



# Requirements and Guidance for Printing on Tyvek®

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**DESIGN OF A SAFE AND COMPLIANT STERILE BARRIER SYSTEM**

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## Agenda

- ❑ What are the printing and labelling requirements for sterile barrier systems?
- ❑ Variable data printing on Tyvek® medical grades
- ❑ How to evaluate the printing quality?
- ❑ Case study - Printing assessment on Tyvek®
- ❑ Conclusion and next steps

# What are the printing and labelling requirements for sterile barrier systems?

- Compatibility with the labelling system
- Biocompatibility or No ink transfer
- Identification
- Serialization
- Readability
- Traceability
- Verification
- Marketing



1/30/06 Lot#A12345678



3-point micro cartridge



For professional use only.



Read instruction manual of machine prior to use.



Single use. Use only if package is undamaged.



## What are the printing and labelling requirements for sterile barrier systems?

### Annex 1 – GENERAL SAFETY AND PERFORMANCE REQUIREMENTS - Chapter II Requirements regarding design and manufacture

<i>Medical Device Regulation</i>	Medical Device Directive	Comments
<p>11.8. The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition <b>additional to the symbol used</b> to indicate that devices are sterile.</p>	<p>8.7. The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.</p>	<p><b>Added requirement to include symbol and specific label</b></p>

## Annex 1 – GENERAL SAFETY AND PERFORMANCE REQUIREMENTS - Chapter III

### Requirements regarding the information supplied with the device

<i>Medical Device Regulation</i>	MDD	Comments
<p><b>23.3. Information on the packaging which maintains the sterile condition of a device ('sterile packaging')</b>  <i>The following particulars shall appear on the sterile packaging:</i></p> <ul style="list-style-type: none"> <li>(a) <i>an indication permitting the sterile packaging to be recognized as such,</i></li> <li>(b) <i>a declaration that the device is in a sterile condition,</i></li> <li>(c) <i>the method of sterilization,</i></li> <li>(d) <i>the name and address of the manufacturer,</i></li> <li>(e) <i>a description of the device,</i></li> <li>(f) <i>if the device is intended for clinical investigations, the words: 'exclusively for clinical investigations',</i></li> <li>(g) <i>if the device is custom-made, the words 'custom-made device',</i></li> <li>(h) <i>the month and year of manufacture,</i></li> <li>(i) <i>an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month, and,</i></li> <li>(j) <i>an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.</i></li> </ul>	<p>13.3 The label must bear the following particulars:            ...</p>	<p><b>New specific requirement for sterile packaging labelling</b></p>

# What are the printing and labelling requirements for sterile barrier systems?

## EN ISO 11607-1:2006

ISO 11607-1:2006 specifies the requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices until the point of use.

### 5.4 Compatibility with the labelling system

#### The **labelling system shall**

- Remain **intact and legible** until the point of use,
- Be **compatible** with the materials, sterile barrier system, and medical device during and after the specified **sterilization** process(es) and cycle parameters and shall not adversely affect the sterilization process, and
- Not be** printed or written in ink type which can be **transferred** to the medical device nor **react** with the packaging material and/or system to impair the utility of the packaging material and/or system, nor change color to an extent which renders the label illegible.

# What are the printing and labelling requirements for sterile barrier systems?

## UDI – Unique Device Identifier

UDI is a unique numeric or alphanumeric code;

Displayed in both human readable (plain text) and machine readable (AIDC) form;

That consists of two parts: Device Identifier (DI) and Production Identifier(s) (PI).

