



INDIVIDUAL IDENTIFICATION OF MEDICAL PACKAGING BY THE MULTIBEAM LASER MARKING: THE IDEAL MARKING SOLUTION

EXECUTIVE SUMMARY

1. Multibeam laser marking supports **high quality Datamatrix (DM) code** direct marking on broad range of primary packaging, including polymers, glass, elastomer, coated metals.

2. Multibeam laser marking offers differentiating advantages vs alternative marking technologies

→ MULTIBEAM LASER VS STANDARD LASER

- Multifold increase in marking **speed, typically x3-5**
- Significant reduction in TCO where superior speed is relevant

→ MULTIBEAM LASER VS UV PRINTING

- Multibeam laser marking is ROI **<10 years for 10s millions parts produced.**
- Better marking integrity along product lifecycle
- **Higher uptime:** no regular maintenance, no start-up phase

→ MULTIBEAM LASER VS RFID

- Massive **advantage on TCO** for medium to large production compared to an RFID OPEX

3. Laser marking is the **least impactful approach from an environmental** standpoint, compared to RFID and ink-jet printing.

Driven by the UDI regulation and a solid forecast growth over the next decades, pharmaceutical companies and their contract manufacturers are setting up individual traceability on their production to offer always improved product quality to their patients.

The information carried along the supply chain needs to include the production lot, date and manufacturing site at the minimum. For industrial marking methods like ink-jet or laser, the ideal vehicle is a **2D datamatrix code** (2D DM code) directly applied on the primary package ; for wireless communication based method like RFID, an active chip has to be permanently connected to the product.

What the pharmaceutical industrials need is a means of securely retrieving the data stored on their product at any time along the production, packaging and distribution chain. A means that is technically and economically sound to their industrial reality and the society patients are living in.

While laser marking has always been a great candidate for marking technical packages, it used to be short on the marking speed required to deliver such markings on production lines operating at 300 to 600 ppm. This limitation is blown up by the dramatical acceleration brought by multibeam laser marking, a 15-year old innovation now actively deploying into the industrial market.

This paper highlights latest improvements in multibeam laser marking solution for in-line identification of medical devices (§1), its ability to deliver secure reading of the data stored (§2) and its economics (§3) in perspective with alternative identification solutions as RFID and ink-jet.

1. PERMANENTLY MARKING MEDICAL DEVICES PRIMARY PACKAGES

Definitely not an easy task ! Parts are moving, primary packaging materials are both technical and diverse (polymers, elastomers, glass, coated metals), the available marking area is small and full traceability requires a lot of data ...

Operating at 600ppm means 100ms cycle time, 300ppm gives 200ms. Effectively available marking time might be lower – sometimes down to 30-50% of the cycle time - to account for the other operations involved in delivering a conform marking, like precise positioning and data communication.

The data content generally fits within a DM 12x12 to DM 16x16 2D Datamatrix code, with respectively 90 to 160 cells to be marked per code.



VULQ1-S System multibeam laser marking head

For more information on Datamatrix coding, see GS1 : [The data content generally fits within a DM 12x12 to DM 16x16 2D Datamatrix code, with respectively 90 to 160 cells to be marked per code.](#)

Multibeam laser marking combines state-of-the-art laser technologies (dynamic laser beam shaping, galvanometric scanning) with process innovation to readily deliver on these requirements:

→ **FULL-STAMP** marking, supported by **VULQ1-S FLASH** series: the 2D datamatrix code is fully 'printed' in one single laser light pulse (<10ns), **millions of times faster than state-of-the-art**. This technique is particularly well suited to small datamatrix codes, typically from 500µm to 3mm.

→ **PIXEL-STAMP** marking, supported by **VULQ1-S BEAMS** series: each cell of the code is printed with one laser pulse, similar to a parallelized dot code marking. Marking time is typically **3-5x shorter than state-of-the-art**.

