B BRAUN
SHARING EXPERTISE

FAQs Product Labeling with UDI*

* Unique Device Identification

Table of contents

FAQs Product Labeling with UDI (Unique Device Identification)

It is not only since the introduction of the MDR that we have repeatedly received inquiries from our customers regarding product labeling and product identification. For these reasons, we have prepared the following FAQs to provide you with all relevant information on UDI, DataMatrix, etc. in a self-service format.

The FAQs provide answers to product identification at B. Braun in general. However, more specific questions, such as direct product labeling of reusable medical devices, are also addressed. With this direct labeling, the subsidiary Aesculap AG, for example, ensures that reusable Aesculap instruments can be clearly identified in the sterilization cycle.

If you have any further questions, we will of course be happy to help you via the corresponding contact form.

1. UDI – Unique Device Identification at B. Braun

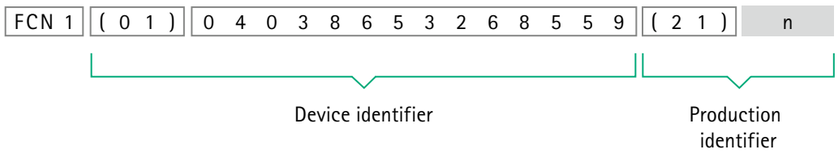
1.1 What is the UDI?

In 2007, the U.S. Congress passed a legislation requiring the FDA to establish a regulation for a Unique Device Identification (UDI) system for medical devices. UDI is intended to help increase patient safety by uniquely identifying a medical device. This should also improve the quality of information used in the market surveillance process, such as medical device notifications, market corrections and recalls. UDI should make it easier for both manufacturers and authorities to identify product problems more quickly and take appropriate action. UDI is also expected to help prevent improper handling, ensure safe logistics of goods and counteract product piracy. It can help customers to find, order and identify the right product, and ultimately receive the right product.

In the meantime, further countries have anchored the UDI in national legislation. e.g. in Europe with the new Medical Device Regulation (MDR).

1.2 What is the composition of a UDI?

- The UDI is composed of the UDI-DI and the UDI-PI:
  UDI = DI + PI
- The UDI-DI (DI = Device Identifier) designates the Global Trade Item Number (GTIN), which represents a unique item number per product and packaging level worldwide.
- The UDI-PI (PI = Production Identifier) is the batch or serial number from production and thus varies. Sterile products also have the best-before date available in the PI.



1.3 What are the general UDI requirements for product identification?

Before a product is placed on the market, the manufacturer assigns it a UDI and affixes it to all levels of packaging. The UDI data carrier is placed on the label and, if possible, on the product. In addition, the manufacturer must ensure that additional UDI attributes are correctly recorded in the respective UDI database (e.g. GUDID in the USA or EUDAMED in the EU). The illustration below shows examples of required data at product group level (so-called basic UDI data) and article level (UDI data), which must be transferred automatically via an interface for EUDAMED. The manufacturer is responsible for compliance with all UDI requirements.

MDR
Device

Basic UDI-DI & UDI-DI attributes

Basic UDI-DI set of data in UDI database

Principle: Each UDI-DI inherits the attributes of its linked Basic UDI-DI and devices DI

Basic UDI-DI

- Applicable legislation (MDR) (*)
- 2. Basic UDI-DI value (*)
- 2b Basic UDI-DI Issuing entity (*);
- 6. Manufacturer SRN (*)
- 5. Name and address of manufacturer
- 7. Name and address and SNR of AR
- 9. Risk class (*)
  - Implantable (Y/N) (*)
  - For IIb implantable: Suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip, connector (Y/N) (*)
  - Measuring function (Y/N) (*)
  - Reusable surgical instrument (Y/N) (*)
  - Active device (Y/N) (*)
  - Intended to administer / remove a medicinal substance (Y/N) (*)
- 11. A. Name and/ or, if applicable, device model that identifies the device(s) with this BASIC UDI-DI in the technical documentation and/ (Name and/ or model shall be provided)