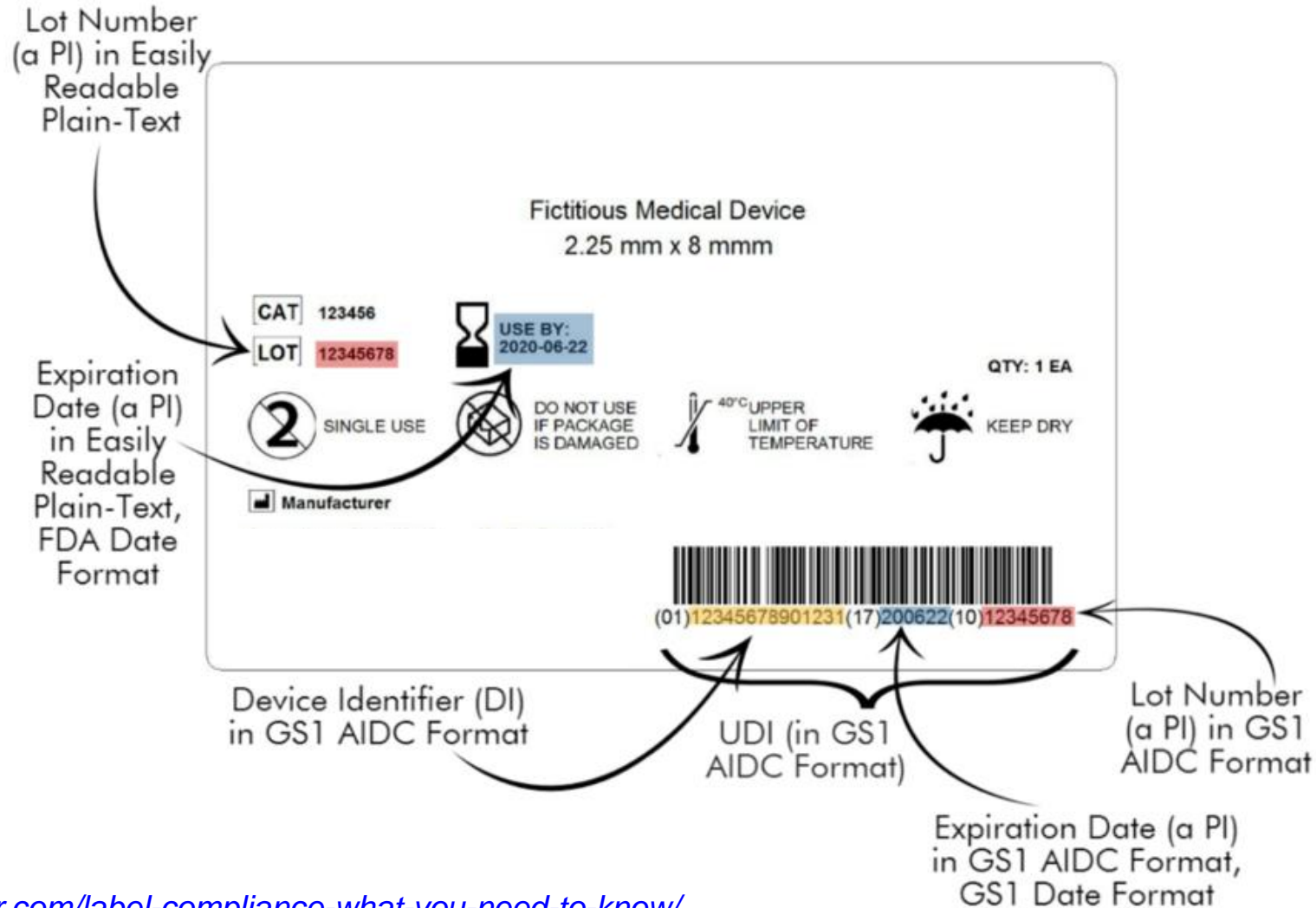
**DI** – GTIN, Global Trade Item Number - Mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device.

**PI** – AI, Application Identifier, Variable portion of a UDI which can include lot, batch or serial number, expiration date or date of manufacture and identification code.

**DI** (Device Identifier) + **PI** (Production Identifier) = **UDI**

# What are the printing and labelling requirements for sterile barrier systems?

## UDI Example





# What are the printing and labelling requirements for sterile barrier systems?

## GS1 DataMatrix

GS1 (Global Standards One) uses the DataMatrix code as an alternative to linear codes and designates the result as GS1 DataMatrix. The symbology format of the DataMatrix according to ISO / IEC 16022 is used.

ISO/IEC 16022:2006 defines the requirements for the symbology known as DataMatrix:

Data Matrix symbology characteristics, data character encodation, symbol formats, dimensions and print quality requirements, error correction rules, decoding algorithm, and user-selectable application parameters.

