

## “Sterne offers laser marking for silicone-based medical devices”

**UDI** – Subsidiary of the Exsto group since 2022, Sterne specializes in the development and manufacturing of silicone elastomer-based products. The company excels in extrusion, injection, overmolding, and co-extrusion within industrial environments. Based in Cavaillon, Vaucluse, it has a 4,000 m<sup>2</sup> facility, including 700 m<sup>2</sup> of cleanrooms classified as ISO 6, ISO 7, and ISO 8.

In addition, Sterne holds ISO 9001:2015 certification as well as ISO 13485:2016 certification, which confirms that the medical device sector is one of the company’s main markets. Medical device production requires compliance with UDI (Unique Device Identifier) marking processes to ensure product traceability throughout its lifecycle, whether under the US FDA regulations or European regulations. It is important to note that if the medical device is intended for reuse, the UDI marking must be done directly on the product, either in the form of a barcode or a DataMatrix code.

To support its clients in achieving compliance, Sterne has equipped one of its cleanrooms (ISO 6) with a laser engraving system. The company has chosen a laser engraver that provides high-quality, reliable, and durable marking. Engraving dimensions can go up to 100 mm × 100 mm, with no minimum size requirement other than visual readability. Laser marking of medical devices can be performed on all types of biocompatible materials and surfaces (smooth, curved, etc.) safely, in a highly protected environment.

In addition to laser engraving, which allows the creation of evolving series such as lot and serial numbers, Sterne also uses pad printing in its cleanroom, although in this case, the marking are non-evolutive. Both processes work on a wide range of silicone (according to technical specifications). Sterne’s agility, expertise, and mastery of skills enable Sterne to offer tailored and specific solutions to meet its medical clients’ needs. The company is thus capable of using provided files and working according to specifications to better adapt to product constraints.



Example of laser engraving sizes on silicone (with a QR Code to scan to test its legibility).