UDI-DIs

- 0. UDI-DI value (*)
- 0b. UDI-DI Issuing Entity
- Secondary ID (value and issuing entity)
- 11.B. Reference, Article or Catalogue number (*)
- Is device directly marked (Y/N) (* if Y)
- Direct marking UDI-DI value (*if not null)
- Direct marking UDI-DI issuing entity (*if not null)
- 1. Quantity of device (s) (*)
- 3. Type of UDI-PI (*)
- 4. Unit of use UDI-DI (*)
- 12. Clinical size (*)
- 14. Storage / handling conditions
- 10-15. Name(s)/ Trade name(s) (including languages)
- 13. Additional product description
- 22. URL for additional information
- 16. Labelled as single use (Y/N) (*)
- 17. Maximum number of reuse (*)
- 18. Device labelled as sterile (Y/N) (*)
- 19. Need for sterilisation (Y/N (*)
- 20. Containing latex (Y/N) (*)
- 21. CMR / Endocrine disruptor
- 23. Critical warnings or contra- indications
- 8. Medical device nomenclature (CND) code (1)
- 24. Status
- 25. (A.2.6) Reprocessed single-use (Y/N) (*)
- 26. (A.2.12) Annex XVI (*)
- 27. (A.2.13) In the case of devices designed and manufactured by another legal or natural person as referred in Article 10 (15), the name, address and contact details of that Natural / legal person

UDI-DIs (container package DI)

- 0. UDI-DI value (*)
- 0b. Issuing entity (*)
- 1. Quantity per package (*)

1) Nomenclature decision: https://ec.europa.eu//docsroom/documents/34264

(*) may not be changed
Mandatory
Mandatory if applicable
Optional

Quelle: MedTech, Version Juli 2019

1.4 What is needed for the UDI?

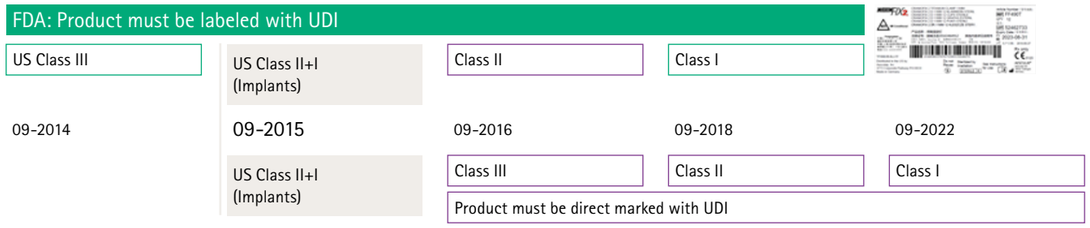
The UDI is part of the labeling of medical devices. Each product label must include the UDI in a human readable form as well as in a machine readable form.
All reusable medical devices must be directly labeled. The Data Matrix, which B. Braun uses as standard, has therefore proven itself as a solution for a machine-readable code, which is applied ex works if this is possible in terms of space on the product or according to the current technical status. This applies, for example, to all reusable instruments, devices and containers from Aesculap AG. Sterile products such as implants or single use products are excluded from direct labeling.

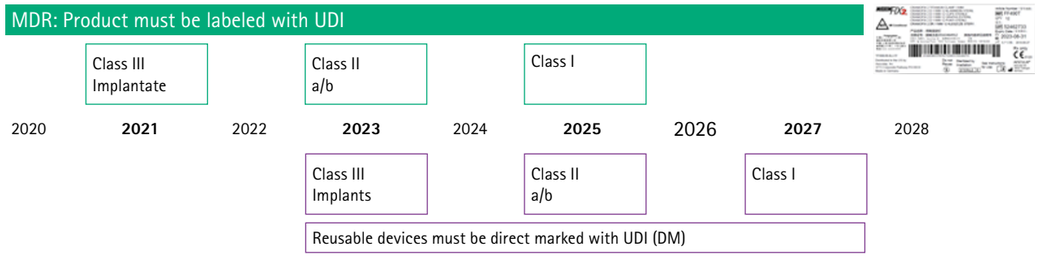
Since UDI only allows coding according to standards such as GS1 or HIBC, the UNICOS code previously used for Aesculap products was switched in 2016 to an sGTIN code (serialized GTIN) from the non-profit organization GS1, which represents a global standard.