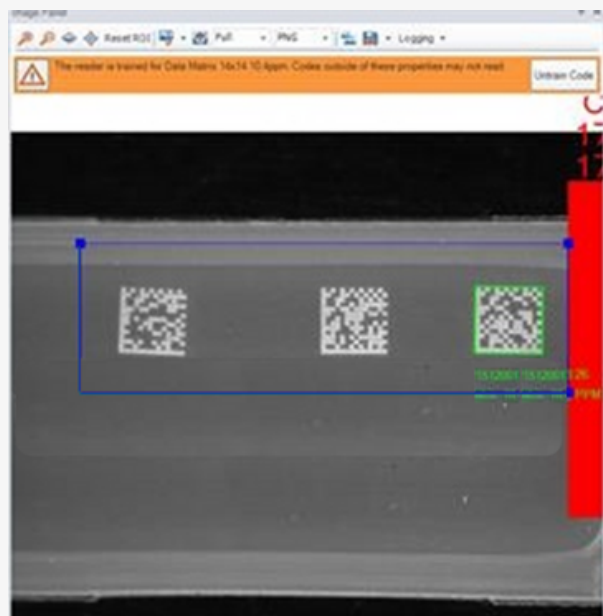
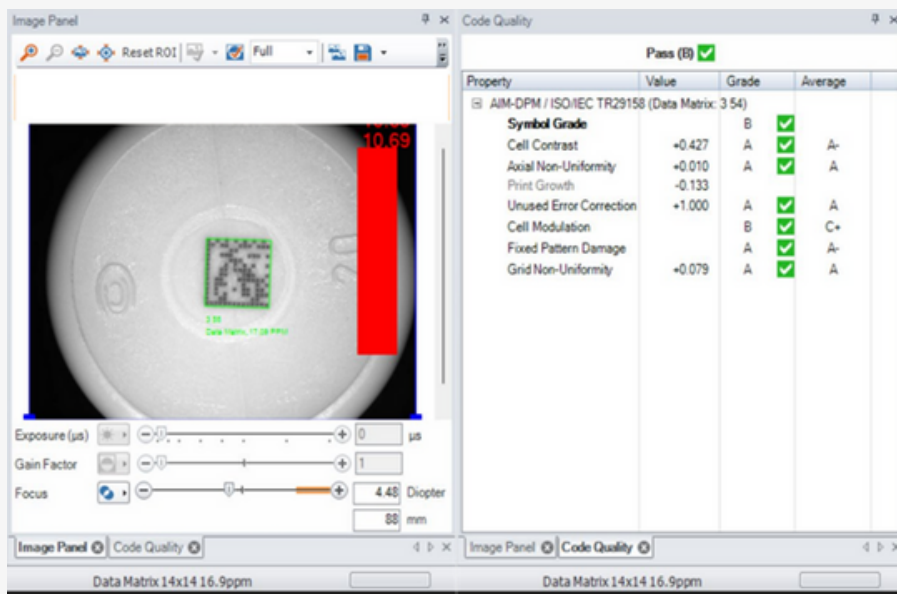
Internationally patented processes, more details found on www.qiova.com

Multibeam laser marking solutions are available in near infra-red (NIR) or visible wavelength, down to the ultra-short pulse (USP) duration regime. While the type of primary packaging material used in pharmaceutical production is diverse, most if not all can be marked with the right choice of laser light.

A few examples can be found below:

→ **Marking on polyethylene (PE) bottle** (Figure 1): 5mm DM 14x14 datamatrix code is marked in <150ms with PIXEL-STAMP marking, using green pulsed laser. The contrast is generated by color change, driven by photo-chemical reaction of the material. No debris are generated during the marking process.

