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| **Signature** | **Role** | **Event Date** | **Vote** |
| Poulot, Stephane [SYNEU] (spoulot) | Compliance | 26-May-2023 03:33:16  EDT | Approve |
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| Schmalz, Christian [SYNEU] (cschmal1) | Research and Development | 30-May-2023 07:39:11  EDT | Approve |

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# Revision History

|  |  |  |
| --- | --- | --- |
| ***Rev Level*** | ***Change Number*** | ***Brief Description of Change*** |
| 8 | 103152954 | Migration into Adaptiv of document SE\_037727 AH as is |
| 9 | 103172218 | Admin.: Switch to new template F-S082  Content: Comprehensive revision containing inter alia …   * Addendum and / or revision in respect of UDI-DPM requirements (items 1, 5, 6.3.2, 6.5, 6.7) * General or editorial revision (items 5.1, 6.3.1, 6.3.3, 6.3.4,   6.3.5, 6.7.3, 6.7.4, 6.9, 7.5, 9, 10.3, 10.3.2)   * Additional materials added to table (item 6.1.1) * OCR fonts added (item 6.2) * Manufacturer logos added (item 6.3.6) * One set of priority matrixes enhanced with an approach for one global market (cumulative marking definitions) (item 6.4) * Addendum and revision in respect of indications on drawings/ etching command (item 6.5) * Chapter ‘article number’ added (item 6.6) * Chapter traceability by ‘production date’ added (item 6.7.2) * Chapter ‘variable marking elements’ added (item 6.8) |

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|  |  | * GS1 'ABC' ... 2D-DataMatrix size, form, content, space requirements; ‘Plain Readable Text Code’, etc. (items 6.10, 6.10.1, 6.10.2, 6.10.3) * Chapter ‘Definition and Abbreviations’ updated (item 9) * Definition for determination of ‘Country of Origin’ added (item 10.4.1) * ‘Material codes’ for EMEA-AP-LAT + USA and for CN added (new, item 10.5) * Chapter ‘Symbol Libraries CAD’ added (new; item 10.6) * Chapter Remarks added (new; item 10.7) |
| 10 | 103459268 | * Updated template version and formatting (F-S082).   Clarification:   * Responsibilities (4.0), text height (6.3.1), phrasing for placement of marking on cylindrical parts (6.3.3 & 6.3.5). * Manufacturer logos; moved definitions to beginning of section (6.3.6). “MDD Class” (6.9). Legacy drawing updates (5.0). * Part space for etch, marking within family tables, COO, and CE Conformance, location for exemption documentation. CE marking exceptions, MDD reference (6.4). * COO definition (10.4), determination of COO (10.4.1). * Update to table; clarified minimum / standard text heights for UDI, and minimum logo height to be consistent in this document. Added note 6. (6.3.2) * Etch format recommendations, field reference error (6.5), lot number format (6.7.1). * Typo correction & general updates (6.10.1, 6.10.3, 7.5.1).   Updated CAD Symbol Library reference (10.6).  Addition:   * FDA Final Rule document reference (11.0), COO exceptions comment (5.0). * Optical Character Recognition (OCR) as an allowed font to allow plain text to be read with machine (6.2). * UDI specific DPM Exemptions (6.10), and examples of acceptable GTIN (DI & PI) formatting (6.10.2) * Updates related to EU Regulation 2017/745 (MDR) (5, 6.3.2, 6.4, 6.5, 6.9, 7.4, 7.5, 8.1, 8.3, 9, 11)   Removal:   * Document reference (not released) (11.0). * Lot #, Serial # for searching within GUDID, and other items within note 3 (5.0). * Note 8 (6.4), non-applicable information. (6.7.3 & 6.7.4), Redundant information (6.9 & 6.10.1). Reference to non- released work instruction (10.4.1), and non-applicable information. (6.7.1). * Section (7.1.1) regarding single use sterile devices and text regarding ownership of COO list (10.4.2) |

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|  |  | - Section (3), remove Salzburg, Austria from scope |
| 11 | 103589650 | Addition:   * New Note at the end of section 2 Replacement: * EN 980 with EN ISO 15223-1:2016 in section 11 |
| 12 | 103772684 | * Updated to include EU MDR Direct Marking requirements * Section 5 added second bullet for EU MDR, updated note 3 for US FDA and added note 4 * Section 6.3.2 added section to table for 2D DataMatrix * Section 6.3.3 added picture showing 2D DataMatrix and text * Section 6.4 added EU MDR regulation requirements * Section 6.7 added EU MDR regulation requirements * Replaced Human Readable Plain Text Code with Human Readable Interpretation throughout document * Removed “Part” from all “direct part marked” & and “P” “DPM references”. * Added 2 new direct marking procedures to reference list |
| M | 23612 | * Added new note at the end of section 2 * Section 6.1.1 added new column for “Molded in, embossed or debossed” process * Section 6.3.2 added picture showing New style of Depuy Synthes Logo and New style of CE Mark with Notified body number stacking * Section 6.3.6 added New style of Depuy Synthes Logo in Manufacturer logos – usages * Section 6.9 added CE Marking requirements for ‘-US’ Articles * Section 6.9 added New style of CE Mark with Notified body number stacking and note added to use the new style with preference * Section 6.10.1 added Implementation Strategy for 2D Data Matrix * Section 6.10.1 updated the Matrix Sizes and Space requirements table and notes * Section 6.10.1 note added for DataMatrix barcode within 1/6 of the diameter of curvature * Section 8.2 added New style for TP Mark with Notified body number stacking * Section 9 updated the definition for Article # * Section 10 added new section 10.8 to define the example of tables used in drawings for etch requirements |
| N | 37675 | - Section 6.3.6 added DPS Logo with Continuum Loop Icon Overview and Versions. Added “**DS**” as an DPS Logo simple  wordmark in Manufacturer logos – usages |

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| --- | --- | --- |
|  |  | * Section 6.4 Note added for UDI DM exceptions from EU Commission Help Desk Ticket * Section 6.5.2 added for Marking Product manufactured in Palm Beach Gardens * Section 6.7.3 note added for Serial # Uniqueness * Section 6.10, Table for Data elements updated with minimum DM as GTIN (for FDA) and GTIN + ‘Lot #’ or ‘Serial #’ (for MDR), for Product Class I and Remarks added * Section 6.10 remarks added for UDI DM “Exemption Reason” * Section 6.10.1 note added for UDI Matrix and UDI HRI placements * Section 6.10.1 new table added for space requirements for Chemical Marking, Dot Peening and Mechanical Engraving process with X-dimension 0.45, 0.35 and 0.25. Existing space requirements table renamed as ‘for laser marking’ with X- dimension 0.25, 0.2 and 0.15. * MDR Reference updated in Section 7.5 * Section 10.4 and 10.6 Note added for Palm Beach Gardens strategies * Section 11 added reference document - SE\_717009 Synthes Variant Set Up Process and 100651587 - MD PLM Document   and Change Management Procedure (Shared) |
| P | 52248 | - Section 6.10.1 note added to Implementation Strategy for 2D Data Matrix |

# Purpose

This work instruction defines how products (the unpackaged product) are required to be marked to ensure that they can be readily identified.

This work instruction establishes guidelines regarding the placement of markings, marking with regard to function, and general purpose markings – taking into account materials, marking processes and technical aspects.

However, the work instruction does not regulate any of the alternative methods for the identification of products - such as 'Indirect Part Marking' (IPM), 'Sterile Packaging' or the 'Inventory Control Sheet' technique.

Note: The work instruction anticipates that all systematic deviations from the marking priorities as defined in item [6.4](#_bookmark10) are specified in the specific product development project and/or in the change order, see item [10.7](#_bookmark38).Note: Device drawings referring to this work instruction for the identification of the Notified Body number as represented by ‘**CEXXXX**’ must be etched with the Notified Body Identification Number ‘**0123**’, per section 6.9. Thus, XXXX=0123.

Note: Device drawings referring to this work instruction for the implementation strategy of 2D DataMatrix barcode must be etched, per section 6.10.1.

# Scope

This work instruction is valid for all products developed and manufactured by or for and marketed by Synthes as the legal manufacturer. For individual product groups, supplementary requirements may be established but must follow the directives of this work instruction.

This guideline is mandatory for all employees of Synthes and vendors who are engaged in the above mentioned activities at or for one of the following locations:

|  |  |
| --- | --- |
| ***Location / Production Plant*** | ***Location / Production Plant*** |
| Balsthal, Switzerland | Raron, Switzerland |
| Bettlach, Switzerland | Raynham, MA, USA |
| Brandywine, PA, USA | Selzach, Switzerland |
| Elmira, NY, USA | - |
| Grenchen, Switzerland | Suzhou, China |
| Hägendorf, Switzerland | Tuttlingen, Germany |
| Mezzovico, Switzerland | Umkirch, Germany |
| Monument, CO, USA | West Chester – Paoli, PA, USA |
| Oberdorf, Switzerland | Zuchwil, Switzerland |
| Palm Beach Gardens, FL, USA | Wilson Drive Manufacturing, PA, USA |

# Roles/Responsibilities

The following divisions together decide about the marking content of a specific product:

* R&D (Product Development)
* DQE (Design Quality Engineering)
* RA (Regulatory Affairs)
* Purchasing

|  |  |
| --- | --- |
| ***Role*** | ***Responsibility*** |
| R&D | * Propose content, layout and make of a marking * Dissemination of the proposed marking requirements to involved third parties. |
| DQE | - Review the proposed marking content, layout and make from an engineering and manufacturing point of view |
| RA | - Review the proposed marking content from a regulatory point of view. |
| Purchasing | - Dissemination of the marking requirements identified to involved third parties. |

Remark:

All decisions made, have to be formally documented (e.g. ‘Technical Review Meeting Minutes, Change Order) for the product in question.

# General Requirements

Products are marked with key symbols and text for clear identification. Marking requirements may differ depending on the country or sales region. The type of marking required indicates whether it must be machine readable or guarantee legibility by a user with and without the use of reading aids, according to the conditions set forth in the table of item [6.3.2](#_bookmark7) – Legibility. When possible, it is recommended that the entire identification marking be placed on a single surface.

Standard marking of Synthes product may consist of the following elements:

* UDI DM compliant marking **3\*)** - Global Trade Item Number (GTIN) as well as ‘Lot #’ or ‘Serial #’ as content of a ‘2D DataMatrix barcode’ element of type ’GS1’ or as part of a ‘GS1’ compatible alphanumeric ‘Human Readable Interpretation element.
* UDI DM compliant marking **4\*)** - Global Trade Item Number (GTIN) as well as ‘Lot #’ or ‘Serial #’ as content of a ‘2D DataMatrix barcode’ element of type ’GS1’ and as part of a ‘GS1’ compatible alphanumeric ‘Human Readable Interpretation element
* CE Marking - **1\*)**
* **C**ountry **o**f **O**rigin (COO) Marking - **1\*)**; **3\*)**

1\*) Exceptions to marking of COO can be made on a case by case basis, with the approval of the Trade Compliance Team.

* Lot Number or Serial Number (or Production Date) – **1\*)**; **2\*)**; (**3\*)**)
* Article Number - **1\*)**; **2\*)**; (**3\*)**)
* Material Type - **2\*)** (implants only)
* Logo (Manufacturer)
* (Product) System Information

(e.g. DHS, PFN, UFN, UniLOCK, Click’X, USS, etc.)

* Information of functional relevance for the user (e.g. pictograms, dimensions, etc.)

## Note:

1\*) The elements marked are mandatory elements for EMEA / AP / LAT – MDD, MDR and customs requirements.

2\*) The elements marked are mandatory elements for China respectively the Chinese domestic market.

3\*) The elements marked are mandatory elements for the USA – FDA and customs requirements. i.e GTIN, LOT or Serial and/or 2D DataMatrix barcode

4\*) The elements marked are mandatory elements for EU MDR i.e. GTIN, LOT or Serial and 2D DataMatrix barcode.

* With the exception of functionally relevant information, all marking elements can be gathered from entering the ‘GTIN into the publicly searchable FDA GUDID database.
* Whenever possible, marking content should be selected so as to fulfill the requirements of one global market – cumulative requirements of the USA and ‘EMEA / AP / LAT’ markets; for comments see item [10.7](#_bookmark38) – ‘Remarks’. When this is not possible, single market specific marking would apply.
* Additional marking requirements from local authorities shall be followed and added to the basic requirements. The use of characters of local language specific character fonts also comes under the heading ‘additional marking requirements’.
* Drawings released prior to the initial effective date of this procedure are not required to be updated until a drawing revision is required. Drawings created or revised after the effective date of this procedure are required to meet the requirements of this procedure.

## Placement of Marking

The marking must be placed so as not to have a negative impact on mechanical strength or any other product risk. It is the responsibility of product development to evaluate the effect of the marking on mechanical strength of the device and to document their findings – see item [6.4](#_bookmark10)**.**

# Marking Process

Identification marking of product is typically done through acid etching, engraving, printing, coloring, laser etching or other suitable processes. All processes used for marking are subject to current Synthes specific process and work instructions. The processes used may not have a negative impact on product safety and must be proven by the risk management as adequate.

## Specifications

The appropriate process for applying marking symbols and identifications is determined with regard to legibility, durability, material and surface area properties. In certain cases, the final determination of the procedure can only be made after successful completion of special tests (e.g. clinical reprocessing, etc.).

* + 1. Process Selection Matrix

The marking process should normally be determined based on the following decision matrix:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Process**  **Material** | **Laser** | | **Engraving or engrave and fill engraving with epoxy or synthetic resin paint** | **Chemical / acid etching** | **Printing (by pad or screen)** | **Marking with epoxy or synthetic resin paint** | **Molded in, embossed or debossed** |
| **Temper Coloring**  **/ Color Change** | **Engraving** |
| Ti + Ti alloys  (light anodize colors) | + | - | + | - | + | NA | NA |
| Ti + Ti alloys  (dark anodize colors) | + | + | + | - | 0 | NA | NA |
| Stainless steel alloys | + | 0 | + | + | + | + | NA |
| Stainless Steel Alloys coated / finished | + | 0 | + | 0 | 0 | 0 | NA |
| Al + Al alloys | + | + | + | - | + | 0 | NA |
| Al + Al alloys finished | + | + | + | - | + | 0 | NA |
| Plastics | + | 0 | + | - | + | - | + |

Legend: + recommended; - not recommended; 0 recommended with conditions

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Process**  **Criteria** | **Laser** | | **Engraving or engrave and fill engraving with epoxy or synthetic resin paint** | **Chemical / acid etching** | **Printing (by pad or screen)** | **Marking with epoxy or synthetic resin paint** | **Molded in, embossed or debossed** |
| **Temper Coloring**  **/ Color Change** | **Engraving** |
| Text | + | + | + | + | + | 0 | + |
| Marking large surfaces | 0 | - | - | + | + | - | NA |
| Color marking | - | - | + | - | + | + | NA |
| Thin parts (<1mm) | 0 | - | - | + | + | - | NA |
| Small symbols/marking | + | + | - | - | + | - | NA |

Legend: + recommended; - not recommended; 0 recommended with conditions

## Font

For the purpose of legibility only serif-free Linear-Antiqua font type is approved. DIN 1451-1 and DIN 30640 contain five font types, of which Helvetica is defined as the Synthes standard font.