It applies to all Data Matrix symbols produced by any printing or marking technology.

(17)100521(10)ABC123



(01)09099999543217

# What are the printing and labelling requirements for sterile barrier systems?

## GS1 DataMatrix

GS1 DataMatrix is composed of two separate parts: finder pattern and the encoded data.

The finder pattern defines the shape, square or rectangle, the size, X-dimension and the number of rows and columns in the symbol.

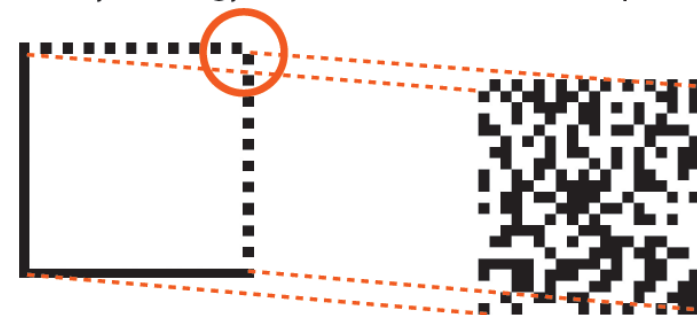
The square form is the most commonly used and enables the encoding of the largest amount of data.

The rectangle form may be selected to meet the constraints of speed of printing on the production line.

Square



Rectangle

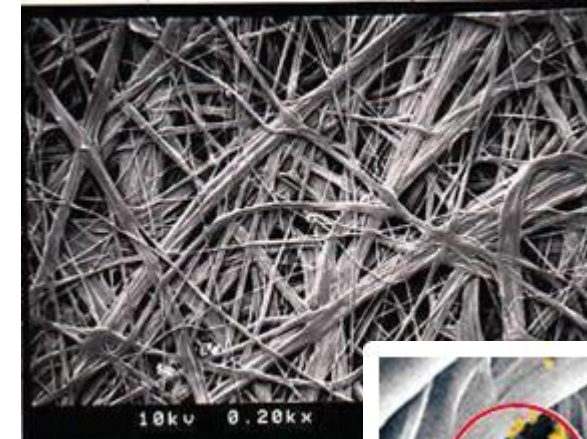
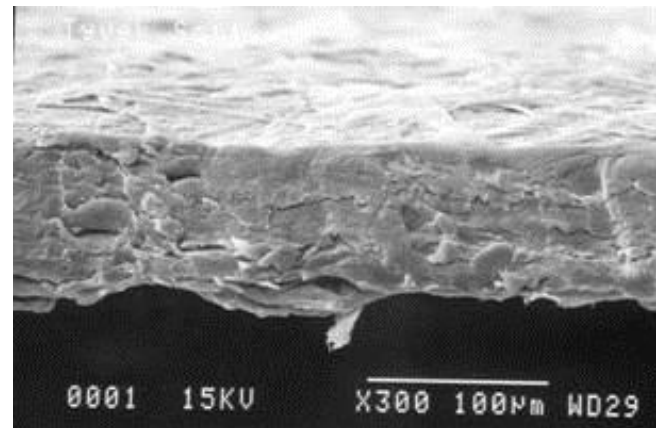