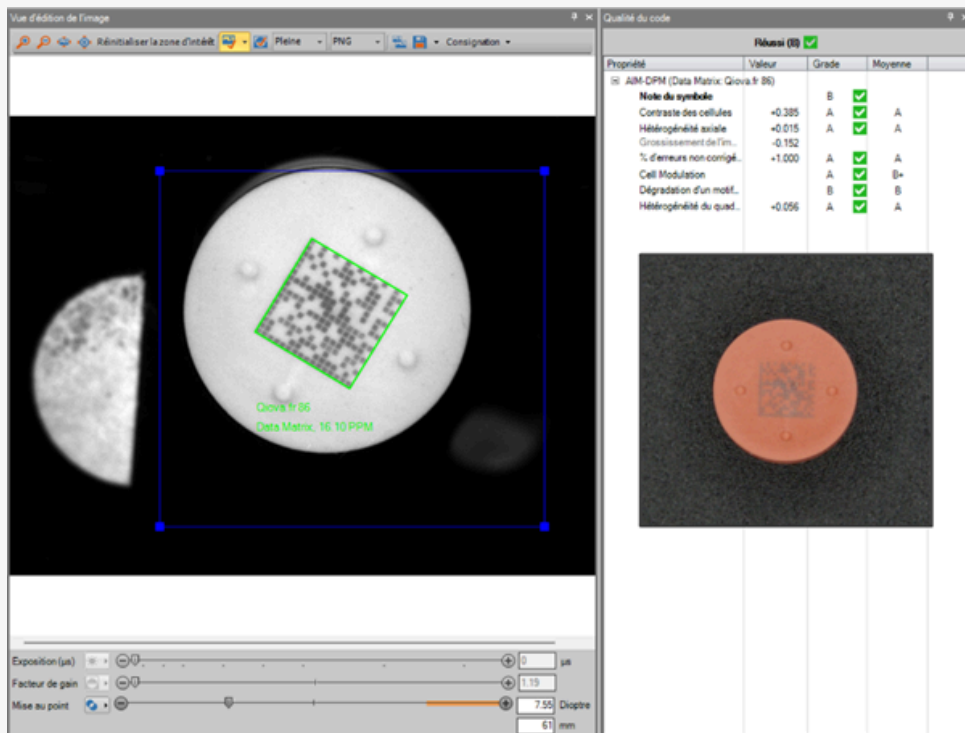
Figure 1: Marking on polyethylene (PE) bottle: 5mm DM 14x14 datamatrix code is marked in <150ms with optimal quality (Grade A), using green pulsed laser



→ **Marking on eye-drop strip containers** (Figure 2): typical of packaging used in sterile manufacturing, as the PE bottle above. 2mm DM16x16 datamatrix code is marked in <65ms with optimal quality (Grade A), using NIR ultra-short pulse laser

Figure 2: Marking on eye drop container - 2mm DM16x16 datamatrix code is marked in <65ms with optimal quality (Grade A), using NIR ultra-short pulse laser





→ **Marking on cartridges elastomer plungers** (Figure 3) : 2,5mm DM 16x16 datamatrix code is marked in one single pulse (marking time <10ns) with FULL-STAMP marking, using green pulsed laser. The contrast is generated by color change, driven by photo-chemical chemical reaction of the material. No debris are generated during the marking process.

→ Figure 3: Marking on cartridges elastomer plungers : 2,5mm DM 16x16 datamatrix code is marked in one single pulse (marking time <10ns) with industrial quality (Grade B), using green pulsed laser

→ **Marking on single use syringes glass body** (Figure 4): 1,5mm DM 14x14 datamatrix code is marked in <50ms with PIXEL-STAMP marking, using NIR ultra-short pulse laser. The contrast is generated by micro-ablation of the material surface. Very little debris are generated during the marking process. Multibeam marking also reduces significantly the risk of micro-cracking.

Figure 4: Marking on single use syringes glass body : 1,5mm DM 14x14 datamatrix code is marked in <50ms, using NIR ultra-short pulse laser. Multibeam marking reduces significantly the risk of micro-cracking.



→ **Marking on vials clear anodized aluminum caps** (Figure 5): 2mm DM 12x12 datamatrix code is marked in one single pulse (marking time <10ns) with FULL-STAMP marking, using NIR pulsed laser. The contrast is generated by micro-polishing of the material surface, similar to laser cleaning pass.