The five DIN font types are copyright protected and are therefore only supported in a limited fashion by CNC software for milling and LASER etching. If none of the licensed font types is available, the following font types may be used alternatively: Arial and Frutiger (45 / light, 65 / bold) in Microsoft applications and for printed etch; Helvmed, 1451B (Trumpf) and D1451 (Rofin) as machine manufacturer specific copies of the font Helvetica per DIN 1451 for laser etch.

For alphanumeric code texts, machine readable font types shall be used whenever possible and appropriate. Where possible, Optical Character Recognition (OCR) fonts B and F are recommended in order to provide machine readable text. Whenever possible, Operations is to take note to include at a minimum of single line width of white space between characters.

The use of a font type not listed above must be approved by product development (PD/R&D) prior to its use.

Note:

- In addition to the font type a line weight is designated i.e. ‘normal’ or ‘bold’. Normal is the default line weight, unless otherwise specified.

## Size and Position

* + 1. Text Height

In accordance with DIN 1451-1 the text height (‘FS’ or ‘Font Size’) is recommended as follows:

* + - * The text height is the height of the capital letter “H” (in mm) independent of line weight and relative to the outer edge, i.e. the absolute height.
      * The height of text on a drawing is only given in 1/10mm increments (i.e.

1.2mm, 2.7mm).

* + - * The height of the ‘Lot #’ is 2/3 of the height of the ‘Article #’, in general. The rule ceases to exist for text height < 1.5mm.
    1. Legibility

In relation to the aim of ensuring the legibility of markings on Synthes products intended for hospital personnel, the term ‘legibility’ is defined as follows: marking is considered legible if it can be read by a person with normal or corrected eyesight at a distance of 20 to 40 cm.

Synthes text height guidelines for legibility:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Function of marking** | **Intent of marking** | **Standard Text Height** | **Minimum Text Height** | **Examples** |
| **General Information** | Legible by customer without magnification | 3 mm 4\*) | 0.5 mm | ‘Article #’, ‘Lot #’, ‘Serial #’, ‘COO mark’ |
| **Functional Information** | Legible by customer without magnification | 3 mm **4\*)** | 1 mm | "Medial", "lateral", "L",  "R", "125°", “Ø12 x 400, "NOT FOR HUMAN USE" |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Function of marking** | **Intent of marking** | **Standard Text Height** | **Minimum Text Height** | **Examples** |
| **Traceability of critical**  **sub-components 1\*)** | not intended to be  legible by customer; legible by Synthes at  5x magnification | 1 mm | 0.4 mm | Locking ring for DHHS, scaled products, power tools and equipment |
| **Synthes Logo; DePuySynthes Logo5\*)** (manufacturer) | Legible by customer without magnification | 3mm **3\*)**; **4\*)**  5mm **2\*)**; **4\*)** | 0.6 mm | synsymrund DPS_Logo  DPS_Logo |
| **CE-Mark 5\*)**  (MDD / MDR  requirement) | Legible by customer without magnification | 3 mm **3\*)**; **4\*)**  5 mm **2\*)**; **4\*)** | 0.5 mm; |  |
| **UDI – Direct Marking ‘HRI Element,** only (FDA requirement) | Legible by customer without magnification | 1 – 3mm  6\*) | 1 mm 6\*) | (01)12345678901234  (10)1234567890 |
| **UDI Direct Marking 2D DataMatrix Barcode** | Legible by customer without magnification | Refer to section 6.10 | |  |

Remarks:

1\*) Subcomponents identified through risk analysis as the ones requiring an individual lot number.

2\*) Standard height for power tools and cases (as well as layout size). 3\*) Standard height for implants and instruments.

Note:

The specified height was, contrary to the recommendations made in the MDD and MDR regulation, defined as the standard height because it creates a consistently well readable and well balanced marking for the majority of our products.

4\*) Marking elements are not limited to the text heights listed. Marking shall be as large as possible relative to the importance of the marking and the space available on the device.

5\*) The etch indication on the drawing defines type and size of the logo to use.

6\*) The preferred text height for UDI DM is 1mm – 3mm. Etching smaller than 1 mm is considered acceptable when available space on the part requires a smaller font for part bounding purposes. However, this means that the marking would not qualify as a UDI DM if it is less than 1mm in text height, and should be marked as exempt in the DHF in the appropriate company PLM system.

* + 1. Orientation of Marking on Round Parts

The following guidelines must be applied regardless of the marking process:

* Longitudinal markings are centered and located along the longitudinal axis of the part – in single or multiple lines fashion.
* Place markings in circumferential direction symmetrically around the axis.
* It is preferred to place the markings on the largest diameter of cylindrical parts. If sufficient space is not available, marking on other diameters is acceptable.





* + 1. Proportion of Marking on Round Parts

For round parts, the font height on the longitudinal axis should not exceed 50% of the diameter. For limitations when marking 2D DataMatrix barcode, see item [6.10.1](#_bookmark21); subchapter ‘Placement of Matrix’.

* + 1. Orientation of Marking in General

In practice the following rules for implants and instruments have proven to be successful:

* + - * The identification marks or text must be legible when the device is held in the right hand in such a way that the device is pointing to the left – ‘right hand rule’.

No allowance is made for holding the part in the left hand. For examples of the “right hand rule” - see below.



The marking on the top of a screw head must be legible from the outside to the center.



The 2D DataMatrix barcode is not orientation constrained; however, the matrix is generally oriented with the rest of the text, when present.

* + 1. Manufacturer Logos – Usage

The following information defines use and style of manufacturer or brand identifying graphical marking elements. ’FS’ stands for ’Font Size’ and ’GS’ for ’graphic size’.

## Synthes-Logo

* + - * **‘SYNTHES LOGO’** ... as a simple graphic in ’single-line style fashion’; size range: ’GS’ = 0.6 mm - 3.9 mm in steps of 0.1 mm.

(for general use)

* + - * **‘SYNTHES LOGO’** … as a simple graphic in ’double-line style fashion’; size range: ’GS’ ≥ 4 mm in steps of 1 mm.

(for general use)

* + - * **‘SYNTHES LOGO’** ... as a simple graphic in ‘filled-style fashion’; size range: ’GS’ ≥ 4 mm in steps of 1 mm.

(for printed or electro chemical etched applications or for applications on material uncritical in regard of its corrosion resistancy towards surface etching, only)

* + - * **‘SYNTHES LOGO’** … as graphic with ’word mark’ in ’double-line style fashion’; size range: ’FS’ ≥ 4 mm in steps of 1 mm;

ratio ‘word mark’ to graphic (‘FS’:’GS’) = 1 to 1.1.

(for general use)



* + - * **‘SYNTHES LOGO’** ... as graphic with ’word mark’ in ‘filled-style fashion’; size range: ’FS’ ≥ 4 mm in steps of 1 mm;

ratio ‘word mark’ to graphic (‘FS’:’GS’) = 1 to 1.1.

Synthes_Pelvic_P286 Kopie(for printed or electro chemical etched applications or for applications on material uncritical in regard of its corrosion resistancy towards surface etching, only)

**DePuySynthes Logo** (DPS-Logo)

* + - * **‘DPS LOGO’** ... for general use for small marking elements (size range: 0.6 mm – 3.9 mm)

### Attention: No logo is available for that purpose at present!

* + - * **‘DPS LOGO’** ... for general use for medium to large marking elements (size range: ≥ 4 mm)

### Attention: No logo is available for that purpose at present!

* + - * **‘DPS LOGO’** ... as simple graphic in ‘filled style fashion’; size range: ’GS’ = 0.6 – 4 mm in steps of 0.1 mm.

DPS_Logo(for printed or electro chemical etched applications or for applications on material uncritical in regard of its corrosion resistancy towards surface etching, only)

* + - * **‘DPS LOGO’** … as graphic with ’word mark’ in ‘filled-style fashion’ + horizontal layout;

size range: ’FS’ ≥ 2.5 mm in steps of 0.5 mm; ratio ‘word mark’ to graphic (‘FS’:’GS’) = 1 to 1.78.

DPS_Logo (for printed or acid etched make, molded in make only)

* + - * **‘DPS LOGO’** ... as graphic with ’word mark’ in ‘filled-style fashion’ and vertical layout;

size range: ’FS’ ≥ 2.5 mm in steps of 0.5 mm; ratio ‘word mark’ to graphic (‘FS’:’GS’) = 1 to 1.78.

 (for printed or acid etched make, molded in make, only)

**DePuySynthes Logo** (DPS-Logo with Continuum Loop Icon)

## Logo Overview

The DePuy Synthes logo should always be locked up with the Johnson & Johnson endorser whenever possible. The endorser may only be dropped in special circumstances such as size constraints or production limitations.



## Logo Versions

## Primary: Logo with Endorser

Use the primary logo whenever possible. The inclusion of the endorser is integral to maximizing brand recognition across various touch points.



## Secondary: Logo without Endorser

Use the secondary logo only when size constraints or production limitations render the primary logo endorser text illegible or unreproducible.



## Tertiary: Continuum Loop

Can only be used when the Primary and Secondary logo are not present & cannot be applied to the product.

When utilized it cannot be used as an action indicator on buttons or touch points.



* + - * **‘DPS LOGO’** … as graphic with ’wordmark’ in ‘filled-style fashion’ + horizontal layout;

size range: ’FS’ ≥ 2.5 mm in steps of 0.5 mm; ratio ‘word mark’ to graphic (‘FS’:’GS’) = 1 to 2.

(for printed, laser, acid etched, molded in make, only)

* + - * **‘DPS LOGO’** ... as graphic with ’wordmark’ in ‘filled-style fashion’ and vertical layout;

size range: ’FS’ ≥ 2.5 mm in steps of 0.5 mm; ratio ‘word mark’ to graphic (‘FS’:’GS’) = 1 to 2.

(for printed, laser, acid etched, molded in make, only)

* + - * **‘DPS LOGO’** … as graphic with ’word mark’ in ‘double-line style fashion’ + horizontal layout;

size range: ’FS’ ≥ 2.5 mm in steps of 0.5 mm; ratio ‘word mark’ to graphic (‘FS’:’GS’) = 1 to 2.

(for printed, laser, acid etched, molded in make, only)

* + - * **‘DPS LOGO’** ... as graphic with ’wordmark’ in ‘double-line style fashion’ and vertical layout;

size range: ’FS’ ≥ 2.5 mm in steps of 0.5 mm; ratio ‘word mark’ to graphic (‘FS’:’GS’) = 1 to 2.

(for printed, laser, acid etched, molded in make, only)

* + - * **‘DPS LOGO’** ... as simple ’word mark’ in ‘filled-style fashion’ layout; size range: ’FS’ = 0.6 to 5 mm;

**DePuy Synthes** (for general use, refer section 6.2 for Font)

* + - * **‘DPS LOGO’** ... as ’word mark’ in ‘filled-style fashion’ layout; size range: ’FS’ = 0.6 to 5 mm;

(for special circumstances only. To request approval contact: [DPSBrandcenter@its.jnj.com](mailto:DPSBrandcenter@its.jnj.com), refer 6.2 for Font)

Note:

* + - * In a logo with ‘word mark’ the ’font size’ variable ’FS’ is the leading one.
      * The logo symbols needed for the graphical representation on the 3D models in the drawing (representation graphics) and on the real parts (laser graphics) are found in the corresponding CAD library – see item [10.6](#_bookmark37) – ‘Symbol Libraries CAD’.

## Priority Matrix and Example

The subsequent tables define the scope and the priority of appearance of marking elements for specific product types. The approach used in the tables is the one of a global market – cumulative marking. Resorting to market specific etching should only take place whenever the former is not possible.

When there is not enough space on the part to etch all the required elements or when etching could possibly weaken the structural strength of the part, they shall be placed on the label and/or packaging.

Labels and packaging together must contain, except for the ‘information of functional relevance’, the full set of marking information. Within a family of products, uniform marking must be maintained. An exception to this would be a family table within a drawing that has different dimensions for a series of parts. Just because the smallest part on the drawing cannot fit a mark does not mean that the others can not fit it.

The omission of UDI DM marking elements and CE marks with or without notified body ID must be justified and accordingly documented (e.g. ‘Technical Review Meeting Minutes, Change Order) for the product in question in the Design History File (DHF) – signed by R&D, DQE and RA. In case of a family of parts the justification has to address each individual part of this family.

## Direct Marking (DM) requirements following U.S. FDA regulations concerning Unique Device Identification (UDI):

Per CITE: 21 CFR. §801.40(b), all implants, instruments, power tools plus accessories, as well as cases, trays and modules intended to be sold on the United States domestic market must be marked whenever possible with a GTIN, and depending on the product class with a ‘Lot #’ or a ‘Serial #’, as well – see item [6.10](#_bookmark20) for more detail.

Exempt thereof are implants and instruments for single use because they allow identification up to the point of implantation. Reusable devices that cannot be marked require a DM exception rationale in the DHF.

Other additional exempt options are defined by the US FDA. Entering into any of these exempt options has to be agreed to by regulatory affairs and accordingly be documented in the development project or change order.

## Per Office Journal of the European Union Regulation (EU) 2017/745, Part C The UDI System:

Section 4.10 Devices that are reusable shall bear a UDI carrier**\*** on the device itself. The UDI carrier for reusable devices that require cleaning, disinfection, sterilization or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the lifetime of the device. The requirement of this Section shall not apply to devices in the following circumstances:

1. any type of direct marking would interfere with the safety or performance of the device
2. the device cannot be directly marked because it is not technologically feasible.

Section 4.11 The UDI carrier shall be readable during normal use and throughout the intended lifetime of the device.

Section 6.2 Reusable devices requiring cleaning, disinfection, sterilization, or refurbishing between uses.

Section 6.2.1 The UDI of such devices shall be placed on the device and be readable after each procedure to make the device ready for the next use

## Section 6.10 Reusable devices can only be marked with HRI information due to space constraints, it should be indicated as ‘directly marked’ in the EUDAMED database according to EU Commission Help Desk Ticket Number 30219.

**\*** UDI carrier encompasses AIDC and HRI information

## Country of Origin” (COO) Requirements:

As stated in the Global Trade Compliance Policy Standard GTC-STA-1004 for origin and marking, JNJ is committed to ensuring that all of its legal entities comply with requirements for determining, declaring, and marking the Country of Origin. All product manufactured by or on behalf of Synthes is subject to the COO marking as stated in this document.

Regarding guidance for the identification of the country of origin and the appropriate country code (‘COO Code’) see item [10.4](#_bookmark34).

