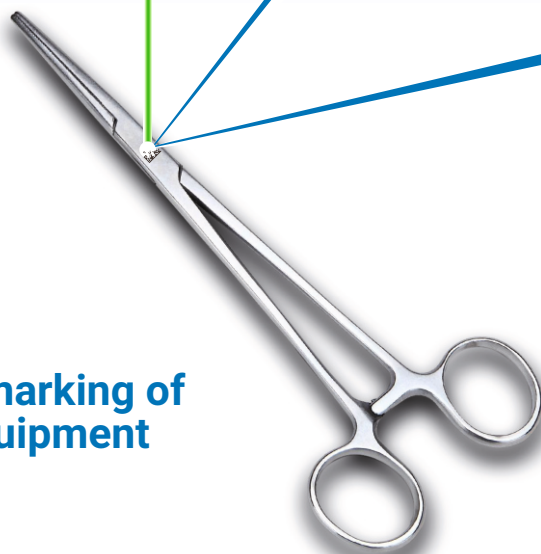
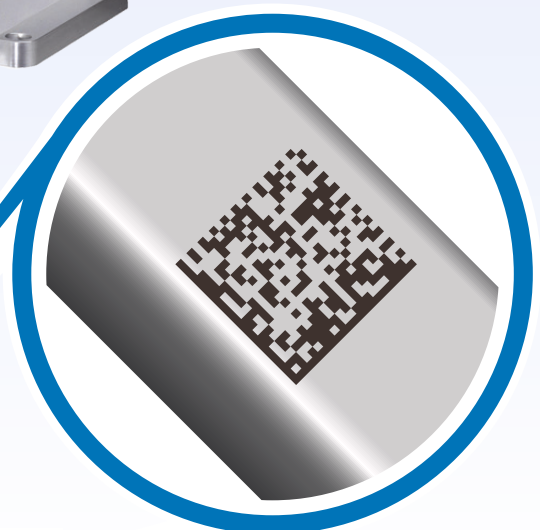


MARKING MEDICAL DEVICES



Permanent marking
for your devices



New rules
regarding marking of
medical equipment

www.etchmark.co.uk

ÖSTLING
MARKINGSYSTEMS

Direct Marking Required

The marking method for medical devices and their packaging has already been regulated by the FDA for all risk classes in 2013. All Packaging in the US has to be marked according to this method today.

For the direct part marking (DPM) of the device itself, only the lowest risk class I remains to be mandatory (by 2022). All other medical devices are already required to implement UDI marking (**Unique Device Identification**) on the device itself.

The European Medical Device Regulation (MDR) was introduced in 2017 and will enforce UDI marking starting in May 2021. Introduced in several steps, these rules will eventually apply to all devices used for more than one patient. In the UK, most Medical Devices have to be registered before the end of 2021 in order to be sold there.

The keywords for these markings are permanent and unique. It has to be possible to trace the individual product from initial production all the way to its final use and eventual scrapping. The marking has to contain production date, product ID and specific serial number. And the marking has to last through the entire life cycle of the product and through all reprocessing made between patients in autoclaves and other methods of cleaning and disinfection.

The marking can be human-readable as well as machine-readable using a barcode or 2D code. On small devices a 2D Data Matrix code is the most practical.

Only a few companies are licensed by the FDA and in Europe to define formats for UDI Codes.

The largest are GS1 and HIBCC. Östling is an approved Solution Provider for GS1 as well as HIBCC.