→ Figure 5: Marking on vials anodized aluminium caps: 2mm DM 12x12 datamatrix code is marked in one single pulse (marking time <10ns), using NIR pulsed laser



Beyond these enabling marking performance, multibeam laser marking also helps simplify retrofitting or installation on new lines:

- When applicable, **FULL-STAMP** marking gets rid of risks of unconformities related to unstable conveying of products
- Working distance between laser head output and product is typically **100-200mm**.
- **Marking quality** is maintained over a few millimeters, well above the typical positioning tolerances of the surface to be marked.

2. RETRIEVING DATA SECURELY

What pharmaceutical companies ultimately need is **to retrieve the information stored on the product** at any point of its lifecycle, in a secure and robust manner.

Laser marking has unique benefits from this angle: **the code is permanently attached to the primary packaging**; there is no risk of damaging the chip or losing a label, which would harm data retrieval.

Readability conformity target for the pharmaceutical sector is **>99,9%**. This requires repeatable and robust high quality marking with respect to real-life industrial tolerances.

But it also requires a well-adapted and repeatable reading setup, as the conformity of the data retrieval is a result of the adequate combination of high-quality marking and reading systems. For DM code reading, standard industrial cameras combined with the proper lighting are fine.

While marking mostly happens close to the filling stations to ensure maximum reliability in the coupling between the active ingredients and the traceability information, the reading of the DM code will happen many times downstream, in the packaging and distribution sites. The co-existence of different reading technologies (cameras) across this ecosystem can be daunting...

So, how to deploy a new in-line marking solution without creating bursts of non-conformity?

In the industrial space, the figure of merit to evaluate the probability of conform data retrieving is supported by the Direct Part Marking (DPM) grading scale, internationally defined by ISO standards.

Grading evaluation applies on the combined performance of the marking and reading systems, on a scale ranging from A (optimal) to F (worse). Grading A to C is acceptable in most situations, while particularly sensitive application might only accept down to grade B.

From a given DM code marking quality output, it is therefore possible to build deployment strategy based on qualification of reading systems using Datamatrix code grading. Supposing cameras are already in place, the main levers are the lighting conditions and software settings. The incorporation of AI-based learning in the reading software is a very powerful tool to optimize reading robustness without any hardware change.

The intrinsic DM code marking quality obtained with multibeam laser systems paves the way for robust data reading. The markings shown in Figure 1, Figure 3 or Figure 6 feature optimal grading when read with a basic setup combining Cognex Dataman camera, annular LED lighting and non-specific software learning.

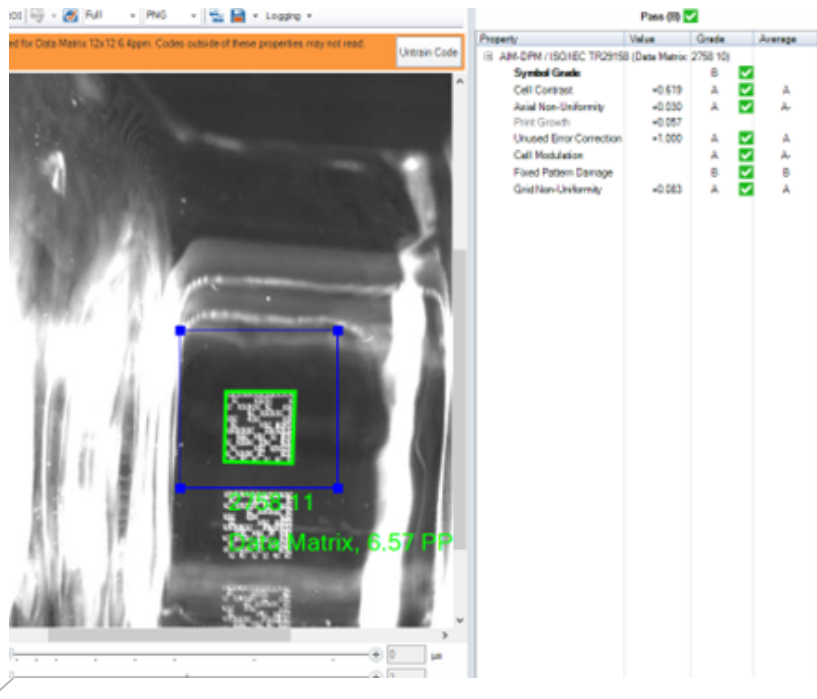


Figure 6: Industrial level quality (grade B) for 1mm DM 12x12 code marked on glass surface, under white LED lighting.

