HOW?

Within the range of solutions, Macsa ID offers efficient, clean and high-quality laser coding on all types of surfaces, such as:

1. SPA C 10 + 30

2. SPA F – Pulsed

3. SPA F FILM

4. D-5000 DUO (UV/GREEN) Series

Application	Technology	Best Option
Cardboard packaging	Laser (CO2)	1. SPA CP 30
Flexible film and foil	Laser (Fiber Film, UV, Green)	4. D-5005 UV
Labels	Laser (Fiber Film)	3. F Film 50W
Stainless steel surgical tools	Laser (Fiber, UV, Green)	2. SPA F 20
Sachet packets	Laser (Fiber, Green, UV)	4. D-5005 Green
Plastic tools	Laser (CO2, Fiber, Green, UV)	4. D-5010 Green
Vials	Laser (Fiber, CO2)	1. SPA CB 10 P
Contact Lenses	Laser (CO2)	1. SPA CB 10 P

MACSA INTEGRA SOFTWARE

For the complete solution, control, manage and optimise your production lines with the different software modules of Macsa ID's Integra suite. High quality marking with visible and accurate information helps meet legislative requirements and protect user safety, keeping the right product in the right hands.

Program GS1 approved GTIN numbers with our serialization solutions.

- Track distribution and use of surgical instruments
- Control package from product to pallet.
- Guarantee optimum productivity and consistency
- Protect patient safety

Supported by integra by Macsa id

integrapromos&serialization
Software to generate UNIQUE codes at super high speed.

Disclaimer: The summaries included in this document are for informational purposes only and is not intended as legal advice. For a full description on the EU's Medical Device Regulation, go to:

www.eur-lex.europa.eu/legal-content/EN/TXT/?qid=1583321569300&uri=CELEX:32017R0745

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Macsa id
a code you can trust

CODIFICATION OF MEDICAL DEVICES

+ Easy identification
+ Legislative compliance
+ Peace of mind

TRACEABILITY FROM PRODUCTION TO PALLET

To ensure **peace of mind** of companies and clients, medical devices must be **easily identifiable** at all levels of packaging and use.

Under EU Medical Device Regulations 2017/745 and 2017/746, after 26/5/2020, companies who operate in this sector need reliable coding and marking systems to quickly locate and guarantee the quality of the products to ensure **legislative compliance** and the **safety of the public**.

These coding systems and solutions have been developed to control traceability of high-precision products from the moment it leaves manufacturing, through to its shipment, all the way to pharmacy shelves, hospitals and healthcare practices.

Macsa ID solutions allow you to trace the route medical devices travels from its production to the pallet, all the way up until its use.

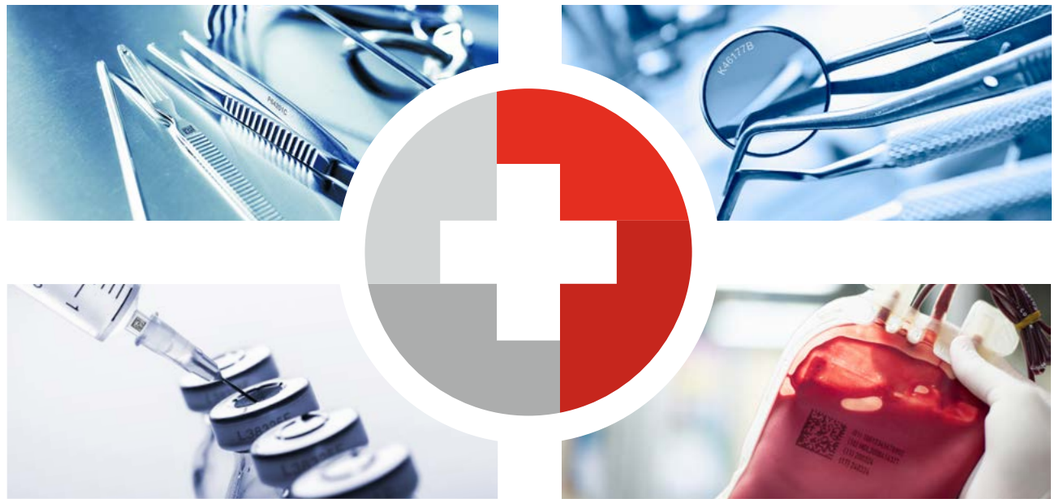
CODING AND MARKING FOR MEDICAL DEVICES

At Macsa ID, we meet the diverse needs of the medical device sector, offering a wide variety of technological solutions suitable for a myriad of materials and products, applicable to any production line.

WHICH DEVICES?

Class I – Low risk:
Reusable Surgical Instruments, Plasters, Disposable Gloves, Scalpel, Urine Collection Bottles, Contact Lenses

Class II B – Moderate risk:
Pacemakers, Automated External Defibrillators, Ventilators



Class II A – Moderate risk:
Dental Materials, Hearing Aids, Contact Lenses, Diagnostic Ultrasonic Devices, Tracheotomy Tube

Class III – High risk:
Heart Catheters, Insulin Pens, Blood Bag

WHAT?

UDI code – comprised of the UDI-DI (device identifier) and UDI-PI (production identifier) through a globally accepted device identification and coding standard. It can be given in linear barcode or DataMatrix format.

Machine readable

(01) 76123456789001
(11) 160715
(17) 260130
(10) 0001

Example of the commonly used GS1 DataMatrix code for capturing UDI code

Human readable

(01)76123456789001(11)160715(17)260130(10)0001

DI (Device Identifier)
Fixed article identification number unique for each packaging level of a product.

- Global Trade Item Number (GTIN)

PI (Production Identifier)
Variable production data

- Lot or batch number
- expiry date
- date of production
- serial number (mandatory for implants)

Example of the GS1-128 linear bar code commonly used to capture UDI code:

Questions to Consider:

- Is package label space an issue?
- What size or orientation?
- Can all parties in the supply chain read it?
- What type of identification is appropriate for your application?

WHEN?

New legislation is being implemented over the next few years, and Macsa ID has the solutions to help you fulfil the requirements.

MAY 26, 2021
UDI marking must be present on Class III devices and implants.

MAY 26, 2023
UDI marking must be present on Class IIa/IIb devices and on Class III devices that require direct marking.

MAY 26, 2025
UDI marking must be present on Class I devices and on Class IIa/IIb devices that require direct marking.

MAY 26, 2027
UDI marking must be present on Class I devices that require direct marking