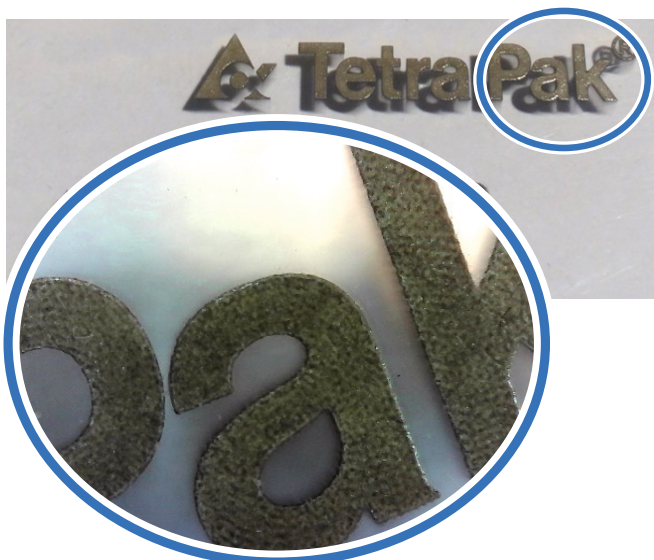
How do you make sure to conform to these standards & regulations? You are welcome to contact us for further information about the correct marking method for UDIs.

What Type of Marking Methods and Marking Systems conform to the main FDA & MDR requirements?

Permanent Marking: Obviously, you cannot use inkjet devices or any type of label, since labels can be torn off and ink will wear out with time and eventually be fairly easy to rub off. **Dot-Peen marking** can be a good solution for certain products as long as the risk for infections is low. **Lasermarking** and **Electrolytic Etching**, however, are two of a very limited group of systems that can provide markings of sufficient long-term quality to be compatible with all FDA and European requirements.

The risk of infections:

Maintaining a high level of hygiene is obviously important using medical devices. Accordingly, these devices must not contain material superfluous to their intended function. Decorations comprising potential bacterial sites or coloring pigmentations are definite no-no's! Therefore, polymer-based components intended for medical use are difficult to mark with traditional lasers, since these create marking contrast by heating or chemically stimulating – pigmentation! Obviously, it is also important to avoid infections in food-handling applications, another problem area for traditional lasers.



◀ Figure:
"Marking inside polymers
used for food-handling components"

A marking that will last for the entire life-cycle of the product

Obviously, a permanent marking must itself avoid decreasing the life-cycle of the device.

A common problem with traditional laser marking is corrosion:

In particular, stainless steel devices may not endure several thousand autoclaves after a traditional laser marking, without starting to rust.

The solution? Use our new range of cutting-edge medical lasers.

Östling Marking Systems has developed new marking methods for nearly 50 years. Today we are happy to announce the introduction of an entire product line of state of the art lasers based on our long experience of developing marking systems. These laser systems are specifically designed for the marking and validation of these markings on devices and components intended for medical, dental and food-handling applications.

Marking on steel and other metals

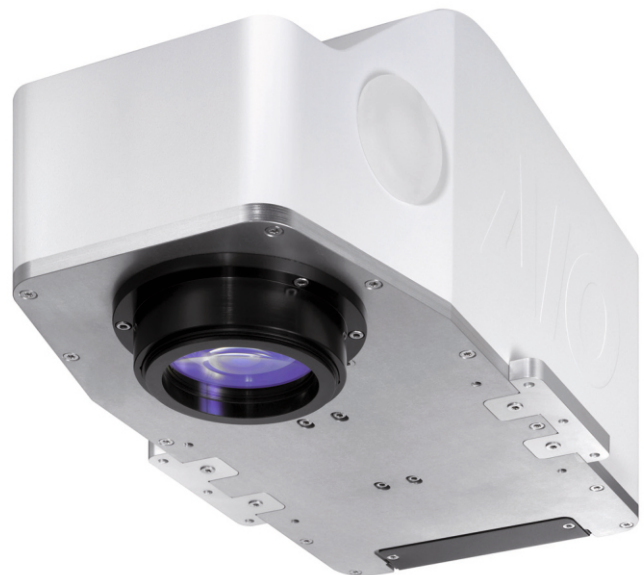
By optimising pulse-width, peak-power density and wavelength for the application, our Vanadate lasers minimise the risk of rusting. Our best lasers for the application will even increase the passivation of the surface and thus increase its resistance to rust. With our otherwise excellent fiber lasers, however, we still recommend passivation after the marking – please enquire for more details.