Finally, challenges in robustly retrieving traceability information might also arise from environmental conditions. There might be scratches on the surface where the DM code is marked, or tiny water droplets messing up with the reader’s decoding algorithm...

Here again, multibeam marking offers unique solution-pathways.

The dramatically faster marking speed of multibeam laser marking systems allows to seamlessly implement such a simple and efficient mitigation strategy. This is illustrated in the marking of cartridges anodized aluminum caps (Figure 7). A batch of 7 DM codes is marked around the cartridge cap in less than 10ms, effectively delivering robust reading conditions (Figure 8) despite scratchy surfaces.

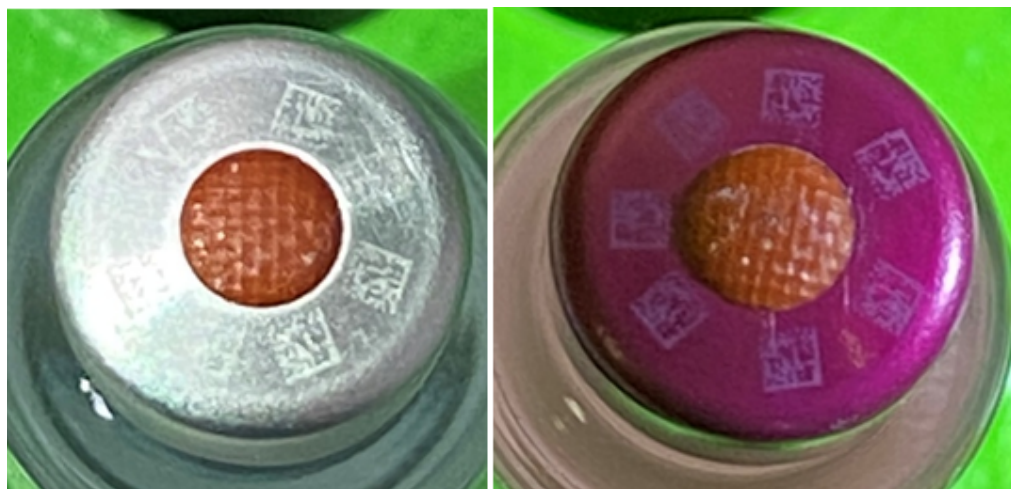
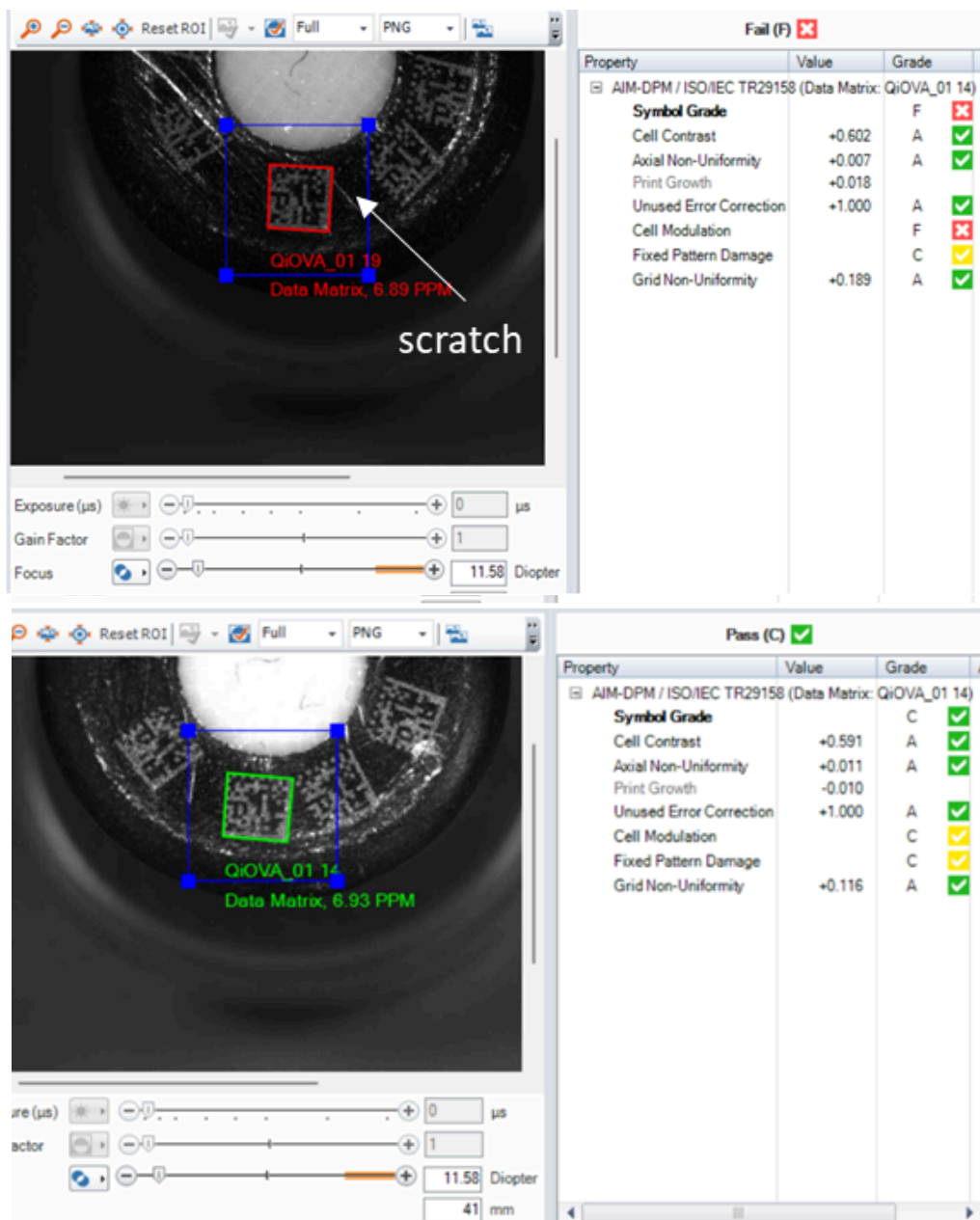