Finder pattern

Data

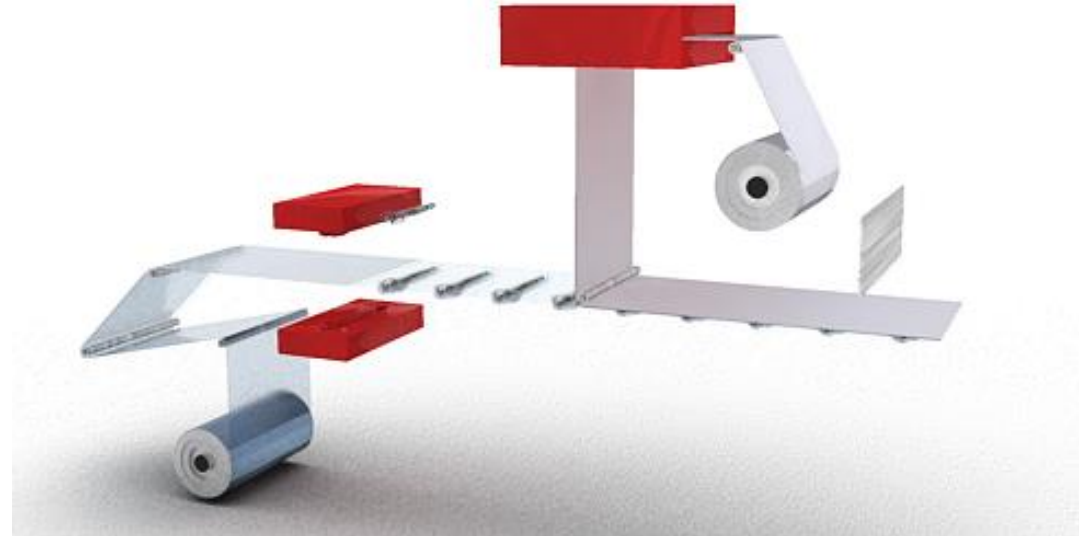
## What is DuPont™ Tyvek for sterile packaging?

- ❑ High-density polyethylene (HDPE)
- ❑ Flashspun continuous filaments formed into a sheet
- ❑ **Filaments multi-directional**
- ❑ Bonded using heat and pressure
- ❑ Average diameter = 4 microns
- ❑ no binders / fillers
- ❑ **No corona treatment or anti-static coating**



## Variable data printing on Tyvek® medical grades

- Flexographic printing
- Thermal transfer printing
- Inkjet printing
- Laser (electrostatic) printing



## Variable data printing on Tyvek® medical grades

### ❑ Flexographic printing

- For best results, the smooth side of the sheet has to be used.
- Keep tensions below 0.75 lb/in (1.3 N/cm) of width.
- Maintain web temperatures below 175° F (79° C).
- For fine line screens with dots, use a harder durometer plate with a min, complemented with a soft or medium density cushion.
- Alcohol-based polyamide inks - The solvent-based inks typically provide the best adhesion and rub resistance. Adding microcrystalline wax will reduce the offsetting.
- Water-based inks - These inks make it possible to achieve high-quality results while complying with environmental regulations.

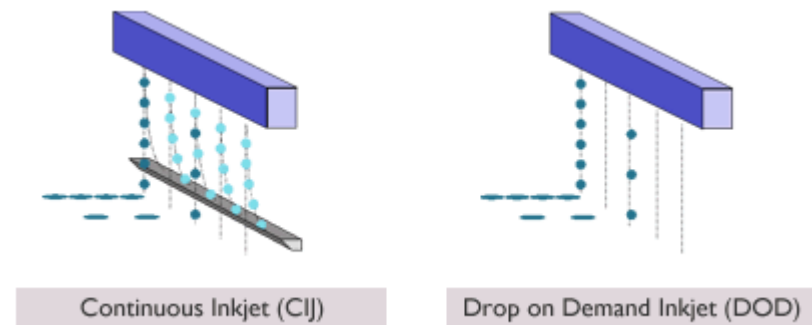
## Variable data printing on Tyvek® medical grades

- ❑ Thermal transfer printing
  - The most common process for printing variable information.
  - Wax ribbons give the best results on Tyvek®.
  - If more durability is required, a wax/resin 90/10 should be used.
  - Printing alpha-numeric information 300- to 600-dpi printers should be used.
  - C ANSI barcode quality can be achieved using thermal transfer technology.

## Variable data printing on Tyvek® medical grades

### □ Inkjet printing

- Continuous and drop-on-demand inkjet printers have been successfully tested.
- Inks which can be used: Oil based, water based, UV curing inks, and solvent-based.
- Oil and water-based inks are slower drying and tend to feather on Tyvek®.
- UV inks cure almost instantly.
- Typically, 200- to 300-dpi print heads are used.



Source: <http://imieurope.com/inkjet-blog/2016/2/8/industrial-inkjet-printing>

## Variable data printing on Tyvek® medical grades

- ❑ Laser (electrostatic) printing
- Conventional laser printing is **not recommended** for Tyvek® because of the high temperatures. It will melt the Tyvek®.