All metals can be laser-marked with our medical lasers: all grades of steel, copper, brass, aluminium, titanium, nickel, chrome, magnesium, zinc, silver and gold. For stainless steel we still recommend passivation with some of our lasers – please enquire.

Lower volume marking and back-up marking of metals can be conveniently made with our medical etching units – EU-PULSE – see separate brochure!

Marking plastics, composites, glass and semiconductors (using zero additives):

A unique combination of Vanadate laser pulse parameters and wavelength allow us to tailor the marking of just about all types of plastics, semiconductors and composites even on many polymers lacking pigmentation. The surface will not be harmed since the marking is entirely based on colour-change. On transparent materials such as different types of Plexiglas (mainly PC or PMMA) and medical glass we prefer to mark the component internally, thus reducing surface change to zero.



Our new laser, developed specifically for medical, dental & food-handling applications, allowing the tailoring of laser-pulses individually for every specific application and the selection of an optimal wave-length.

The laser will mark with a high contrast and precision on most plastics, composites, semiconductors, glasses and metals without adversely changing its surface structure and without using any pigmentation or additives.

Using Lasonall M-series Lasers: Case Stories

Our **Lasonall M-series** lasers provide the best solution for medical, dental & food-handling applications

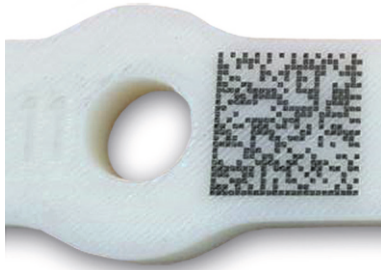
Project:

To mark medical & dental devices and tools for implants, all made of high-quality stainless steel or titanium. Some of the devices are designed to last for as much as 30 years, which means that they will be subjected to quite a few autoclaves during their lifetime.

Solution:

AIO M, with peak-power density optimised for a rust-proof marking of the steel devices. The medical laser software contains several preset laser parameters for different grades of steel. In addition, passivation e.g. in accordance with ASTM A967/A967M is always recommended.

Optional high-quality solution for lower volumes:
Etching with EU Pulse - see separate brochure.



Project:

A component to be used during brain surgery was not allowed to contain any pigmentation whatsoever and consisted of completely pure PP.

And yet, a high-contrast marking of a 2D Code had to be provided without seriously affecting the surface structure of the device.

Solution:

AIO MG+ with preset parameters specifically for high-contrast marking on pure PP.

Project:

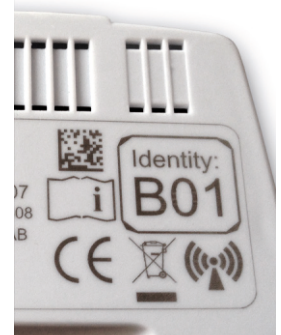
To make a very detailed marking on hygienic products intended to be in constant contact with a patient. The device is made of a mixture of ABS/PC with a very weak pigmentation. The pigmentation is NOT added to facilitate the laser marking as such. Among other things, a detailed Data Matrix code has to be made.

The total marking time, including all alphanumeric signs, logos and code may not exceed 4 seconds. In addition, the marking cannot produce indentations at all, since these may become sites for bacteria.

Solution:

AIO MG with high-resolution optics. Low pigmentation laser parameters are selected for the specific ABS/PC combination used in the device. In less than 4 seconds a very dark, high-contrast, high precision marking was provided. Closer inspection with a microscope could not detect any specific indentations or cavities in the marking.

Our Östling CodeVision System is used to identify, validate, position, check and store all markings made.

