the labels and despite a possibly unreadable surface of up to 25%, the information can be processed.

Products with the new barcode are indicated by the information in plain text to the right of the Data Matrix.



If you have further questions concerning the conversion to the Global Trade Item Number as well as the coding, please contact your contact person at Medicoplast or use our contact forms on the homepage:

[www.medicoplast.de](http://www.medicoplast.de)

[info@medicoplast.de](mailto:info@medicoplast.de)

High quality medical devices are our core competence. The conversion to GTIN will further increase our product quality in Regulatory. This adapting to the world leader in product coding enables our customers to increase efficiency and compliance in all areas of warehouse logistics and electronic processing of booking processes.

Medicoplast International GmbH

Aufbau und Inhalt des Data Matrix Code / Structure and content of Data Matrix Code:

- (00) NVE  
Nummer der Versandeinheit / Serial Shipping Container Code
- (01) EAN  
Europäische Artikelnummerierung / European Article Number
- (02) GTIN (Globale Artikelidentnummer, Global Trade Item Number)
- (30) Menge  
Unit / Quantity
- (10) LOT-Nummer  
Batch-Number
- (17) Ablaufdatum (Jahr/Monat/Tag)  
Expiry Date (Year /Month/Day [YY/MM/DD])
- (240) Artikelnummer  
Item-Number
- (241) REF
- (242) Produktionsnummer  
Production Number
- (91) Interne Nummer  
Internal Number
- (37) Anzahl GTIN-Einheiten pro Transporteinheit  
Number of GTIN Units in Transport Packing



Ziffer / Number (00), (02):

Basis UDI-DI für die unterste Gebrauchseinheit  
UDI-DI je Versandeinheit  
Base for the lowest unit of use  
UDI-DI for packing unit

Ziffer / Number (30),(10),(17)

UDI-PI

GS 1 Basisnummer / GS 1 Base number:

4061961