1.5 By when did the UDI have to be implemented?

Currently, the following „compliance dates" from the UDI regulations from the USA and Europe apply:

Date	Note
24.09.2014	US Class 3 products must be labeled according to US UDI requirements.
24.09.2015	Life support and life sustaining devices, regardless of US product class, must be direct labeled.
24.09.2016	US Class 2 devices must be labeled according to US UDI specifications. US Class 3 devices that can be reprocessed must be direct labeled.
24.09.2018	US Class 2 products that can be reprocessed must be direct labeled.
24.09.2020	US Class 1 or unclassified products must be labeled according to US UDI requirements.
25.05.2021	EU Class 3 devices and implants must be labeled according to EU UDI specifications.
24.09.2022	US Class 1 or unclassified devices must be direct labeled according to US UDI specifications.
25.05.2023	EU Class 2a/2b devices must be labeled according to EU-UDI requirements. EU Class 3 devices and implants must be directly labeled according to EU-UDI requirements.
25.05.2025	EU class 1 devices must be labeled according to EU-UDI requirements. EU Class 2a/2b devices must be directly labeled according to EU-UDI requirements.
25.05.2027	EU Class 1 products must be directly labeled according to EU-UDI specifications.





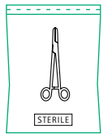
1.6 Does the UDI only apply to imports into the U.S.?

No. The general contents of the UDI will continue to be reviewed by countries such as China, Japan, Saudi Arabia, Brazil, Australia, etc. It is expected that the UDI will be applicable worldwide in the future. Representatives of these countries (International Medical Device Regulators Forum - IMDRF) have now published a guide on how the UDI can be implemented in their markets. This explains, among other things, which devices must be coded at device level.

1.7 What do manufacturers have to consider regarding the MDR?

1.7.1 UDI (UDI-DI + UDI-PI)

A product identification (UDI-DI) is assigned to each product and each higher packaging level. It should be noted that at the individual packaging level of a single product, the UDI-DI and therefore the GTIN remains the same, but a bundle of that product is assigned a new UDI-DI or GTIN (see figure below). In addition, a base UDI-DI (BUDI) is created as a higher-level key for the EUDAMED and the relevant documents.

Produktpackaging				
Labeling procedure	Laser engraving	Thermal inkjet	Continuous inkjet	Thermal transfer
Packaging level	Final product clamp	Foil bag as inner barrier	Individual packaing outer barrier	box with multiple individual packaging units
Print information	UDI data matrix code with HRI and CE-marking	Sterile specifications + package information leaflet	Preprint pronted with variable data	Label with product information
Trade number (GTIN)	Same GTIN	Same GTIN	Same GTIN	Different GTIN

In addition, the batch or serial number production identification (UDI-PI) is determined. However, while the UDI-DI is mandatory, the manufacturer is free to choose whether to include a serial number or a batch number in the UDI-PI. In combination with a batch number, the individual product cannot be individualized. In contrast, in combination with a serial number, the individual product can be made unique - in this combination, individual instrument tracking would be possible.
An obligation on the part of end users to track individual instruments is therefore not currently required by the FDA UDI or the MDR!

1.7.2 UDI data carrier

Once the UDI-DI and UDI-PI data have been correctly defined for the respective packaging level up to the product, this information is then integrated into the UDI data carriers (usually one-dimensional barcodes or Data Matrix) for the respective labeling.

1.7.3 UDI database in EUDAMED

All article numbers and their UDI data are entered into the European database for medical devices "EUDAMED" as described in section 1.3. The database entries are maintained and regularly checked in periodic data reviews.

1.7.4 Integration of Basis UDI-DI (BUDI)

The Basic UDI-DI (BUDI) is created at the product family level by the Regulatory Affairs department. A BUDI thus groups products (article numbers) with the same intended use, the same risk class, the same basic design and with comparable manufacturing steps into a family.
This BUDI acts as an access key to information in the EUDAMED database. It's in the technical documentation, the certificate, the declaration of conformity, and reports such as the clinical summary report of a product.

2. Linear barcode (1D code) or Data Matrix (2D code) as UDI data carrier?

The current GS1 recommendation to the healthcare industry is to use the GS1 Data Matrix for medical device identification. The scanning environment (reading data from products with less and less space for the UDI data carrier), the growing mass of data to be read, and regulatory requirements necessitate the use of a 2D code (Data Matrix) instead of a linear barcode.

2.1 What is a linear barcode?

A linear barcode is also called a 1D code. It is a sequence of bars and gaps of different widths, sometimes supplemented by rows of characters - a classic bar code. Since the bars are always arranged in a single row, this is also referred to as a one-dimensional code.
The GS1-128 is predominantly used as the linear barcode at B. Braun. The use of the GS1-128 code ensures a high degree of processing reliability and does not differ in content from other GS1 data elements.