## MDD / MDR Requirements of CE Conformance:

All implants, instruments, power tools plus accessories as well as cases, trays and modules intended for distribution on the EU and EFTA market must be marked, among others, whenever possible with the appropriate CE mark (CE or CEXXXX) to show their conformity with the market. This per CITE: MDD 93/42/EEC Annex XII or EU Regulation 2017/745 (MDR) where applicable - see item [6.9](#_bookmark19) for more detail.

**Priority Matrix Tables with a global market approach** (cumulative marking):

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Priority of the marking elements for implants** | | | | | | | |
| **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** |
| Information | ‘Lot #’ | ‘Article #’ | ‘CE Mark’ | Country | Manufacturer | System | Materi |
| of | or |  | 1\*) | of Origin | (Logo) | Informatio | al |
| Functional | ‘Serial #’ |  |  | (COO) | 2\*) | n | Design |
| Relevance | 7\*); 2\*); 3\*) |  |  |  |  | 5\*) | ation |
|  |  |  |  |  |  |  | 4\*) |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Priority of the marking elements for instruments** | | | | | | | |
| **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** |
| Information of Functional Relevance | ‘Lot #’ or  ‘Serial #’ 7\*); 3\*);  10\*) | ‘Article #’ | ‘UDI DM Element’ (= GTIN as well as ‘Lot #’ or ‘Serial #’) 6\*); 7\*); 8\*); 10\*) | ‘CE Mar k’  1\*) | Country of Origin (COO) | Manufacture r  (Logo) | System Informati on  5\*) |
| **Priority of the marking elements for power equipment including accessories** | | | | | | | |
| **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** |
| Information | ‘Lot #’ | ‘Article #’ | ‘UDI DM Element’ | ‘CE Mar | Country | Manufacturer | System |
| of | or |  | (= GTIN as well as | k’ | of Origin | (Logo) | Informati |
| Functional | ‘Serial #’ |  | ‘Lot #’ or ‘Serial #’) | 1\*) | (COO) |  | on |
| Relevance | 7\*); 3\*); |  | 6\*); 7\*); 8\*); 10\*) |  |  |  | 5\*) |
|  | 10\*) |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Priority of the marking elements for trays, graphic cases and modules** | | | | | | | |
| **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** |
| Information | ‘Lot #’ | ‘Article #’ | ‘UDI DM | CE Mark’ | Country | Manufacturer | System |
| of | or |  | Element’ | 1\*) | of Origin | (Logo) | Informati |
| Functional | ‘Serial #’ |  | (= GTIN or |  | (COO) |  | on |
| Relevance | 7\*); 3\*); |  | GTIN as well as |  |  |  | 5\*) |
|  | 10\*) |  | ‘Lot #’ or |  |  |  |  |
|  |  |  | ‘Serial #’) |  |  |  |  |
|  |  |  | 6\*); 7\*); 8\*) 10\*) |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Priority of the marking elements for veterinary products – implants + instruments 9\*)** | | | | | | |
| **1** | **2** | **3** | **4** | **5** | **6** | **7** |
| Information of Functional Relevance | ‘Lot #’ or ‘Serial #’ 3\*) | VET ‘Article #’ | Country of Origin (COO) | Manufacturer (Logo) | System Information 5\*) | Material Designation 4\*) |

Remarks:

1\*) The presentation of the CE symbol has to follow the directive‚ MDD 93/42/EEC, Annex XII and EU Regulation 2017/745 (MDR), Annex V.

2\*) In cases of extremely limited space on implants, the logo becomes 2nd priority. 3\*) For requirements pertaining to single item identification, see item [6.7.3](#_bookmark17).

4\*) No Material Code is required to be directly marked on the product unless specifically required by R&D, a local authority or a regulatory body - see item [10.5](#_bookmark36) with regard to available codes.

5\*) No (Product) System Information is required to be directly marked on the product unless specifically required by PM or R&D.

6\*) See item [6.10](#_bookmark20) for applicable ‘UDI DM’ code elements.

7\*) If there isn’t enough space for the ‘UDI DM’ element but enough for the ‘Lot #’ or the ‘Serial #’, then the ‘Lot #’ or ‘Serial #’ has to be put there.

8\*) When selecting the UDI DM ‘2D DataMatrix barcode’ then the ’Lot #’ or ’Serial #’ has to be added in HRI for the ’EMEA / AP / LAT’ (ROW) market, as well.

9\*) Including veterinary products for which there exists one global market, only.

10\*) If instruments are going to be marked with a UDI DM ‘HRI element, that is GTIN and ‘Lot #’ or ‘Serial #’, only put ‘Lot #’ or ‘Serial #’ once in GS1 format.

## CE Marking Exceptions:

The following are acceptable ‘CE Notified Bodies’ exception reasons for not applying ‘CE Marking on a device:

|  |
| --- |
| **Reason** |
| Custom made devices |
| Clinical Investigative Devices |
| Systems or Procedure Packs |

## Sequence of Appearance of Marking Elements:

There are no rules concerning the sequence of appearance, the grouping or layout of the marking elements other than those necessary to meet geometric, cosmetic and functional aspects of a product - see item [6.3](#_bookmark6).

Examples of market specific marking options for an implant:

 **‘EMEA / AP / LAT Market**’ Version

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 2183234A |  |  | SWISS | 473.545 | ce_ce0123-gleich_1 | PFN LONG | TAN |

 **‘US Market’** Versions (UDI compliant minimum etch)

|  |  |  |
| --- | --- | --- |
|  |  | SWISS |

(… using ‘2D DataMatrix barcode’)

(… or using ‘HRI)

|  |  |
| --- | --- |
| (01)4711081500711 (10)2183234A | SWISS |

 **‘Global Market’** Versions (EMEA / AP / LAT’ + US Market Versions combined)

(… using ‘2D DataMatrix barcode’)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 2183234A |  |  | SWISS | 473.545 | ce_ce0123-gleich_1 | PFN LONG | TAN |

(… and using ‘Human Readable Interpretation’)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| (01)4711081500711(10)2183234A |  | SWISS | 473.545 | ce_ce0123-gleich_1 | PFN LONG | TAN |

## Markings on Drawings

This section delineates recommendations in formatting options of etch callouts for drawings. Etching using laser technology is the default or standard process to which no reference is necessary.

## The Etching Command:

A drawing may contain one or more ‘Etching Commands’ ’**ETCH …**’ with an attached list of standard and/or application specific ‘marking elements’. A variant with multiple ‘Etching Commands’ is usually chosen only when the elements to mark are split up in different positions; e.g. one ‘Etching Command’ addresses the entire block of standard ‘marking elements’ to be etched in one location and one or more additional ‘Etching Commands’ address application specific ‘marking elements’ to be etched in different positions, like arrows, scales, special symbols and texts, etc. Alternatively, laser etch details may defined within the notes section of the drawing without using an “etch” command.

Immediately behind the ‘Etching Command’ references to notes can be placed which refer to applicable etching processes.

A corresponding CAD symbol which allows to set every single standard marking element as well as to define application specific marking elements is listed/specified in the CAD symbol library – see item [10.6](#_bookmark37) - and is preferably to be used.

**ETCH** [ *‘references to notes’* ] “*marking element 1*“

“*marking element 2*“

“*marking element 3*“ etc.

Recommended standard and application specific marking elements:

* **UDI-MATRIX** *[Var/Var; Var]* or **UDI-TEXT** *[FS; Var]*

(for details to elements and variables see item [6.10.1](#_bookmark21) or item [6.10.2](#_bookmark22) – indication on drawings)

* **LOT #** *[FS]* or **SERIAL #** *[FS]* or **P-DATE** *[FS]*

(for details to font size and content see item [6.7.1](#_bookmark15), item [6.7.2](#_bookmark16) or item [6.7.3](#_bookmark17))

* **ARTICLE #** *[FS]*

(for details to font size and content see item [6.6](#_bookmark13))

* **SYNTHES-LOGO** *[GS]* or **SYNTHES-LOGO** *[FS]* or

**DPS-LOGO** *[GS]* or ’**DPS-LOGO**’ *[FS]*

(for details to font or graphic size and execution see item [6.3.6](#_bookmark9))

* **CE** *[FS]* or **CE0123** *[FS]* or **CEXXXX** *[FS]* or  *[FS]* or **TP** *[FS]* or **TP0123**

*[FS] or * *[FS]*

(for details to font size and execution see item [6.9](#_bookmark19) for “CE” or item [8.2](#_bookmark28) for ’Test Product’.)

## COUNTRY OF ORIGIN *[FS]*

(for details to font size and content see item [10.4](#_bookmark34))

* **MATERIAL** *[FS]*

(for details to font size and content see item [10.5](#_bookmark36))

## ’User-specific Element’

(entire content is user specific)

The graphical representation of marking on the product:

* Fixed elements are graphically shown on the part (3D model) using symbols of exact proportions which represent them in a one-to-one fashion.
* Variable elements are graphically shown on the part using appropriate placeholders which ensure the footprint of the elements.
* For the indication on drawings and on 3D models of UDI elements see item [6.10.1](#_bookmark21) and item [6.10.2](#_bookmark22).
* The layout of the marking on the product follows the graphical order shown on the 3D model and not the one indicated by the order the elements appear in the ’etch command’ – see item [10.1](#_bookmark32) for sample drawings.
* The style of the graphical marking elements on the product follows what is graphically shown on the 3D model. The style is also regulated to some extent by the ‘size-style’ definitions attributed to the graphics.

Note:

* The actual number of digits needed for the ‘Lot #’ or the ‘Serial #’ may be greater than the number depicted by the placeholder on the drawing. If the additionally required space potentially affects functionality, a threshold should be defined for safe marking. In that case, the ‘Lot #’ space requirement must be reduced by changing the font size or spacing accordingly.
* Concerning restrictions on the use of P-Date see item [6.7.2](#_bookmark16).

## Other Etch Options:

Another option for etch callout is describing the etch in the notes section of a drawing. For example:

1. “Etch GTIN and lot number with application identifiers, (01) for GTIN, (10) for lot number, height: 2 mm”
2. “Etch Synthes logo, part number and CE mark, height: 4 mm”

When using this option, the etch (whether fixed or variable) should be shown graphically on the drawing to scale, including any placeholders.

* + 1. Marking Product According to the Old Mathys Work Instruction Legacy Mathys drawings refer to work instruction 5.3.0800.001. The use of this instruction is subject to the following restrictions:

Work instruction *5.3.0800.001 – Beschriften von Implantaten und Instrumenten*

*Osteosynthese*’ of Mathys Medizinaltechnik AG is valid only for product unique to the former Mathys product lines still in production which explicitly reference this work instruction.

* + 1. Marking Product manufactured in Palm Beach Gardens

For product designed and manufactured in Palm Beach Gardens, the drawings, CAD items and symbols are managed in Windchill per procedure 100651587. Marking information is provided as notes and symbols are defined as product part items and captured in the product structure. For laser marking process controls, refer to local Palm Beach Gardens procedures.

## Article Number

The article number is the element which primarily identifies the product in the internal and external use.

The article number (‘Article #’) can be found in packaging or market neutral form in a product specification or on a product drawing.

Packaging and market neutral means that ‘Article #’ extensions/suffixes like ’**.05**’ or ’**.10**’ which represent packaging units or the extension/suffix ’**S**’ which indicates ’sterile packaging’ or the extension/suffix ’**-US**’ which indicates that the article is intended for the US market are not reflected on the product – also see item [7.1](#_bookmark24) – ’Sterile Products’. The list of the ‘article #’ extensions mentioned in this paragraph is not final.

There are prefixes and suffixes which are an integral part of an ‘Article #’ such as the suffix **V** for a product made from a vanadium containing titanium alloy or the prefixes **VS**, **VP**, **VW**, etc. for veterinary implant products.

Placeholder for an entire or part of an ‘Article #’ is the capital alpha character ’**X**’ in an appropriate number - e.g. **XXX**.**XXX** or 0**X**.105.**XXX**.

For single articles or views to scale of articles without direct reference to the ’Etching Command’ the effective ‘Article #’ is to be shown – e.g. a 3D view of the largest and the smallest article.

Regarding the default font size recommendation and the minimum font size permitted see item [6.3.2](#_bookmark7)- 'Legibility'.

The value for the ‘Article #’ comes from the product drawing.

## Traceability – Manufacturing Lot Number, Manufacturing Date and Serial Number

Whenever possible, a lot number (‘Lot #’), a production date (P-Date) or a serial number (‘Serial #’) is etched on Synthes product for device traceability. They may be etched as a discrete element or as part of a ‘Direct Marking’ (DM) element - ‘Human Readable Interpretation element and/or ‘2D DataMatrix barcode’ element - as defined by FDA’s ‘Unique Device Identification’ regulation (UDI) for the US market and EU MDR Regulation (EU) 2017/745; see item [6.10](#_bookmark20).

* + 1. Traceability at Manufacturing / Production Lot Level with ‘Lot Number’ The standard solution for traceability to production lot level is the ‘Lot #’.

‘Lot #s’ for the identification of production lots consist of a minimum of 3 and a

maximum of 10 characters. All characters must be of the numeric and capital alpha type. As of the time of release of this document, the standard is 7 characters beginning with an alpha character for part etching. The standard placeholder format for drawings is 8 characters whenever possible ('**ABCDEFGH**'). The use of place holders from drawings as actual ‘Lot #’ is not permissible (i.e. ABCDEFGH or XXXXXXXX).

The only exception for a longer ‘Lot #’ is defined in item [6.7.4](#_bookmark18) – ‘Lot Numbers for Purchased Finished Goods’.

The value for the production ‘Lot #’ comes from the ‘production work order’ (router or purchase order).

Note:

- ‘Lot #s’ are usually allocated uniquely across all products and production lots of a manufacturer, and allow therefore, most of the time, the unambiguous identification of an article at ‘Lot #’ level.

* + 1. Traceability at Manufacturing / Production Lot Level with ‘Production Date’

An alternative method for the traceability of production lots is the manufacturing date (P-Date) which is restricted to one individual production lot per article per day. For this reason, the P-Date is seldom used for finished products.

The use of the P-Date is permissible currently for one single type of product and application, only, which is injection molded single use instruments which cannot be etched after molding and on which a P-Date is generated with date code inserts integrated in the die.

Example:



For the logistic processing, the P-Date set in the die is converted into a six digit ISO date (YYMMDD) and continued as a ‘Lot #’.

A suitable placeholder for the layout of the marking used has to be shown in the graphical representation of the marking on the 3D model used in the drawing.

Note: The value for the ‘Lot #’ used on the label either comes from the delivery documentation of a vendor or from the ‘Lot #’ under which an internally produced semi-finished product was stored.

* + 1. Traceability of Single Devices

Instruments, power equipment and power equipment accessories that require regular service or maintenance are allotted a serial number (‘Serial #’) as unique identifier to trace them down to a single device level.