Figure 7: 1mm GS1 DM 14x14 marked on cartridges anodized aluminium caps with VULQ1-S FLASH series (FULL-STAMP)

See in particular ISO/IEC 29158 for laser-marked Datamatrix code quality assessment and ISO/IEC 16022:2024 for Datamatrix code requirements.



→ Figure 8: laser marking on an anodization defect yields non conform grade, while it is conform otherwise. Multiplying markings creates robustness in retrieving data vs environmental factors

3. COMPARISON WITH ALTERNATIVE PERMANENT IDENTIFICATION TECHNOLOGIES

 Laser marking solutions are much too often regarded as an expensive identification solution, compared to alternative solutions such as ink-jet or RFID. However, when considering the total cost of operation in high volume production, **multibeam laser making cost per part ranges from smaller to equal.**

And this, while bringing the many additional marking benefits brought by laser marking, which are not easy to factor in a cost per part: **direct permanent marking, high resolution, consumable-less, contact-less, environmental-friendly with a broad material compatibility.**

Let's look at the most frequent alternative individual identification options and how they compare to multibeam laser marking.

3-1 MULTIBEAM LASERS VS STANDARD LASERS

The point is clear here: whenever you can fill your expectations with standard laser marking solutions, you should go for this! Multibeam lasers are a premium category of solutions.