## How to evaluate the printing quality?

For example...

- ISO 15415 / ISO 15416
- Tests listed in ISO 11607 Annex B
- ASTM F1319
- ASTM D5264
- DIN EN ISO 105 – B02

## How to evaluate the printing quality?

- ❑ ISO 15415 / ISO 15416
- ISO 15415: specifies the methodologies for measuring, evaluating and grading 2D symbol characteristics in order to indicate the quality of the mark. In addition, the standard identifies possible causes for symbol degradation.
- ISO 15416: For 1D barcode evaluation.

Liner barcode / 1D barcode : ISO 15416	Data matrix/ 2D barcode : ISO 15415
	
Edge Determination Decode Symbol Contrast Minimum Reflectance Minimum Edge Contrast Modulation Defects Decodability Quiet Zone	Axial non-uniformity Symbol Contrast Cell Contrast Cell Modulation Decodability Fixed Pattern Damage Grid Non-uniformity Reflectance Margin Unused Error Correction

## How to evaluate the printing quality?

- ❑ Tests listed in ISO 11607 Annex B

### ASTM F2250:2003

Standard practice for evaluation of chemical resistance inks and coatings on flexible packaging materials.

### ASTM F2252:2003

Standard practice for evaluation ink or coating adhesion to flexible packaging material using tape.

## How to evaluate the printing quality?

- ❑ ASTM F1319-94 (2011)

Determination of abrasion and smudge resistance of images produced from business copy products (Crockmeter method).

- ❑ ASTM D5264

The Sutherland rub test covers a procedure for determining the abrasion resistance of printed materials, equipped with full-width rubber pads and using standardized receptors.