‘Serial #s’ can be generated in two ways:

1. An incrementally increasing numeric value.
2. An incrementally increasing alphanumeric value.

‘Serial #s’ identify a part unambiguously only in combination with the part’s ‘Article #’.

For the size of a ‘Serial #’ the same rules apply as for the one of a ‘Lot #’ – maximum 10 characters.

Note:

* Both of the previously described methods to generate ‘Serial #s’ are used today.
* Products with ‘Serial #s’ do not require additional marking to identify rework since the ‘Serial #’ already uniquely identifies the particular part.
* ‘Serial #s’ should never consist of less than 4 characters to be safely identified as such. Since most systems do not permit supplementing numbers with leading zeros serialization has start at value 1000.
* The only exception for ‘Serial #s’ with more than 10 characters is the one used for power equipment products manufactured in Palm Beach Gardens. For these products, an incrementally increasing alphanumeric, 12 characters long ‘Serial #’ is used which is independent of the product type. For these products, the ‘Serial #’ also identifies the article.
* Application Identifier for Serial # is (21), and it should be unique. Application Identifier should be same on direct part marking on the device and on product label (i.e., If the product contains Application Identifier as (21) in UDI element, then the product label needs to be printed with same application identifier (21)).

A placeholder for a ‘Serial #’ usually consists of a sequence of the capital letter ‘**X**’ – from a minimum of 6 to a maximum of 8 characters, e.g. '**XXXXXXXX**'.

The value of the ’Serial #’ respectively the starting value for the serial numbering within a production work order comes from the production work order (router or purchase order).

* + 1. Lot Numbers for Purchased Finished Goods

For product manufactured by external vendors, vendors may assign their own ‘Lot #’ as long as they meet the same criteria as established for internally assigned ‘Lot #s’, that is, consist of no more than 10 characters.

* + 1. Rework of Partial Production Lots

Rework on part of a production lot must be traceable. This means that the lot information on the reworked articles must be clearly distinguishable from the ones on the remaining articles of the original 'total production lot'.

## Variable Marking Elements – User-Specific Elements

The variable marking elements include 'information of functional relevance for the user' and '(product) system information '. For these elements, the drawing must contain the entire definition either directly on the drawing or indirectly by referencing separate documents and systems - e.g. a CAD library with standardized special symbols – see item [10.6](#_bookmark37).

PD / R&D are responsible for the scope and definition of the variable elements.

## CE Marking

All medical devices marketed by Synthes GmbH as the legal manufacturer must have CE approval. Regulatory Affairs is responsible for acquiring these approvals. CE compliance is to be documented by applying the ‘CE mark’ (see MDD 93/42/EEC, Annex XII or EU Regulation 2017/745 (MDR), Annex V where applicable).

The CE mark must be applied to …

* all medical devices
* their packaging labels
* all product support information that correspond with them (e.g. technique guides, brochures, etc.)

… that are marketed in the countries of the European Community (EC/EU) and the European Free Trade Association (EFTA). See item [6.3.2](#_bookmark7) for legibility limits as well as item [7.5](#_bookmark25) and item [8](#_bookmark26) for special regulations (exceptions) on specific product types.

The ‘CE marking’ on a product may only be omitted in certain well justified situations - see item [6.4](#_bookmark10).

The CE mark consists of two elements, the actual CE symbol and a possible indication of a Notified Body Identification Number. The table below lists the available product classes per MDD 93/42/EEC (Medical Device Directive) and EU Regulation 2017/745 (MDR) with their marking requirements.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **MDD**  **Class** | **MDR**  **Class** | **CE Mark** | | **Product** |
| **CE**  **Symbol** | **Notified Body ID Number** |
| (e.g. 0123) |
| **I** | **I** | ● | **-** | trays, cases incl. modules |
| **I** | **I** | ● | **-** | Instruments |
| **N/A** | **I r** | ● | ● | Reusable surgical instruments |
| **I s** | **I s** | ● | ● | sterile instruments\* |
| **I m** | **I m** | ● | ● | instruments with scaling function |
| **II a** | **II a** | ● | ● | power tools, attachments and power tool operated instruments |
| **II b** | **II b** | ● | ● | Implants |
| **III** | **III** | ● | ● | e.g. bio-resorbable product |

Note:

* \* Class I instruments under MDD which are distributed both sterile and non-sterile shall bear only the “CE” symbol without the Notified Body Number on the device.
* MDD, MDR and FDA product classifications may be different. If clarification is required, review with Regulatory Affairs.

## Synthes GmbH as the Legal Manufacturer:

The Notified Body for Synthes GmbH is ‘TÜV SÜD Product Service GmbH’ with Notified Body Identification Number ‘**0123**’.

## Synthes GmbH as Distributor:

Synthes also markets products in the role of distributor. Notwithstanding the above described regulation, products to which this applies are marked with a CE mark with the Notified Body Identification Number of the Original Equipment Manufacturer (OEM) of the specific products.

## CE Mark styles:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **CE / CE 0123**  in ‘single line’ style |  |  |  |  |
| **CE / CE 0123**  in ‘double line’ style |  |  |  |  |
| **CE / CE 0123**  in filled style |  |  |  |  |

Note:

* For size (FS) < 4 mm always consider a ‘single line’ style.
* For size (FS) ≥ 4 mm use ‘double line’ or filled style.
* ‘Single line’ and ‘double line’ styles are for general use; filled style is for printed or acid etched make, only.
* \* Stacking of Notified body number below to the **CE** Mark is least preferred based on the space limitation.
* It is suggested that the test part variation (TP mark) matches the CE mark variation; see item [8.2](#_bookmark28).

The information to be marked comes from the product drawing – ‘Etch command’ and graphical representation. Style and variation come from the graphical representation in the drawing, only.

The ‘CE mark’ symbols/sketches needed for the graphical representation on the drawing and on the part can be found in the corresponding ‘CAD library’ – see item [10.6](#_bookmark37).

Note:

* The presence of a CE mark on a product does not necessarily mean that the product is released for sale (e.g. product in quarantine or product not released yet through RA).

**CE Marking requirements for ‘-US’ and ‘-12’ Articles**:Article numbers with extension/suffix ‘**-US**’ **and ‘-12’** which indicates that the product is intended for the US market in terms of packaging or market neutral form in a product specification. Article Numbers with an extension/Suffix ‘**-US**’ **and ‘-12’** are used by Synthes GmbH for distinguishing between the different regional requirements, as design features are same as the “Base Item Number”. CE marking is permissible for ‘**-US**’ **and ‘-12’** variants codes, which have a valid CE certification. The Product Drawing does not call out the CE marking requirements for ‘**-US**’ **and ‘-12’** items, as the “Base Item Number” and ‘**-US**’ **and ‘-12’** variants are the same in design including the etching requirements, unless specified otherwise on the product drawing. Any specific etching requirements that differ from the “Base Item Number” must be identified on the product drawing with the specific variant code or range in which it applies.

Note: -US” and “-12” means “Products distributed to the US”.

“-US” is an extension of the Product Code that Synthes introduced prior introducing Variant Management and “12” is a Mod Code that was introduced with the Variant Management.

“-US” is matched with the Mod Code 12 in Regulatory Approval Database (RAD)

## ‘Direct Marking’ Elements for UDI

The UDI requirements of FDA and EU MDR demand that all saleable products that are destined for market must be identified in a worldwide unique fashion. UDI requirements also dictate that this information be available for all products at the time of implantation. One way of doing that is marking the necessary information directly onto the products – Direct Marking (DM).

The addition of DM information to implants is recommended but not mandatory. Implants are exempt from DM but nevertheless must be identifiable at the point of implantation. DM is an acceptable method for identification of implants.

For US FDA, the UDI information must be applied either in the form of a ‘GS1 ECC200’ compatible ‘2D DataMatrix barcode’ element and/or in the form of a GS1 compatible ‘Human Readable Interpretation’’ element, for EU MDR the UDI information must contain both 2D DataMatrix barcode and HRI in accordance with item [6.3.2](#_bookmark7) – Legibility.

The UDI information normally consists of data elements GTIN (Global Trade Item Number) and ‘Lot #’ or ‘Serial #’. The individual elements are identifiable through a leading ‘Application Identifier’ (AI) in round brackets. The elements are sorted per the AI in ascending order.

The field contents of the data elements (AIs) specified comes from the production order (router or purchasing order).

|  |  |  |
| --- | --- | --- |
| **Product Class** | **Data Elements** | |
| **Minimum for DM** | **Recommendation for ’Best Practice’** |
| I | GTIN (for FDA) and  GTIN + ‘Lot #’ or ‘Serial #’ (for MDR) | GTIN + ‘Lot #’ or ‘Serial #’ 1\*) |

|  |  |  |
| --- | --- | --- |
| **Product Class** | **Data Elements** | |
| **Minimum for DM** | **Recommendation for ’Best Practice’** |
| II, IIa & IIb | GTIN + ‘Lot #’ or ‘Serial #’ | GTIN + ‘Lot #’ or ‘Serial #’ 1\*) |
| III | GTIN + ‘Lot #’ or ‘Serial #’ | GTIN + ‘Lot #’ or ‘Serial #’ 1\*) |

Note: FDA product classification does not necessarily match MDD or MDR product classification.

Remarks:

1\*) ‘Lot #’ or ‘Serial #’ used in the product label as an element for UDI (addition with GTIN) may match with UDI direct part marking on the device.

|  |  |  |
| --- | --- | --- |
| **Application Identifier (AI)** | **Data Definition / Type** | **Number of Characters**  **of Data Content** |
| 01 | GTIN | 14 1\*) |
| 10 | ‘Lot #’ | max.10 2\*) |
| 21 | ‘Serial #’ | max.10 2\*) |

Remarks:

1\*) Purely numeric

2\*) Alphanumeric with a maximum of 3 alpha characters (capital characters only) when maximum number of characters reached.

Subsequent subchapters describe the two above mentioned ways of marking UDI Information on parts (DM) in detail.

## UDI Direct Marking Exemptions:

The following are acceptable exception reasons for not applying a UDI Direct Mark on a device per FDA UDI Final Rule Docket No. FDA-2011-N-0090 and EU Regulation 2017/745 Part C the UDI system, section 4.10:

Reusable devices that cannot be marked per the following exemptions require a DM exception rationale in the DHF.

|  |
| --- |
| **Reason** 1\*) |
| Interfere with the safety or effectiveness of the device |
| Technologically not feasible 2\*) |
| The device is a single-use device and is subjected to additional processing and  manufacturing for the purpose of an additional single use (FDA only) |
| The device has been previously marked (FDA only) |

Remarks:

1\*) Human Readable Interpretation (HRI) only exception per EU Commission Help Desk Ticket Number 30219, “If the professional use reusable device can only be marked with HRI due to space constraints, it should be indicated as 'directly marked' in the EUDAMED database. Per this helpdesk ticket, if due to space constraints for devices such as but not limited to drill bits which are generally long, cylindrical shapes, where HRI may fit, but are unable to direct mark a 2D barcode due to part geometry, the devices shall be direct marked with HRI only, and considered direct marked in EUDAMED for the EU MDR”.

2\*) Exemption reason, “Technologically not feasible” is detailed in below listed categories.

* A legible Direct part marking (DM) cannot be added due to a lack of available area on the device This may be, because the device is too small or the lack in area of high reflectivity per 1/6th rule (refer “Placement of Matrix” in section 6.10.1) or features (such as uneven surfaces, holes, etc.) on the device does not permit a legible UDI DM.
* Material capacity and compatibility has an influence on the legibility and gradeability of UDI DM’s. For example, Silicone material is not compatible for UDI Matrix implementation. If there are any available spaces nearer to the silicone material in any other compatible materials also considered as an exempt, to avoid passivation damage to the silicone material after the UDI Matrix implementation.
* Device functionality and assembly conditions (such as tight fit assembly conditions, frequent interactions with mating parts prone to friction) also have potential impact to the UDI DM implementation. For example, some trocars (sharp tip trocars) suffer surface damage after being impacted by mallets during intended use. So, its recommended to exempt the head surface of these devices from UDI DM requirements despite availability of surfaces.
  + 1. GS1 ‘2D DataMatrix barcode’ Element

## Terminology used for 2D DataMatrix barcode



|  |  |
| --- | --- |
| **Term** | **Description** |
| ‘Matrix Size’ | The size of the Matrix as a multiple of a Module and consisting of the ‘Data Region’ including L-Finder and ‘Clock Track’ width. |

|  |  |
| --- | --- |
| **Term** | **Description** |
| ‘Data Region’ | Area within a Matrix which effectively contains the coded data; the area is described by its run length in number of Modules in X and Y direction – Xs\*Ys. |
| Module | The smallest geometric entity/element within a Matrix; a Module may have a square or a round shape; a dark module represents a binary 1 and a white one a binary 0. The size of a module is defined by the ‘X-Dimension’. |
| X-Dimension (X-Module) | Edge length of a square or diameter of a round Module. |
| L-Finder | Defines the size of the ‘Data Region’; the width of the ‘L-Finder’ is 1 Module. |
| ‘Clock Track’ | Defines the Module density of the ‘Data Region’; the width of the ‘Clock Track’ is 1 Module. |
| ‘Quiet Zone’ | Area all around the ‘2D DataMatrix barcode’ element which must be free of any visually disruptive elements; the width of the ‘Quiet Zone’ must be at least 3 Module. |
| ECC 200  Identifier | A ‘Zero Module’ (empty or “white” Module) in the right upper edge of the Matrix. |
| FNC1  Character | Per ECC 200, ‘2D DataMatrix barcode’ must have a leading FNC1 character in the code to indicate that the Matrix is a GS1 compatible one. FNC1 is a special, non-printable, character. Depending on the system, a two-byte control character from an extended ASCII character set (Double Byte Character Set or DBCS) is used for that purpose – Microsoft or IBM systems. |

## Implementation Strategy for 2D DataMatrix barcode

For all reusable medical devices (including reusable instruments and capital equipment that’s classified as a medical device) are to be marked with human readable interpretation (HRI) and 2D DataMatrix barcode for Unique Device Identification (UDI) purposes for MDR requirement and HRI alone for FDA requirement across the Synthes. This also includes all external manufacturers (suppliers) that provide applicable product types to any of the Synthes sites listed in section 3.

Based on the regulatory strategy, its permissible but not mandatory to have the UDI 2D Data Matrix barcode on reusable medical devices before to the MDR compliance dates of application (DoA). The UDI 2D Data Matrix barcode etching indicated on the drawing has thus only mandatorily to be marked on the product as DM at the date of application but can and should be implemented as soon as there is demand and the manufacturing activities are completed.