2.2 What is a Data Matrix?

A Data Matrix code is also called a 2D code. These are optoelectronically readable fonts that consist of bars or dots of different widths and gaps between them with the highest possible contrast.

2.3 What are the advantages of a Data Matrix?

More data in less space.
A Data Matrix, unlike a linear barcode, can capture more data and takes up less space on the label or product.
Because it takes up less space, many more reusable medical devices can be labeled with a Data Matrix using laser technologies: As a result, this machine-readable UDI data carrier can be applied almost across the board to all reusable medical devices - a basic prerequisite for creating end-user acceptance of this solution for single instrument tracking.

2.4 What are the advantages of all machine-readable UDI data carriers?

Increased security.
Data can no longer be recorded incorrectly. Typing errors are eliminated.

Time savings.
Data no longer needs to be transcribed by hand.

Less costs.
4-eyes principle is fulfilled by user and computer.
The Data Matrix can be used for service recording - for example by automatic entries in the electronic patient file.

3. GS1/ sGTIN – global standard for product identification

3.1 What is GS1?

GS1 is a global, private sector organization registered with the ISO registry. Its conceptualization and implementation of global standards serve the goal of optimizing value chains through standardized vendor-independent product identification. Headquartered in Brussels, Belgium, with local member organizations in more than 110 countries.

Their standards solutions cover the following:
- Globally unique and unambiguous numbering systems (for products, locations, services, etc.).
- Technical solutions for machine-readable product identification (barcodes, radio frequency identification (RFID), etc.)
- Methodologies for data exchange with business partners (electronic messaging, master data, etc.)

Such GS1 standards can be used within the framework of a GS1 membership. B. Braun has this membership status. Therefore, for example, Aesculap products can also be equipped with GS1 GTINs.

3.2 What is a GTIN?

A GTIN (Global Trade Item Number) is an identification number managed and assigned by GS1, with which products and packages can be uniquely identified worldwide. It is a passive, numeric value with 13 or 14 digits.

3.2.1 Who assigns the GTIN numbers, and according to which system?

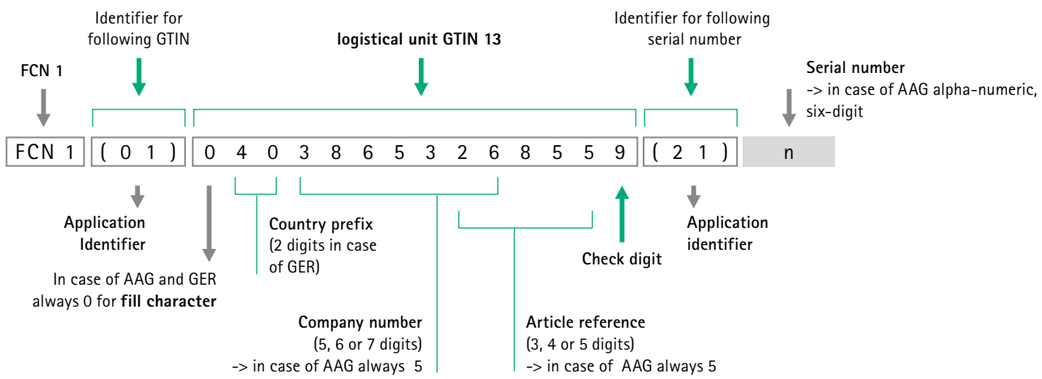
GTIN numbers are assigned by GS1 according to a fixed scheme. This ensures that each number only occurs once worldwide, making unique identification possible in the first place.

3.2.2 Who uses the GTIN?

GS1 is now authoritative in the healthcare sector. Most companies in this sector have committed to the GS1 system. You can find the current list here.

3.3 What is the sGTIN?

At B. Braun, the so-called sGTIN (serialized GTIN) was defined together with GS1 for the reusable Aesculap products in order to clearly identify them in the sterilization cycle by means of the UDI and sGTIN:



For serial numbers, there is the following distinction:
6-digit alpha-numeric number = coding on newly manufactured goods.
5-digit alpha-numeric number = coding on goods repaired by ATS

4. Labeling of Aesculap products within the B. Braun Group

4.1 How is labeling regulated in principle?

The legal framework defines how a medical device must be labeled. Reusable Aesculap products have the following elements labeled directly on the product, if space permits:

- manufacturer
- part number
- UDI in Data Matrix
- serial number as part of the sGTIN in plain text
- CE-marking
- if necessary specification of the material
- if necessary additional information

Implants also have the batch number applied to identify explanted products.