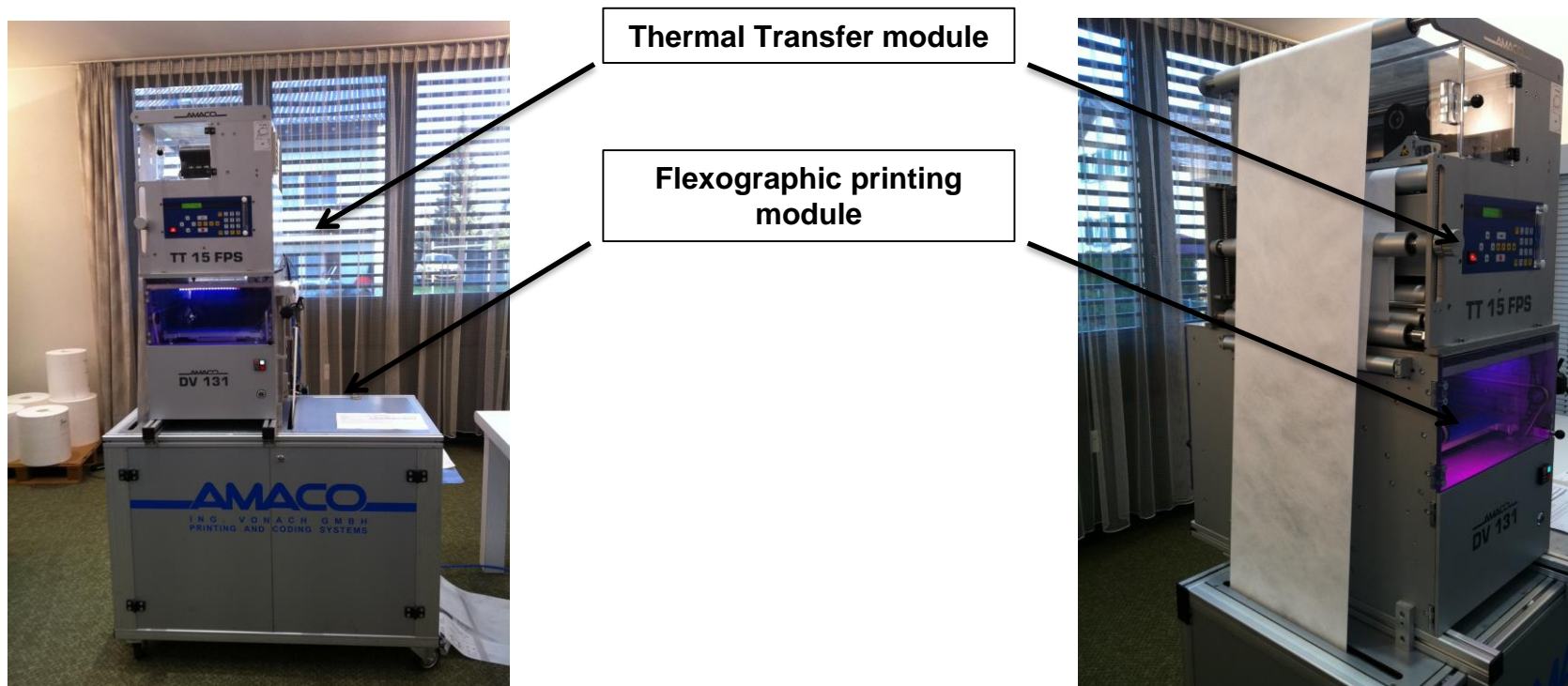
- ❑ DIN EN ISO 105 – Bo2

Light fastness is a method intended for determining the effect on the color of textiles of all kinds and in all forms to the action of an artificial light source representative of natural daylight. This method allows the use of two different sets of blue wool references. The results from the two different sets of references may not be identical.

## Case study - Printing assessment on Tyvek®

DuPont conducted barcode readability tests to demonstrate that the printing of barcodes directly on Tyvek® shows good results.

Both flexography and thermal transfer printing technologies were assessed on Tyvek® 1073B.



## Case study - Printing assessment on Tyvek®





- ❑ Barcode readability test:
  - Result is a pass or a fail
  - 4 barcodes have been tested for flexo, 2 barcodes for thermal transfer
  - The barcodes have been selected according to GS1 standards
- ❑ Three different types of barcode reader were used:
  - Regular 1D laser scanner
  - 2D barcode imager
  - 2D DPM reader (Direct Part Marking)





*Note: Information and photographs supplied courtesy of OPAL Associates B.V.*

## Case study - Printing assessment on Tyvek®

Barcode readability results for DuPont™ Tyvek® 1073B:

	EAN 13	GS1 128	GS1 DATAMATRIX	GS1 DATAMATRIX
<b>FLEXOGRAPHIC PRINTING</b>	 1D Barcode Size: 21 x 8 mm	 1D Barcode Size: 37 x 13 mm	 2D Barcode Symbol size: 18 x 18 Data region size: 9 x 9 mm	 Symbol size: 18 x 18 Data region size: 4.5 x 4.5 mm
Barcode readability with handheld barcode scanner	DuPont™ Tyvek® 1073B	DuPont™ Tyvek® 1073B	DuPont™ Tyvek® 1073B	DuPont™ Tyvek® 1073B
Regular 1D laser scanner	6P/6	0P/6	N/A	N/A
2D barcode imager	6P/6	5P/6	6P/6	5P/6
2D DPM reader	6P/6	0P/6	6P/6	5P/6

	GS1 128	GS1 DATAMATRIX
<b>THERMAL TRANSFER PRINTING</b>	 1D Barcode Size: 55 x 12 mm	 2D Barcode Symbol size: 12 x 12 Data region size: 9 x 9 mm
Barcode readability with handheld barcode scanner	DuPont™ Tyvek® 1073B	DuPont™ Tyvek® 1073B
Regular 1D laser scanner	6P/6	N/A
2D barcode imager	6P/6	6P/6
2D DPM reader	6P/6	6P/6

## Conclusion and next steps

- ❑ A good print quality is very important to guarantee readability and device identification to secure the safety of the patients. Being compliant with standards such as GS1, UDI and ISO norms are the base to achieve this goal.
- ❑ More studies are planned in the future regarding Tyvek® and variable data printing.
- ❑ For more information about printing machine manufacturers or other questions please don't hesitate to ask the Tyvek® medical team and myself who will more than happy to help you!

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