Product drawings released with a 2D Data Matrix specification, are only valid with an approved validation. The 2D Data Matrix shall not be etched on the device until all appropriate documentation is approved for production and inspection of the device. Once the required documentation is available, the 2D Data Matrix shall be etched and inspected per the drawing requirements. Until then, products can be manufactured and shipped as per the latest drawing revision excluding 2D Data Matrix. All other requirements from the drawings are excluded from this exemption and need to be complied with. This approach must be documented in applicable DCR/DCO or CR/CN when the drawing is updated to add the 2D Data Matrix.

|  |  |
| --- | --- |
| **MDR Product Class** | **MDR Compliance Dates for UDI direct marking** |
| Class III | **26-MAY-2023** |
| Class IIA, Class IIB | **26-MAY-2025** |
| Class I (all) | **26-MAY-2027** |

## Matrix Sizes Used

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Type** | | **Matrix Size**  (XxY) | **Data Region**  (Data Area Size) (XsxYs) | **Maximum Data Capacity** | | **X-**  **Dimens ion** (Module  Size) |
| Num. | Alpha- num. |
|  | | **18x18** 3\*) | D16x16 | 36 | 25 | 0.15  0.20  0.25  0.35  0.45 |
| Square |  | 20x20 | D18x18 | 44 | 31 |
| 22x22 | D20x20 | 60 | 43 |
|  | | **12x26** 3\*) | D10x24 | 32 | 22 |
| Rectangular |  | 12x36 | D10x32 2\*) | 44 | 31 |
| 16x36 | D14x32 2\*) | 64 | 46 |
| (Shape) | | [ModulexModule] 4\*) | [ModulexModule] | [Digit] 1\*); 4\*) | | [mm] |

Notes:

1\*) The number of digits the code can consist of – the requirements per numeric character are 1 digit and per alpha character 2 digits.

2\*) Split into two data areas.

3\*) Matrix types which cover the space required by UDI DM minimum requirements in most cases; exception: The ‘matrix size’ 12x26 for ‘Lot #s’ or ‘Serial #s’ that have reached the maximum as defined.

4\*) Where the current data capacity no longer meets the demands (e.g. because an additional data element is needed) the internet has more details on further options/matrix sizes under “GS1 DataMatrix – Introduction.”

## Space Requirements for Laser Marking

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Matrix Size**  (XxY) | **Minimum Required Space for ‘Matrix Types’ per ‘Module Size’** (= ‘X-Dimension’ in mm)  **and including ‘Quiet Zone’**  (XmxYm) | | |
| **‘X-Dimension’** |  | 0.25 | 0.2 1\*) | 0.15 |
| **Square Type** | **18x18 1\*)** | 6x6 | 4.8x4.8 | 3.6 x 3.6 |
| 20x20 | 6.5 x 6.5 | 5.2 x 5.2 | 3.9 x 3.9 |
| 22x22 | 7 x 7 | 5.6 x5.6 | 4.2 x 4.2 |
| **Rectangular Type** | **12x26 1\*)** | 4.5 x 8 | 3.6 x 6.4 | 2.7 x 4.8 |
| 12x36 | 4.5 x 10.5 | 3.6 x 8.4 | 2.7 x 6.3 |
| 16x36 | 5.5 x 10.5 | 4.4 x 8.4 | 3.3 x 6.3 |
|  | [1x1] | [mmxmm] | [mmxmm] | [mmxmm] |

## Space Requirements for Chemical Marking, Dot Peening and Mechanical Engraving

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Matrix Size**  (XxY) | **Minimum Required Space for ‘Matrix Types’ per ‘Module Size’** (= ‘X-Dimension’ in mm)  **and including ‘Quiet Zone’**  (XmxYm) | | |
| **‘X-Dimension’** |  | 0.45 1\*) | 0.35 | 0.25 |
| **Square Type** | **18x18 1\*)** | 10.8 x 10.8 | 8.4 x 8.4 | 6 x 6 |
| 20x20 | 11.7 x 11.7 | 9.1 x 9.1 | 6.5 x 6.5 |
| 22x22 | 12.6 x 12.6 | 9.8 x 9.8 | 7 x 7 |
| **Rectangular Type** | **12x26 1\*)** | 8.1 x 14.4 | 6.3 x 11.2 | 4.5 x 8 |
| 12x36 | 8.1 x 18.9 | 6.3 x 14.7 | 4.5 x 10.5 |
| 16x36 | 9.9 x 18.9 | 7.7 x 14.7 | 5.5 x 10.5 |
|  | [1x1] | [mmxmm] | [mmxmm] | [mmxmm] |

Notes:

1\*) Preferred sizes

## Placement of Matrix:

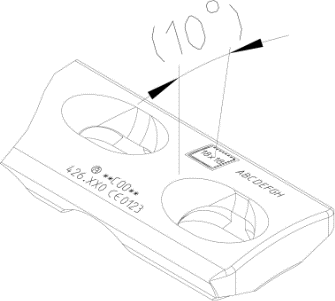
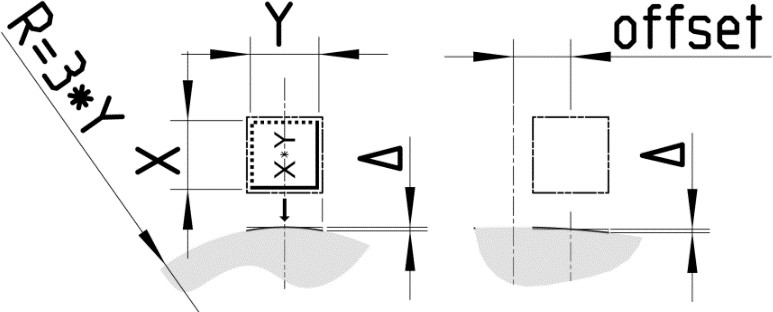
* Determine the biggest suitable area for the application of the ‘2D DataMatrix barcode’ element while taking into account criteria such as flatness, finish, possible stress concentration zones, already defined “no etching permitted” zones and possible existing or placed marking elements.
* Except for ‘information of functional relevance’, already placed marking elements may be relocated.
* Align ‘2D DataMatrix barcode’ element to other elements of marking, if available.
* A possible curvature of the area of placement must meet both the requirements of the marking process as well as the one of the reading process.
* Per the GS1 Guidelines: “It is recommended to have Human Readable Interpretation of the Application Identifiers (AIs) and their associated data near the GS1 DataMatrix Symbol in which they are encoded. The precise location and font used for the Human Readable Interpretation are determined by the specific application guidelines. Typical conventions place the primary information, such as the Global Trade Item Number (GTIN), in the human readable data underneath the barcode. The characters, however, should be clearly legible and must be obviously associated with the symbol.”
* When marking a curved surface, the DataMatrix barcode should be limited in size to approximately 1/6 of the diameter of the curvature. A rectangular DataMatrix barcode is most suited to this type of application. If the surface can be treated to have matte or textured finish, which reduces the reflectivity of the surface being marked, it is possible to further increase the size of the DataMatrix barcode being marked. For example, the matte or textured finish diminishes the effect of the intense light bar apparent in the illustration below which the rectangular DataMatrix barcode is designed to sit within, thus ensuring a consistent contrast across the complete surface of the DataMatrix barcode.



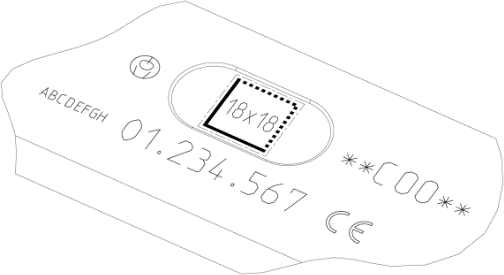
Rectangular DataMatrix barcode within 1/6 of the diameter of curvature

At no point may the area of placement be more curved or have a smaller radius of curvature than 3\*Xm in ‘X-Direction’ (height) or 3\*Ym in ‘Y-Direction’ (width) when laser etching a 2D DataMatrix barcode. In addition the direction of application for a 2D DataMatrix barcode should be normal to the surface of application. For that reason, whenever possible, 2D DataMatrices should be placed symmetrically over the axis or the center of a radius. Where asymmetric placement is desired it must be ensured that the maximum difference in the projection distance is not greater than the one which results from a 2D DataMatrix barcode placed symmetrically over the axis of the smallest radius of curvature – see sketch. If the direction of the normal for the

application cannot be derived from the main coordinate system of the part or a logical alternative thereof, it needs to be properly defined – see sketch. Remark: Larger deviations from the normal lead to diffusion and attenuation of the laser beam and subsequently to blurring in the results.



* + When mechanically etching a 2D DataMatrix barcode – dot peening or drilling – the area of placement has to be plain and the direction of application normal to it.
  + If 2D DataMatrices must remain legible for an extended lifespan but are prone to abrasive wear due to their area of placement, then they have to be placed in a recess window – see sketch. Remark: The need for a recess window may also result from the application process. In addition, recess windows make locating 2D DataMatrices easier.



* See item [6.10](#_bookmark20) for acceptable reasons for not marking UDI.

## Indication on Drawings:

On a product drawing the command line to etch UDI information in form of a

‘2D DataMatrix barcode’ element within the ‘ETCH’ command is executed as follows:

**UDI-MATRIX** *[’Matrix Size’]/ [’X-Dimension’]; [’*2nd*AI’]*

The variables can take the following values:

- ’Matrix Size’: **18x18**, **20x20**, **22x22**, **12x26**, **12x36**, **14x36**

- ‘X-Dimension’: **0.45;0.35;0.25; 0.2; 0.15**

* ‘2nd AI’:

… ’**(10)**’ for ’Lot #’

… ‘**(21)**’ for ‘Serial #’

… ’**N/A**’ for no ’2nd AI’

For each of the variables, a default value has been defined or a preset value has been set as is the case for the CAD symbols:

* Default ’Matrix Size’: **18x18**
* Default ‘XDimension’: **0.2** (for Laser Marking)
* Default ‘2nd AI’: **(10)**

Note:

* For each of the variables a corresponding value has to be indicated.

Command line samples for ‘2D DataMatrix barcode’ element: UDI-MATRIX 18x18/0.25; (10)

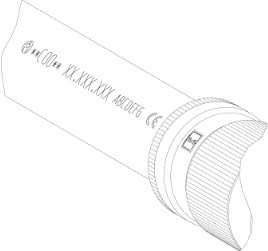
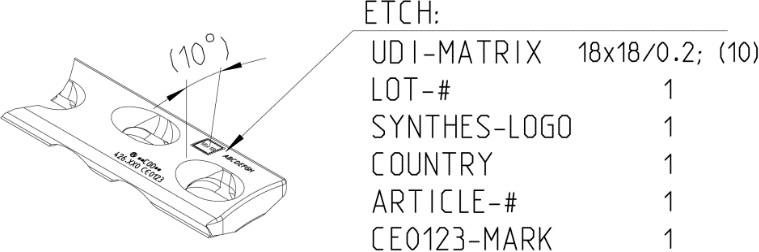
UDI-MATRIX 18x18/0.2; (21) UDI-MATRIX 20x20/0.15; N/A

etc.

## Graphic Representation on the Part:

To display orientation and location of a ‘2D DataMatrix barcode’ element a placeholder symbol of appropriate size (and type) needs to be selected from the CAD systems library for standard symbols – see item [10.6](#_bookmark37) - and placed accordingly. If needed, a normal vector to the application surface should be specified.

## Examples:



## Comments on Execution:

* The preferred application method for ‘2D DataMatrix barcode’ elements is laser etching. Other methods of application, e.g. dot peening, CNC engraving or acid etching may be used as well. The resulting module shape can be square as well as round.
* Alternative application methods or process variants are tied to the ‘ETCH’ command via note references.
* The quality of ‘2D DataMatrix barcode’ elements with square module form must be for some aspects of minimum grade C (≥ 1.5) quality per AIM DM-1-2006 on the final product.
* ‘2D DataMatrix barcode’ elements with round module form are graded per the same specification and to the same quality level as the ones with square module form.
  + 1. GS1 ‘Human Readable Interpretation’ Element

The ‘HRI element of the UDI information may be applied on a product in place of or in addition to a ‘2D DataMatrix barcode’ element for US FDA only, the EU MDR requirement is to have both 2D DataMatrix barcode and HRI.

In the ‘Human Readable Interpretation’ form the data elements are shown in single or multiple lines and with leading ‘AI’s in parenthesis. The data elements belonging to a ‘HRI element build a unit and therefore have to be placed next to each other – one after the other or one below the other – and sorted with ‘AI’s in ascending order. The text must fulfill the legibility requirements as defined in item [6.3.2](#_bookmark7).

## Information content (Input sample):

|  |  |  |  |
| --- | --- | --- | --- |
| GTIN (DI) | (01)12345678901234 | (14 numeric characters) | |
| ’Lot #’ (PI) | (10)ABCDEFGH | (10 alphanumeric characters max,  of which max. 3 may be of ’alpha’ type) | |
| Default Linear (Preferred) | | | Default Stacked | |
| (01)12345678901234(10)ABCDEFGH | | | (01)12345678901234 (10)ABCDEFGH | |

If the marking of the Device Identifier (DI) and Production identifier (PI) onto a reusable device as HRI cannot be grouped, their spatial separation is allowed.

|  |  |
| --- | --- |
| **Acceptable if Default Linear (Preferred) is Not Possible** | **Acceptable if Default Stacked is Not Possible** |
| Non Default Stacked | Separated |
| (10)ABCDEFGH (01)12345678901234 | (10)ABCDEFGH  (01)12345678901234 |

Following examples of HRI are NOT allowed.

|  |  |
| --- | --- |
| **Linear** | **Stacked** |
| (10)ABCDEFGH(01)12345678901234 | (01)12345678901 234(10)ABCDEFGH |

## Note: Typically, alpha characters represent variable data, and numerical characters represent fixed data.

## Indication on drawings:

Marking UDI information in HRI format is made on the product drawing per the following command line:

**UDI-TEXT** *[FS]; [’*2nd*AI’]*

The variables in it can take the following values:

- ’Font Size’: **1**, **0.9**, **0.8**, **0,7**, **0.6**, **0.5**

- ‘2nd AI’:

… ’**(10)**’ for ’Lot #’

… ‘**(21)**’ for ‘Serial #’

... ’**N/A**’ for ’no 2nd AI)

Note:

* For each of the variables a corresponding value has to be indicated.

For each of the variables a default value has been defined or a preset value has been set as is the case for the CAD symbols:

* Default ’Font Size’: **1**
* Default ‘2nd AI’: **(10)**

Command line samples for HRI elements: UDI-TEXT 1; (10)

UDI-TEXT 0.7; (21)

UDI-TEXT 0.5, N/A

etc.