However, due to the high capacity of medical manufacturing lines (300ppm to 600ppm), it is more than often that the classical pen-writing-like approach fails to deliver. The answer might be to duplicate systems, therefore duplicating CAPEX and adding additional integration costs as well as increased risk of downtime.

VULQ1-S multibeam laser marking systems typically deliver x3-5 increase in throughput for a 50% premium. The math is simple.

Additionally, where FULL-STAMP marking applies, marking time dramatically reduces down to 10ns, together with integration costs and risks. FULL-STAMP marking delivers for instance 1mm DM code on anodized aluminum (Figure 7) or 3mm DM code on polymers packages like ABS.

3-2 LASER VS RFID

RFID might be considered when packaging is difficult to mark and/or there is very little space available. Its very strong point is the ability to read collectivity and remotely. Compared to lasers, the initial investment is also much lower.

However, in the context of high volume manufacturing, cost of the chips and infrastructure required to program them makes this identification solution unsustainable.

\$ Only considering a reasonable chip cost of 0.1c€ and production volume of 1M parts per year, multibeam laser marking is ROI in 1 year (see Figure 9 and Table 1). And multibeam lasers do deliver high quality Datamatrix codes with size <1mm.

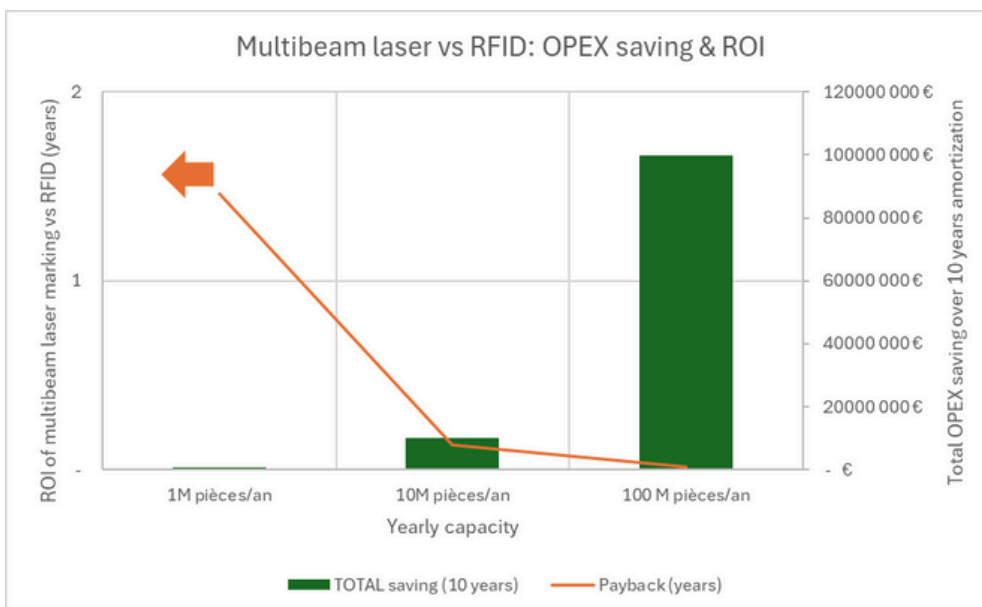


Figure 9: multibeam laser marking is largely dominant vs RFID for production volume of millions parts per year.


Volume scenario	Volume (pcs/year)	Unit cost RFID	Unit cost Multibeam Laser
1M pieces/an	1000000	10305 €	0,0159 €
10M pieces/an	10000000	10031 €	0,0016 €
100 M pieces/an	100000000	10003 €	0,0002 €

Table 1: Comparison of cost per part identified, comparing RFID and multibeam laser marking in various volume production scenarios.

3-3 MULTIBEAM LASER VS INK-JET

In the medical traceability context, we will focus our analysis on UV ink-jet printers for their ability to mark on primary packaging and the higher resistance of their marking.