Aesculap AG has made it a rule to apply a data matrix to every instrument if the product is suitable for it. At the same time, however, a code only has to be applied if the instrument has met all the requirements. Here are the following conditions:

- suitable material (validation for Data Matrix marking available for the respective material)
- surface as flat as possible
- for rotationally symmetrical parts Ø > 5mm
- technological feasibility

4.2 How does B. Braun prove that the company's implementation of Data Matrix coding is GS1-compliant?

This is demonstrated by a combination of three things:

- Confirmation of participation in the global GS1 system. This confirmation shows that B.Braun is a participant in the global GS1 system by listing the GLNs assigned to B.Braun. With regard to individual instrument tracking, it is also important to declare that the symbol standard for the Data Matrix is adhered to.
- Already in 2016, B.Braun received the confirmation that the content of the Data Matrix is GS1-compliant. This confirmation proves that the read content of the Data Matrix on the sample device meets the requirements of GS1 and is therefore compliant with the GS1 specifications. Since all content is controlled in the same way via the UDI software, this confirmation refers to the individual coding of the entire product range.
- Confirmation of the readability of the Data Matrix code is ensured by validated manufacturing processes.


GS1 Germany

2016

Certificate of Participation in the Global GS1 System

GS1 Germany hereby confirms that the company

B. Braun Konzern Aesculap Ortho/Chir., Melsungen

is part of the global GS1 System with the Global Location Number (GLN):

40 38653 00000 5

The GLN ensures the uniqueness of the licensee and entitles him to use the GS1 Standards in all business processes.

GS1 Identification Standards:
GTIN (Global Trade Item Number),
SSCC (Serial Shipping Container Code), etc.

GS1 Data Carrier Standards:
EAN-13, GS1-128, GS1 DataMatrix, etc.

GS1 Communication Standards:
EANCOM®, GS1 XML, EPCIS, etc.

The GS1 Standards comply, among other things, with the following international rules: ISO 9735, ISO/IEC 15418, ISO/IEC 15459, ISO/IEC 18000-3, ISO/IEC 18000-6. The GS1 Codes also meet symbology standards of ISO, EN and DIN.

Therefore, the optimum conditions required for the seamless cross-company, transnational and industry-wide exchange of data and goods along the value chain are met.

GS1 Germany – as a member of the international GS1 community – represents the worldwide applicable GS1 Standards for the German market.

Cologne, 09/06/2016

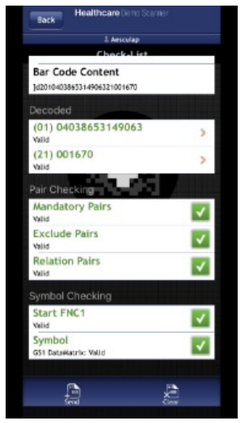
Jörg Pretzel
GS1 Germany GmbH

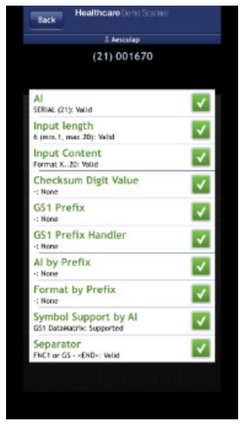
Global Standards. Make Business Efficient.

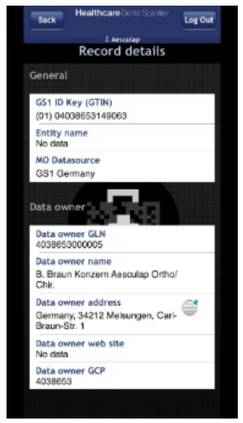
CERTIFICATE

4.3 How do I check the GS1 compliance of the Data Matrix code?

The decoding of the GTIN can, for example, be done via one of the GS1 apps and looks as follows in particular:







Currently, two apps that are available for free through the Apple Store are recommended:
1. GS1 Healthcare Barcode Scanner
2. iGepir

4.4 Is the labeling MDR compliant?

B. Braun adapts its solution for instrument tracking of reusable instruments, which is aligned with the specifications of the UDI and MDR, in accordance with the latest technical findings in order to apply the Data Matrix technology, including serialization, to as many instruments as possible for comprehensive use. Technical limitations are continuously questioned in order to constantly expand the number of coded instruments. This approach is MDR-compliant.