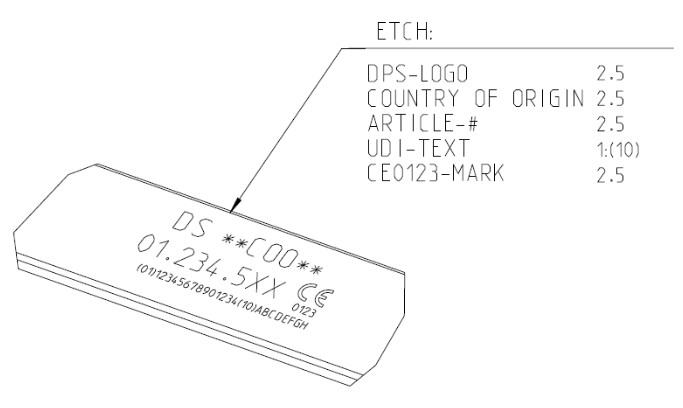
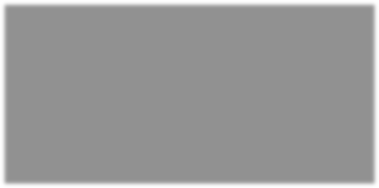
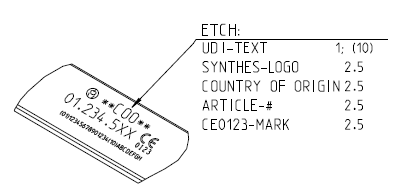
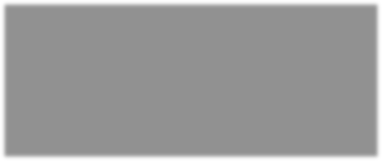
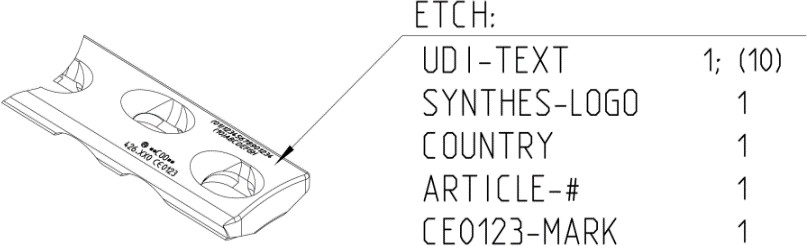
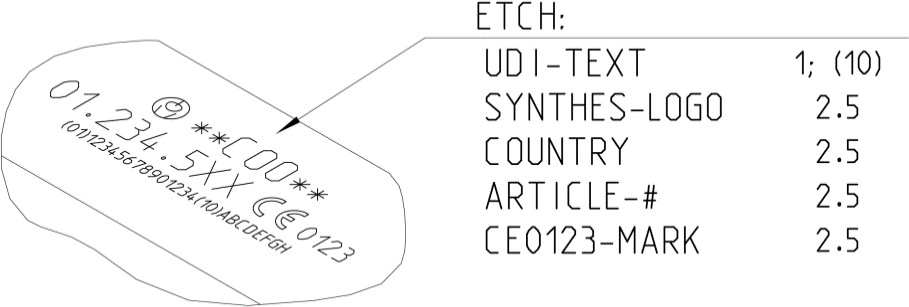
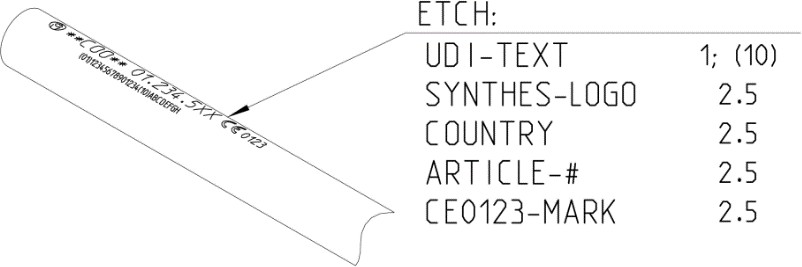
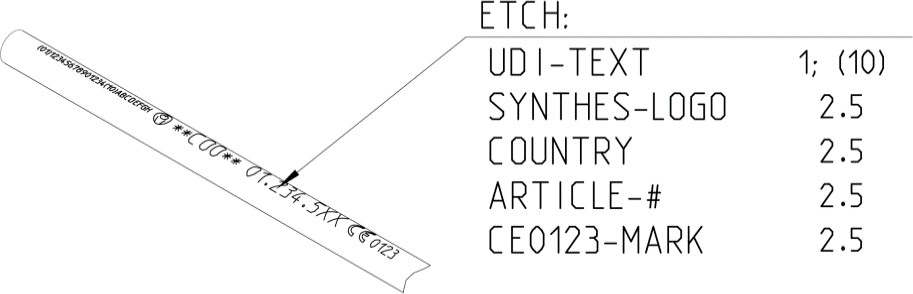
## Graphic representation on the part:

Use one of the following place holder symbols, by default in ’Font Size’ 1 mm, for the representation of a HRI element on the part:

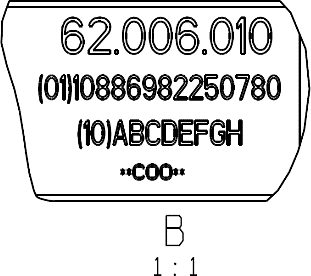
(01)12345678901234(10)ABCDEFGH (single line symbol version)

(01)12345678901234 (multiple line symbol version) (10)ABCDEFGH

## Samples:



Device Specific GTIN instead of placeholder sample:



Note:

* As placeholder for the ’Application Identifier’ (AI) always use the true value.
* The placeholder for the GTIN should typically be the above shown sequence of numeric characters. In some cases the device specific GTIN value may be used instead of the place holder.
* As placeholder for ’Lot #’ or ’Serial #’ use values as defined in item [6.7](#_bookmark14).
  + 1. ‘Direct Marking’ of Product Produced by Third Party (OEM Product)

For product which Synthes functions only as distributor, the responsibility to meet requirements in regard to UDI remains with their legal manufacturer.

# Marking for Specific Product Categories (Special Requirements)

## Sterile Products

To differentiate between sterile and nonsterile versions of the same product, an ‘**S**’ is placed behind the ‘article #’ on the label, only, unless defined otherwise.

## Multi-Part Products / Assemblies

A product is considered an assembly when it consists of a minimum of two individual assembled components that could be disassembled if necessary.

The marking of assemblies is placed on one of its components as defined in the priority matrices. In the case of an instrument assembly, the remaining components are not marked unless they are discrete articles themselves, or have either a cutting function, contain scales or are critical to the proper functioning of the assembly. In the case of an implant assembly all of the remaining components are marked as a minimum with a ‘lot #’ for traceability.

All other additional markings intended to reduce the risk of misassembled components in the field or during reprocessing and maintenance are individually defined per system by R&D/PD.

## Screwdrivers

The following tables are to be used for information of functional relevance used with screw drivers.

For simple identification of drive type and size and possible cannulation irrespective of the language, Synthes screwdrivers are marked with corresponding graphic symbols and dimensions.

Depending on the space, the marking may be placed either on the handle (material permitting) or the shaft. If the space for the marking is extremely limited, “text only” symbols may be used.

|  |  |  |  |
| --- | --- | --- | --- |
| Feature | **HEX**  **Driver Blade** | **Stardrive Driver Blade** | **Combined Types Driver Blade** |
| Drive-Symbols for Symbol Size ≥ 5mm 1\*); 2\*); 5\*) | symbols_01 | symbols_03 | symbols_05 |
| Drive-Symbols for Symbol Size < 5mm 1\*); 2\*); 5\*) | symbols_12 | symbols_14 | symbols_16 |

|  |  |  |  |
| --- | --- | --- | --- |
| Feature | **HEX**  **Driver Blade** | **Stardrive Driver Blade** | **Combined Types Driver Blade** |
| Alternative  ‘Text Only’ Symbols 1\*); 5\*) | HEX3.5 | T25 | HEX3.5 / T25 |

|  |  |
| --- | --- |
| Feature | **Cannulation** |
| Symbol for Use on Handles Only 2\*); 4\*) | symbols_18 |
| Alternative ‘Text Only’ Symbol  1\*) | **CANNULATED** |

Remarks:

1\*) For proportions of marking on round shafts see item [6.3.4](#_bookmark8).

*2\*)* Sketches, symbols and UDFs for use in models and drawings can be found in the libraries for Synthes specific CAD elements – see item [10.6](#_bookmark37).

3\*) For examples of screwdriver markings see item [10.3](#_bookmark33).

4\*) The symbol “cannulation” is not suitable for strong downscaling. 5\*) Drive sizes and combinations may vary.

## Veterinary Products

Instruments, implants, power equipment and accessories used exclusively for veterinary applications receive veterinary product specific identification article numbers (’Article #’s). Veterinary products are not medical devices as defined by MDD 93/42/EEC and EU Regulation 2017/745 (MDR), therefore are not to be marked with the CE mark (CE, CEXXXX or CE0123). Marking shall follow the priority matrix in item [6.4](#_bookmark10).

For most veterinary implant product the ’Article #’ will include a product specific **prefix**, including but not limited to the following acronyms and their meanings:

* “**VP**” for ‘Veterinary Plate’
* “**VS**” for ‘Veterinary Screw’
* “**VC**” for ‘Veterinary Clamp’
* “**VR**” for ‘Veterinary Rods’
* “**VW**“ for ‘Veterinary Wires’

Example: **VP2050.07** – for a ‘Vet DCP-Plate 3.5 wide; 7-holes; 86 long; Steel’

## Custom Made Devices

In addition to the marking of standard product, as described in item [6](#_bookmark5)– Marking Process, custom made devices may carry the text ‘**CUSTOM MADE DEVICE**’ in the language of the country of the customer (ref.: MDD 93/42/EEC; Annex I.II 13.3(g) or EU Regulation 2017/745 (MDR); Chapter III 23.1(b)), the additional marking adjusted in size to the rest of the marking. Custom made devices must not be CE marked. Furthermore, for data privacy reasons, no patient details, e.g. patient name, shall be placed on the product.

* + 1. Marking per Customer Request

Marking add-ons per customer request are not permitted on standard product with the exception of PSI and/or ‘low volume SD’ product. The exceptions must be documented.

## Medical Electrical Equipment

In reference to medical electrical equipment, common identification markings together with additionally required medical electrical equipment data can be placed on a specifications label which is permanently fixed on the product.

# Specific Product Marking Content

Different types and uses of product have different marking content requirements – as opposed to those of standard sales product. Product can be classified in the following three groups with respect to their marking requirements.

## Product for Non-Clinical Use

Synthes uses products for non-clinical uses such as demonstrations, trainings (including ‘wet-labs’) or as showcase objects. Products for these non-clinical uses shall be marked as such – see also MDD 93/42/EEC Annex X, EU Regulation 2017/745 (MDR) Article 19 section 3 and CFR Part 814.80 – ‘Premarket Approval of Medical Devices’.

The standard add-on used irrespective of usage reads ‘**NOT FOR HUMAN USE**’ (or

## ‘DO NOT IMPLANT’; NFHU; DNI).

If a product is ordered for a specific non-clinical use, other terms (in any language) may also be applied, like ‘**Muster**’, ‘**Kurs**’, ‘**Demo**’, ‘**Sample**’, ‘**Course**’, etc. An addon combination of standard text and specific use text is possible as well, e.g. ‘**SAMPLE – NOT FOR HUMAN USE**’; **‘SAMPLE – DO NOT IMPLANT’; ‘SAMPLE - NFHU’** or **‘SAMPLE – DNI’**.

The customer is responsible for the definition of the marking addon as well as for where and how it is to be placed on the product.

## Product for Testing Purposes – Test Product

In order to clearly differentiate between salable goods and product intended for use as test specimens, such test product must be marked wherever possible with either ‘**TEST PRODUCT**’ or ‘**TP**’ and labeled accordingly. Mention must be made that test specimens need to have marking equal to final salable product in order to evaluate the effect of the marking. The TP marking can be integrated as ‘**TP**’ or ‘**TPxxxx**’ in place of the characters of the later CE marking into the standard marking elements. The ‘**TP**’ may also be placed on any nonfunctional portion of the specimen conditioned to receive the markings.

‘TP Mark’ variants:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TP / TP 0123**  in ‘single line’ style |  |  |  |  |
| **TP / TP 0123**  in ‘double line’ style |  |  |  |  |
| **TP / TP 0123**  in filled style |  |  |  |  |

Note: Application criteria identical to those for CE; see item [6.9](#_bookmark19).

## Product for Clinical Investigation

A product for clinical investigation within the European Community will carry, in addition to the standard marking, the text ‘**EXCLUSIVELY FOR CLINICAL INVESTIGATION**’ or a text of equal content in the language of the country of the investigation – see MDD 93/42/EEC Annex VIII or EU Regulation 2017/745 (MDR) Chapter III 23.1(q). The product shall not bear the CE marking.

A product for clinical investigation within the USA will carry, in addition to the standard marking, the text ‘**INVESTIGATIONAL DEVICE FOR INVESTIGATIONAL USE**’ – see

also 21 CFR Part 812.5 – ‘Labeling of Investigational Devices’.

If space is limited, this information shall be written on the label, only.

For all other countries, EU regulations apply as long as there are no country specific requirements.

## Product Marking Matrix

Following is a brief overview of the product types addressed, their use (with examples) and their marking requirements.

|  |  |  |  |
| --- | --- | --- | --- |
| **Product Type** | **Use** | **Examples** | **Marking Requirements** |
| Clinical Use | General applications | Implants and instruments released for sale | Standard marking |
| Restricted Clinical Use | Patient specific applications | Patient specific implants (custom made devices) | see item [7.5](#_bookmark25) |
| Test Product | Design verification or  design validation | Mechanical test specimens, Reprocess testing, wet or dry lab prototype | see item [8.2](#_bookmark28) |
| Product for Clinical Investigation | Clinical trials | Products used for official clinical trials, IDEs | see item [8.3](#_bookmark29) |
| Product for Non-Clinical Use | Course/training material, demonstration material,  bone model construct, etc. | Product marked with “Course”, “Demo”, etc. (declassed product) | see item [8.1](#_bookmark27) |

# Definitions and Abbreviations

Terms, acronyms and abbreviations, as well as definitions of terms used in this document.