UV ink-jet printers have no problem of marking speed up to 600ppm. For a 5mm DM code, the OPEX associated with ink is relatively limited and do not weigh too much on the cost per part, even high volume. But printers need weekly if not daily maintenance to operate, when lasers operate automatically and switch immediately from one recipe to another.

 Factoring in these costs, multibeam laser marking offers an advantage in terms of OPEX, which offsets the initial CAPEX difference at few tens of millions parts/year volume over 10 years of amortization period (see Figure 10 and Table 2).

On a longer run, the 15/20-year lifetime of DPSS lasers would strengthen further their advantage in cost per part.

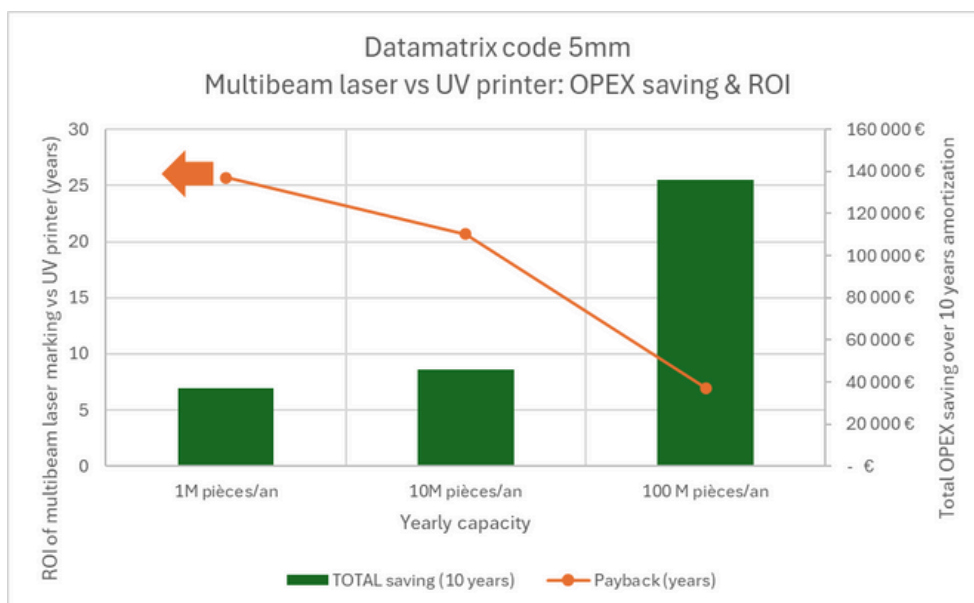


Figure 10: multibeam marking is ROI in <10 years vs ink-jet marking for a few ten millions parts per year with a better marking durability.

Volume scenario	Volume (pcs/year)	Unit cost UV printer	Unit cost Multibeam Laser
1M pieces/an	1000000	0,01960 €	0,01590 €
10M pieces/an	10000000	0,00205 €	0,00159 €
100 M pieces/an	100000000	0,00030 €	0,00016 €

Table 2: Comparison of cost per marking, comparing UV ink-jet printing and multibeam laser marking in various volume production scenarios.

A FINAL NOTE ON ENVIRONMENTAL FOOTPRINT AND ITS COST



Environmental footprint and its associated cost, today and in a 20-year future, is very difficult to assess.

On a qualitative basis:

- Laser marking involves no chemical or natural consumables at all. Laser light interacts with primary packaging to create contrast. As a consequence, the end of life recyclability of primary packaging is fully preserved.
- UV-inkjet printing obviously involves chemicals, which is not favorable. In the current use case, it is in limited amount, ranging between few liters for high volume to a few tens of liters for very high volumes. The impact of UV printing on the recyclability of primary packaging is unknown.
- RFID is by far the most impactful marking technology from an environmental standpoint. 100 million products means 100 million semiconductor chips, glued to the product with some plastic tape. It clearly harms the recyclability of the product when reaching end-of-life.

**ANY FURTHER QUESTIONS,
PLEASE SIMPLY GET IN TOUCH WITH OUR TEAM**