4.5 What is the structure of the packaging? (Primary/secondary/tertiary/quaternary packaging)

Primary, secondary, tertiary and quaternary packaging are different packaging hierarchies. The primary packaging is the smallest packaging unit. For drugs, for example, the primary packaging is the blister. Depending on the type of packaged goods, different packaging levels can be used. In the example of drugs, the secondary packaging represents the drugs box. The tertiary packaging would then be, for example, a multipack, as often used in hospital pharmacies. The quaternary packaging in this case is the carton containing several multipacks. Of course, there may be other packaging levels depending on the product.

4.6 Data Matrix labeling on products

4.6.1 Which B. Braun products are directly labeled with a Data Matrix code?

All reusable medical devices must be marked with a UDI on the product. The subsidiary Aesculap AG solves this requirement with the GS1 Data Matrix, if this could be applied to the product. The code is applied to the products that offer the space for it due to the possible labeling area. Furthermore, the technical feasibility must be given. Alternatively, the UDI can be applied in plain text.

4.6.2 Is it possible to include a reusable Aesculap instrument that was marked with a UNICOS code before 2016 in my existing instrument management system?

Yes, this is possible. Like the sGTIN, the UNICOS code is a unique serial coding system. Unlike the sGTIN, however, the UNICOS code is not a globally recognized standard. For this reason, Aesculap AG replaced the UNICOS code with the sGTIN in 2016. The UNICOS code is therefore still relevant, as it may still be applied to instruments in existing hospital stocks.
It depends on whether the manufacturer of instrument management systems has developed the functionality to continue to accept the UNICOS code and thus make it readable.

4.6.3 At what extent is B. Braun with the labeling of its reusable Aesculap products with Data Matrix and sGTIN ex works?

In order to comply with the UDI regulations, a uniform coding of all devices with a Data Matrix ex works is aimed at, as far as a Data Matrix coding is possible. A number of measures have been initiated and implemented for this purpose. It is no longer decided by the respective specialist discipline whether the products relevant to it are to be provided with a Data Matrix or not. Due to UDI, every product now receives a Data Matrix - if technically possible.
In the meantime, all article numbers are provided with a Data Matrix by default when a new product is created. If coding with a Data Matrix is not possible, the responsible developer must provide a justification. Since the beginning of 2016, the worldwide connection of all standard laser marking systems as well as multi-axis laser marking systems in production to the UDI software has been completed. **This means that all Data Matrix codes produced ex works now contain an sGTIN (serialized GTIN) as a global standard.**

4.6.4 Is additional labeling on instruments allowed by third parties?

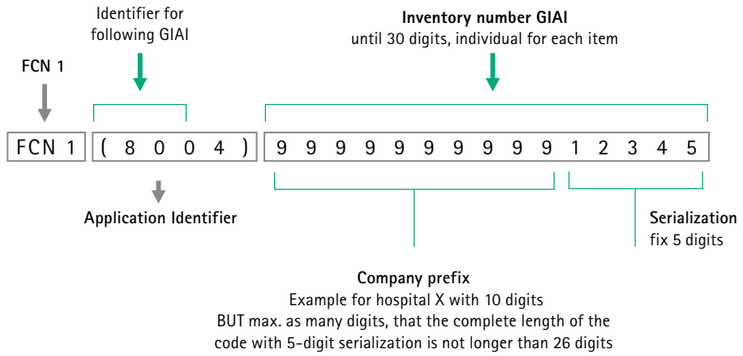
B. Braun confirms that laser marking of Aesculap instruments with additional marking is carried out with the approval of the subsidiary Aesculap AG, but with the sole responsibility of the service company contributing the post-marking in the project. Aesculap AG has indicated that a potential impact of the laser marking process on the quality of Aesculap products can happen. It is not allowed to change or remove the original product marking such as the part number or UDI. In this respect, Aesculap AG cannot be held responsible for direct, indirect or other consequential

damages such as interruption of general business operations and resulting loss of sales, which may be caused by laser marking. The same applies to product functions that may be impaired by laser marking. Furthermore, Aesculap AG is not responsible for any material weakening and resulting restrictions in instrument functions that may result from laser marking.

Otherwise, the general warranty for Aesculap instruments remains unaffected.