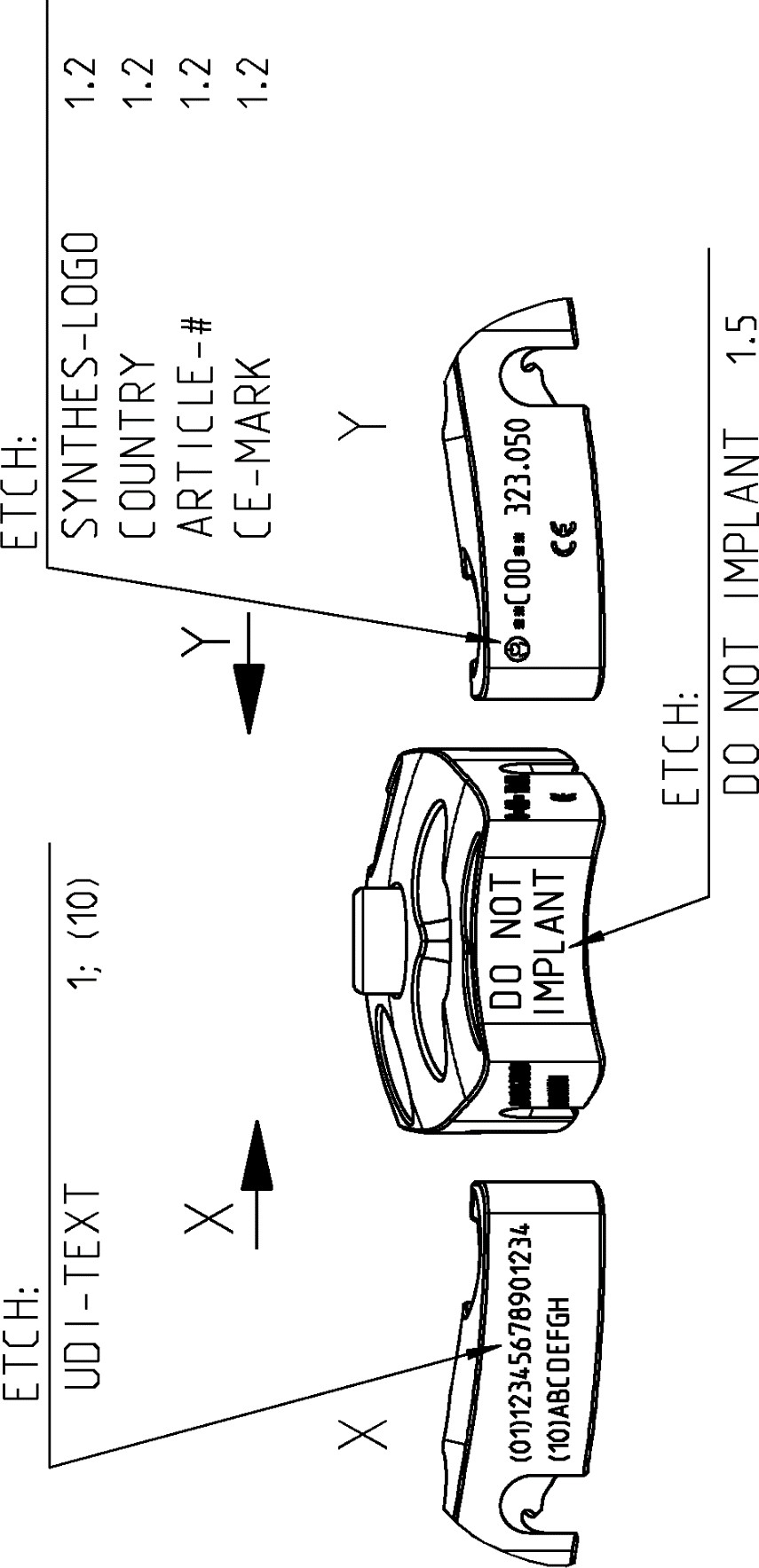
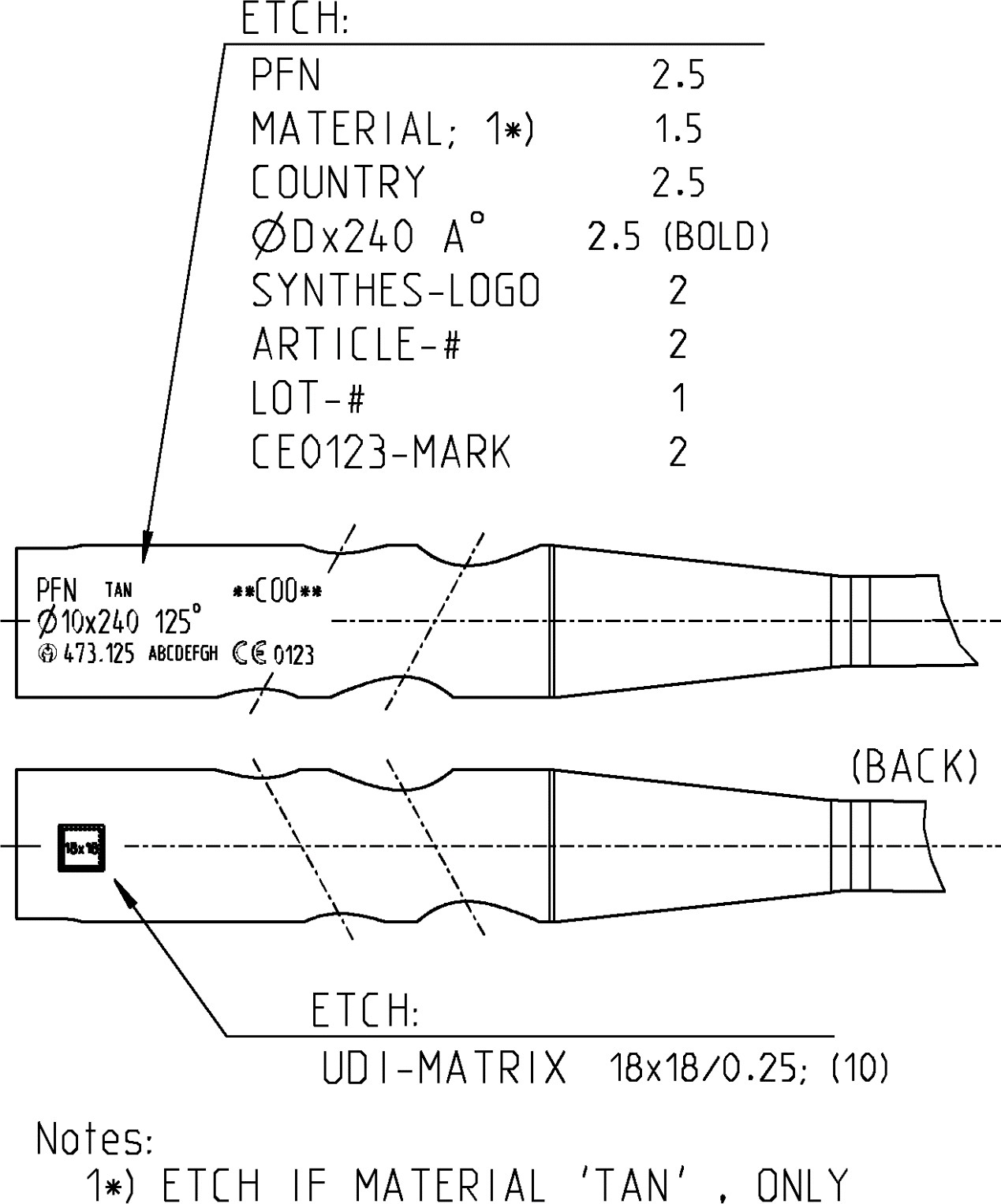
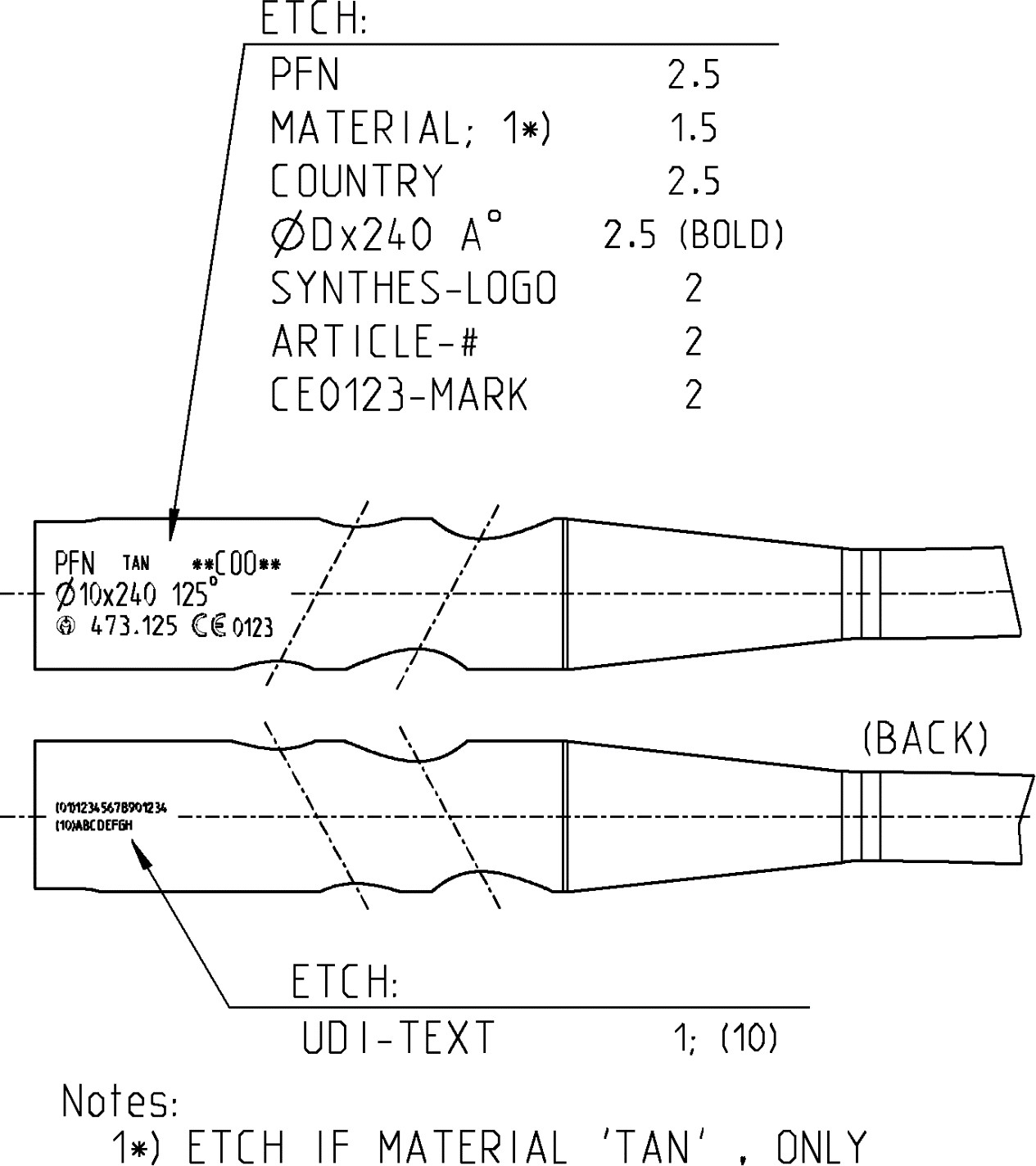
|  |  |
| --- | --- |
| ***Abbreviation*** | ***Term / Definition*** |
| # | Symbol/Acronym for ‘Number’ |
| AI | ‘Application Identifier‘ = code which defines format and type of the content of a GS1 data element; e.g. the AI code for the ‘Lot #’ is 10. |
| Article # | ‘Article Number’ = Sales ID of a Product (or) Catalog number (or) Base Item number marked on the product |
| Base GTIN | GTIN for the unit of measure (UOM) of the lowest packaging level; normally for the amount of 1 piece and thus the GTIN that is marked. |
| CE Mark | CE marking = CE conformity declaration as per regulation MDD 93/42/EWG, Anhang XII or EU Regulation 2017/745 (MDR), Annex V where applicable |
| CMF | ‘CranioMaxilloFacial’ = product range ’Head, Jaw and Facial Surgery’ |
| COO | ‘COO Code’ = Country of Origin Declaration |
| DBCS | ‘Double Byte Character Set’ = extended ASCII character set as used in Microsoft and IBM System. |

|  |  |
| --- | --- |
| ***Abbreviation*** | ***Term / Definition*** |
| DHF | ‘Design History File’ = collection of all data of relevance to the quality of a product. |
| DI | Device Identifier (GTIN) |
| DM | ‘Direct Marking’ = requirement for directly marking the product with a globally unique ID |
| DPS | DePuy Synthes |
| DQE | ‘Design Quality Engineering’ = Department Design Quality Engineering of Product Development (R&D) |
| EMEA / AP / LAT | ‘Europe, Middle East, Africa / Asian Pacific / Latin America’ = market region |
| FS | ‘Font Size’ = absolute height of a capital character or a stand- alone symbol in a etch |
| GS | Graphic Size = absolute height of the DPS-logo graphic |
| GS1 | Global and product neutral standard for product identification |
| GS1  2D DataMatrix barcode | Dot DataMatrix of square or rectangular shape and compliant to GS1 and ECC 200 standardization. The alphanumeric code contained in the matrix uniquely identifies articles on a lot or single item level. |
| GS1 Human Readable Interpretation (HRI) | Human Readable Interpretation refers to the characters printed below, beside or above a barcode. It’s the representation of data from the barcode. Also referred to as HRI and easily readable plain text. |
| GS1 Systems | Global NonProfit Organization which owns, manages and provides the GS1 System for worldwide unique product identification; Successor organization of UCC and EAN. |
| GTIN | ‘Global Trade Item Number’ = globally unique product and manufacturer identifying number, part of the GS1 system. |
| GUDID | ‘GUDID Database‘ = FDA’s publicly searchable global UDI database, which contains all the data tied to each single product. |
| IDE | ‘Investigational Device Exemption’ refers to the regulations under the 21 CFR 812 and covers the clinical evaluation of devices that have not been cleared for marketing |
| IPM | ‘Indirect Part Marking’ = requirement for indirect marking products with a worldwide unique ID, part of FDA’s UDI |
| Lot # | ‘Lot Number’ = unique production ID for products produced in one and the same production lot |
| Low volume SD Product | Special Devices (instruments with certain amount of customization) produced at low volume for a limited market |
| MDR | Medical Device Regulation (EU Regulation 2017/745) |
| N/A | Not Applicable |
| OEM | Original Equipment Manufacturer |
| PD | ‘Product Development‘ = Product Development division (= R&D) |
| P-Date | ‘Production Date‘ = unique production ID for products produced on one and the same Date/Day |
| PI | Production Identifier (‘Lot #’; ‘Serial #’) |

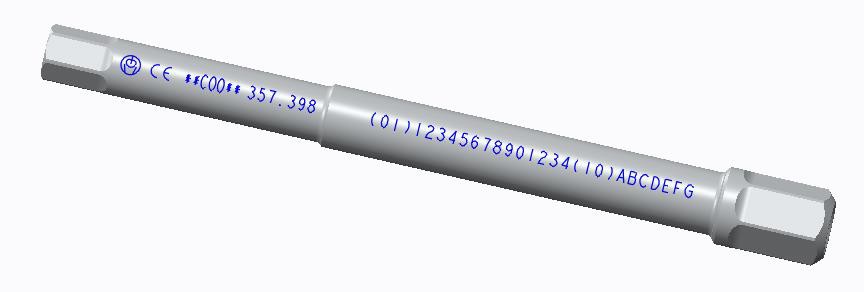
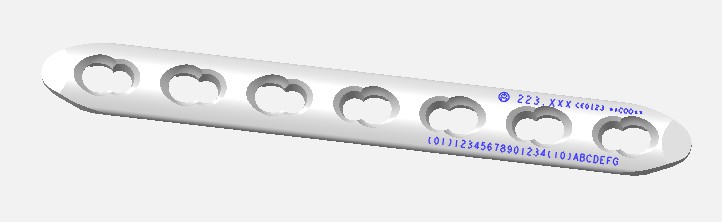
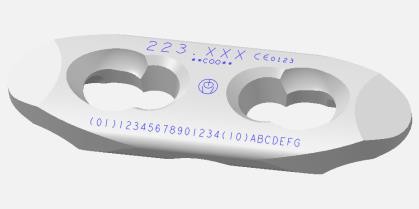
|  |  |
| --- | --- |
| ***Abbreviation*** | ***Term / Definition*** |
| PM | ‘Product Management’ = Product Management Division |
| PSI Product | ‘Patient Specific Implant’ Product |
| R&D | ‘Research & Development’ = Research & Development Division |
| RA | ‘Regulatory Affairs‘ = Regulatory Product Support Services Division |
| Rebranding | Producer or brand mark/logo change |
| Reusable Surgical Instrument | An instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilization have been carried out, per EU Regulation 2017/745 (MDR) Chapter I, 2.3. |
| Router | Different name for a ‘Production Work Order’ |
| ROW | ‘Rest of the World’ (market) = all markets outside USA (OUS) |
| Serial # | ‘Serial Number’ = Unique production ID for a single product |
| UDI | ‘Unique Device Identification’ = FDA’s requirement for a Unique Device Identification System |
| UOM | ‘Unit of Measure’ for products/articles |
| Var | ‘Variable’ = stands for a variable value in a command line |

# Appendix / Notes

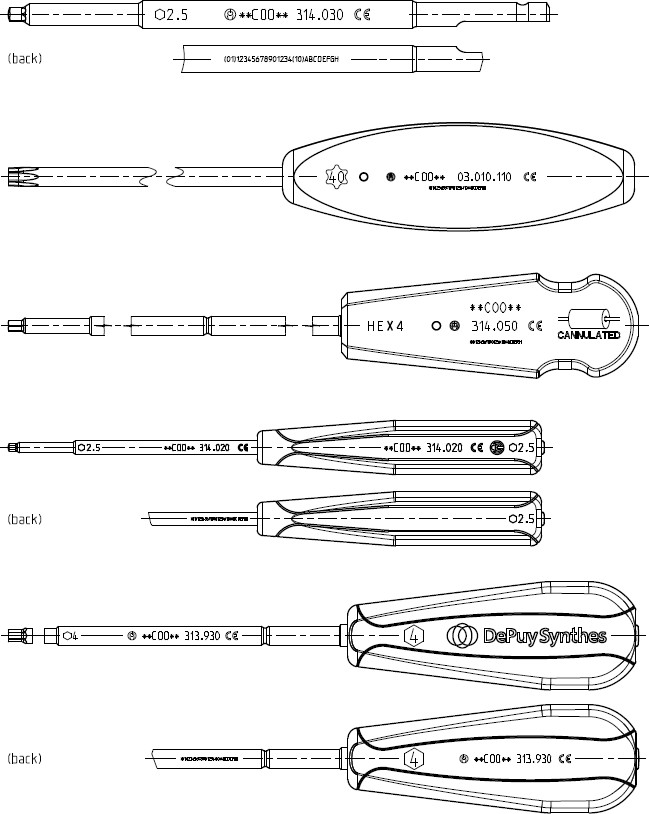
## Examples for the Definition of Etches / Markings



## Examples for Graphic Representations of Etches on Parts



## Examples for Screwdriver Markings



## Country of Origin (COO Code)

The COO to be marked is defined as per section [6.4](#_bookmark10) where the device is physically manufactured.

The order to etch the ’Country of Origin’ (COO) information on the product in specific font size is defined via the appropriate command line in the etch command or drawing notes; see item [6.5](#_bookmark11) for further detail.

Place holder for the graphic representation of the COO information on the part/model is the character sequence ’**\*\*COO\*\***’ in a font size as defined in the command line of the etch command, or specified in the notes. The placeholder itself is not to be etched. Further, the specific country of origin is not to be noted on the product drawing. This will allow flexibility in manufacturing locations without requiring a drawing update.

Note: For product designed and manufactured in Palm Beach Gardens, the drawings may have the specific country of origin, rather than the ’**\*\*COO\*\***’ if deemed appropriate. No additional rationale is required to support this decision.

The font size for the COO information is in principle freely selectable but is usually chosen to be of the same size as the one selected for the ’Article #’ or is adapted in size to fit the space available and match the proportions of the remaining marking elements.

Effectively marked on the part is the name of the COO in English or rather American spelling or in a deviating short form thereof if the fully written name is too long, and in capital letters.

Variations in spelling and abbreviations are permissible as long as the country can be clearly identified; for example “**Italia**” for Italy or “**Brasil**” for Brazil. Also “**SWISS**” is acceptable for Switzerland and **USA** for the United States of America.

Below is a list with currently used country names to be chosen from for marking; item [10.4.2](#_bookmark35) - COO Code List.

* + 1. Determination of the ‘Country of Origin’

’Country of origin’ is the country in which the majority of a device’s subcomponents are produced. This is independent of assembly, packaging or sterilization. In cases where the legal Country of Origin cannot be determined by the vendor, they must consult with their Synthes Purchasing contact. It is important to note that the Country of Origin from a global Customs perspective may not be the same as the Regulatory Country of Origin. To be compliant with global Customs import definitions, the item must be marked with the actual Country of Origin.

* + 1. COO Code List

Country codes currently being used:

|  |  |
| --- | --- |
| **Country** | **Code**  (Etch) |
| Austria | Austria |
| Brazil | Brasil |
| China | China |

|  |  |
| --- | --- |
| **Country** | **Code**  (Etch) |
| Germany | Germany |
| Hungary | Hungary |
| Mexico | Mexico |
| Poland | Poland |
| Switzerland | SWISS |
| United States of America | USA |

The above listing is not final and will be updated from time to time.

## Material Codes

The letter/font size chosen for the material code completely follows the needs and is not subject to any restrictions.

The following codes are used for current implant material:

* + 1. General Material Codes

Material codes for implants according to company internal regulations:

|  |  |
| --- | --- |
| **Material Type** | **Material Code** |
| 316L / (1.4441) ASTM F 138/139 | 316L |
| CoCrMo ’Low C’ ASTM F 1537 Alloy1 | CCM |
| CoCrMo ‘High C’ ASTM F 1537 Alloy2 | CCM+ |
| CrNiMn ASTM F 1586 | COCR |
| Titanium – commercial pure ASTM F 67 | TICP |
| Ti6Al7Nb ASTM F 1295 | TAN |
| TiAlVa ASTM F 1472/136 | TAV |
| Ti15Mo ASTM F 2066 | TIMO |
| PEEK ASTM F 2026 | PEEK |
| UHMWPE ISO 5834–1/2 | UHMWPE |

* + 1. Material Codes Specific to China

Material codes for implants according to Chinese government regulations:

|  |  |
| --- | --- |
| **Material Type** | **Material Code** |
| 316L / (1.4441) ASTM F 138/139 | S |
| Titanium – commercial pure ASTM F 67 | A |
| Ti6Al7Nb ASTM F 1295 | T |

## Symbol Libraries CAD

The sketches, symbols and UDFs to be used in models and drawings are found in the following subsequently listed library for Synthes specific CAD elements.

SERVER\_NAME\cad\CREO\_CONF\DS\_LIB\_C3\...

Note: This does not apply to products manufactured and developed in Palm Beach Gardens where CAD elements are managed in windchill.

## Remarks

Below there are some briefly summarized common remarks on the global approach for labeling and on the usage of a worldwide unequivocal method of product identification (most of them has already been mentioned in some more detailed form throughout the entire document).

## The global Approach for Labeling – Aspects

The global approach for labeling for the product primarily represents the cumulated regulatory requirements of our main markets – USA and Europe – and aims at having to produce only one hardware version per article if possible.

Yet, the global approach for labeling contains and prioritizes also the labeling of elements which are of great interest for our customers and patients or also for us as manufacturer.

The global approach for labeling only partly covers the goals of and requirements for ‘Labeling and Packaging’.

## The global approach for labeling and the ‘Direct Marking‘ (DM)

DM is part of the US FDA and EU rule ‘Unique Device Identification’ (UDI).

Part of the content of DM is about the marking of the ‘Global Trade Item Number’ (GTIN) on the product.

The GTIN linked with a traceability feature – lot or serial number – identifies a product in a worldwide unequivocal manner.

The marking of a GTIN on a product is required only in a few markets. It is to be expected, however, that further regulatory agencies are going to adopt this requirement.

The marking of UDI information may be relinquished if the technical means available do not allow marking results with acceptable benefit to all parties involved – regulatory bodies, notified bodies, the company, customers and patients. All exempt options permitted by the regulatory body are transferred via regulatory affairs into product project and change orders.

## GTIN – Structure

The GTIN used by Legacy Synthes – the GS1 identification key GTIN-14 – consists of several elements of which the most important ones are the base number and the reference to the article. The base number includes, inter alia, the company identifier. The reference to the article identifies each article unequivocally (only) with regard to one particular company identifier.

Regardless of the country of origin or the manufacturer, Legacy Synthes uses a GTIN containing the company identifier of Synthes GmbH in CH-4436 Oberdorf in the base number for all products for which Legacy Synthes signs as ‘Legal Manufacturer’.

Exceptions are e.g. …

* Synthes products manufactured in China and destined for the Chinese domestic market. For these products, Synthes Suzhou is always the ‘legal manufacturer’ and thus has a company identifier of its own.
* Synthes products developed and manufactured by Synthes USA exclusively for distribution on the American domestic market. For these products, Synthes (U.S.A.) in Monument Co 80132 is always the ‘legal manufacturer’ and thus has a company identifier of its own.

## GTIN – Origin and [Data](http://www.linguee.de/englisch-deutsch/uebersetzung/data.html) [Sovereignty](http://www.linguee.de/englisch-deutsch/uebersetzung/sovereignty.html)

Master Data Management has sovereignty over the different GTINs and also functions as their provider – see also SOP-K-002 and SE\_162343.

## DM and Technical Product Documentation (regardless of incident)

The DM information – GTIN and traceability feature – which ought to be used or marked is not defined on the drawing but rather in the router or purchase order. The drawing is neutral and only indicates by placeholders what has to be marked, where and how.

## Complexity of having an identical GTIN on part and label or packaging

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Usage of GTINs** (for information only) | | | | |
| Basic Registrations | EU + US | EU | US 2\*) | CN |
| GTIN on Hardware | EU | EU | US 2\*) | CN |
| Legal Manufacturer for: |  |  |  |  |
| * Market ‘EU+ROW’   1\*)   * Market ‘US+Canada’ | Synthes GmbH Synthes USA  - | Synthes GmbH  -  - | Synthes GmbH  2\*) Synthes USA  - | -  -  Synthes CN |
| - Market CN |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| GTIN on Label for:   * Market ‘EU+ROW’   1\*)   * Market ‘US+Canada’ * Market CN | EU US  - | EU  -  - | Synthes GmbH  2\*) US  - | -  - CN |

Note:

1\*) ROW = including China but without US and Canada

2\*) Keeps US GTIN if registered at a later date for selling on the ‘EU+ROW’ market as well.

The intended usage of the identical (base) GTIN on product and label causes the following problems: On the basis of only one GTIN it is not always possible to determine unequivocally which product status is meant – the one of a packaged article for sale or the one of an unpackaged loose article.

Thus the signification of the GTIN is reduced to being a feature of identification which directly or indirectly identifies the hardware article only.

Once the GTIN has been used in a particular way it cannot be changed anymore or only with immense effort due to its impact on sunset data.

## Examples for Definition of Tables used in drawings to Identify the marking requirements

## Table 1 – Globally distributed products with same Article number

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ERP MATERIAL # | XX (VARIANT #) | MARKING REQUIREMENTS | | | SHEET # |
| ARTICLE # | CE-MARK | CEXXXX-MARK  (CE-MARK + NOTIFIED BODY#) |
| 03.010.092-XX | 15 TO 98 | 03.010.092 | - | YES | SHEET 1 |
| 03.010.092 | - | 03.010.092 | YES | - |

## Table 2 – Globally distributed products with different Article numbers

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| MARKET | ERP MATERIAL # | XX (VARIANT #) | MARKING REQUIREMENTS | | | SHEET # |
| ARTICLE # | CE-MARK | CEXXXX-MARK  (CE-MARK + NOTIFIED BODY#) |
| USA | 355.51 | - | 355.51 | NO | NO | SHEET 1 |
| MDR-RoW | 355.510-XX | 15 TO 49 | 355.510 | - | YES |
| MDD-Row | 355.510 | - | 355.510 | YES | - |

Note:

* + ERP Material # is an Internal variant number used to order, identify, track and maintain the products in the ERP system.
  + Article # is a sale ID marked on the product.
  + The variant range for oUS is “15-49”, while for the US is “50-98” per SE\_717009 (Synthes Variant Set Up Process)

# Reference Documents

|  |  |  |
| --- | --- | --- |
| ***Document*** | ***Title*** | ***Remarks*** |
| SOP-K-002 | Unique Device Identifier | N/A |
| 21 CFR | Code of Federal Regulations, Title 21 | Food & Drug |
| DIN 1451-1 | Lettering; Linear Antiqua without Serifs - General | N/A |
| MDD 93/42/EEC | Directive 93/42/EEC of 14. June 1993 concerning medical devices | N/A |
| SE\_162343 | Barcode GS1-128 | N/A |
| 5.3.0800.001 | FAA – Beschriften von Implantaten und Instrumenten Osteosynthese  (Marking of Implants and Instruments for Osteosynthesis) | Restricted to specific devices;  see item [6.5.1](#_bookmark12) |
| Docket No. FDA- 2011-N-0090 | UDI Final Rule |  |
| EN ISO 15223-1:  2016 | Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements | N/A |
| EN ISO 14971 | Medical Device – Application of Risk Management to Medical Devices | N/A |
| SE\_031717 | Laser Marking | N/A |
| W-C-S052 | Design Control Requirements | N/A |
| EU Regulation 2017/745 (MDR) | Medical Device Regulation (EU) of 5. April 2017 concerning medical devices | N/A |
| 100782184 | Franchise 2D Direct Marking Design Procedure (shared) | N/A |
| 100782225 | Franchise 2D Direct Marking Technical specification (shared) | N/A |
| SE\_717009 | Synthes Variant Set Up Process | N/A |
| 100651587 | MD PLM Document and Change Management Procedure (Shared) | N/A |