4.6.5 Does Aesculap also label instruments from other manufacturers with a Data Matrix?

Only the manufacturer can apply an Eudamed-compliant Data Matrix. For this reason, we always recommend sending the instruments concerned back to the manufacturer and requesting the appropriate labeling of a Data Matrix.
However, within the framework of a service contract, ATS can also apply a Data Matrix to instruments from other manufacturers on behalf of and at the risk of the operator, in case there is sufficient space available.
This Data Matrix is applied in the form of a GIAI (see below for structure) and does not contain any data on the manufacturer or production - it is purely an ordinal number for unambiguous identification of the instrument in the sterile goods cycle of the hospital.



4.7 Data Matrix labeling on packaging

4.7.1 Why is B. Braun's Data Matrix white?

The Data Matrix from B. Braun is not white in every case. This is only the case for the Ecobag® product series. All other products that carry the Data Matrix (Ecoflac®, CE products) have a „normal" Data Matrix.

The Ecobag®, unlike the other products, is a transparent soft plastic bag. When implementing the Data Matrix on the Ecobag®, a way had to be found to ensure the greatest possible readability and user-friendliness. After various tests by GS1 with some users, the best readability was found with an „inverse" Data Matrix. This means that the black squares are not printed (as in the normal case), but the white recesses are printed as white squares.

To ensure optimal readability, the Data Matrix of the Ecobag® should not be held against a white background during scanning. The greater the contrast between the Data Matrix and the background, the better the readability.

4.7.2 What is an „inverse" Data Matrix?

"Inverse" means that instead of the black squares, the white area is printed on the product. It thus represents the negative of a conventional GS1 Data Matrix.

4.7.3 Which packages of B. Braun products are already available with the Data Matrix?

A large number of B. Braun's products already have a Data Matrix. The greatest coverage is found in the CE products. In addition, the Data Matrix is continuously printed on all Ecobag®. The product range, which carries a Data Matrix, is thus getting longer and longer.
Nevertheless, not all B. Braun products will immediately carry a Data Matrix. The changeover will take some time. In addition, there will always be products for which implementation will not be possible.

Aesculap products already have the UDI integrated on all product packaging or labels. The UDI is represented either as a linear barcode (GS1-128) or as a GS1 Data Matrix. In some cases, both symbols are even present on the label.

5. Abbreviations and definitions

- **What is an EAN-128 (GS1-128)?**
  The GS1-128 barcode can encode other important information in addition to the GTIN, such as the batch number or the best-before date. The EAN-128 (now GS1-128) is a linear barcode symbology used mostly, but not exclusively, in the logistics environment.

- **What is a Data Matrix?**
  GS1 Data Matrix can be read by 2D image scanners or camera systems. Most other readers that do not have a two-dimensional image structure cannot read GS1-Data Matrix symbols. It is a two-dimensional code in which a lot of information can be encoded in a very small space in a tamper-proof way. For example, data can be represented on areas smaller than 5 x 5 mm. This makes this barcode suitable for marking very small products and even individual components of products.

- What is a GTIN?
  GTIN means „Global Trade Item Number" and can be seen as a global article number. With the GTIN, each product can be uniquely identified per packaging level worldwide.

- **What does AI mean?**
  AI means „Application Identifier". To encode data in a GS1 data carrier (whether in GS1-128 or a GS1 Data Matrix), the Application Identifier Standard (AIs) is used. The Application Identifier Standard describes the meaning, structure and function of the individual data elements in the GS1 system so that they can be processed in conformity with the system. The AIs are prefixed to the coding number in brackets and identify the type (e.g. article number, batch number or expiry date) of the number.

- **What do the numbers in brackets mean?**
  The „application identifiers" are shown in brackets. They also serve as the „human readable interpretation" of the barcode data. B.Braun uses the following AI's
  01 = GTIN
  10 = Batch (LOT) Nummer
  11 = Date of manufacture
  17 = Expiration date (MHD)
  21 = Serial number

- **What is a QR code?**
  QR stands for „Quick Response" and is a two-dimensional code developed by a Japanese company in 1994. Today it is ISO standardized and available to everyone without license fees. It has nothing to do with the GS1 Data Matrix. A QR code is used when it is to be used to link to a website. It also has a characteristic structure, but this differs from the structure of the GS1 Data Matrix.

- **Who is GS1?**
  In 1977, the European Article Association was founded, later renamed EAN International, and since 2004 has run under the name GS1 Global. It has member organizations in over 100 countries.

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