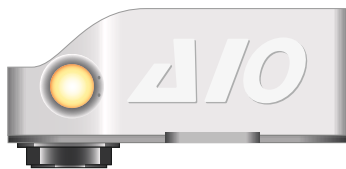


A short presentation of our cutting-edge Medical Lasers the LasOnAll M-series

Lasonall AIO M-series:

We cannot hide the fact that a large part of Östling's innovative laser application development is embedded in the capabilities of our various AIO lasers. Take our decision to "Go Green" for example. This is the ultimate in cost-efficient durable marking for high-quality medical devices, polymer as well as composite and metal based. For devices with long-life cycles requiring high-volume reprocessing. Experience the strength and precision of variable peak power density. It allows our AIO lasers to be accurately tailored to any application with continuously adjustable pulse parameters.

All AIOs are mono-block lasers. Scanner, all optics, the diode-pump, the laser-resonator itself and all control electronics are all housed within one robust enclosure. This adds to AIO's already unique versatility by allowing it to easily be moved from one marking site to another - very useful in a large company or hospital with many departments.



AIO M and AIO MT

Lasonall AIO M and AIO MT

– perfect for marking metallic medical devices and for most pigmented plastic components.

AIO M delivers the best possible marking result on many metals & pigmented polymers – every time. AIO MT is the real work-horse, perfect for high-volume, high speed marking applications with no loss in precision.

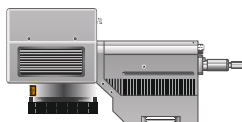


AIO MG, MG+ and MVG

Lasonall AIO MG, MG+ and MVG:

Green indeed! This is the ultimate combination of precision and flexibility.

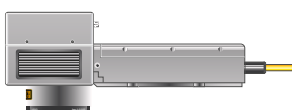
The AIO MG series lasers are designed to mark smoothly and yet with the highest possible contrast and precision on - well - just about anything. This is the reason for selecting the green wave-length: on steel, aluminum, chrome, titanium, copper, brass, silver and gold; on plastics, silicon, textiles, wood and cardboard. In other words - no other wavelength available today allows as many different materials to be marked. Combined with a very short pulse, the AIO MG lasers are also ideally suited to mark non-pigmented polymers without any additives and transparent polymers such as Plexiglas and Glass containers internally. The AIO MG units are truly "All In One" lasers in more ways than one!



XS 5, XS 10 and XS 20

Lasonall XS and FS-Series

Vanadate and Fiber lasers - perfect lasers for confined spaces and for the production line.



FS 20 and FS 50

These particularly small laser-heads (typically 245 x 100 x 145 mm; weight 4,5 kg), can easily be installed swiftly & efficiently on production lines where available space is limited. In robotic applications, you can benefit from sturdy cabling up to 10m in length. Within the XS series, the XS5 provides the highest quality marking on plastics, while the FS50 Fiberlaser will engrave the toughest metal devices in no time at all.

All **lasers** can be equipped with serial as well as digital communication interfaces including Ethernet and Profinet. Our **CodeVision Management System** will make sure that the correct individual marking is identified, validated and applied and will then check and store the markings made with all data concerning that particular device.

Medical Marking Station MiniMax

- highest possible quality to
the lowest possible price

This is the standard Marking Station for all Medical Models.

The laser itself (or laser head for the XS and FS lasers) is placed on top of the box and focusing is enabled by moving the marking-table vertically.

Door and marking table movements can be manual or motorised in this semi-automatic marking station.

Space inside box:

510x330x350 mm (LxWxH)

Size of the „T“-slot marking table: 250 x 330 mm

Marking area: 120 x 120 mm.

Due to the small outer dimensions of the box, 410 x 500 x 652 x 410 (LxWxH), the entire marking station can, for example, easily be moved between different departments of a hospital.



Medical Marking Station LaseMax - Full Size Marking Station for all applications.

Intended for marking much larger volumes or objects requiring more space.

LaseMax can be used with all our Lasers and has a vast volume of internal space - 600 x 800 x 380 (DxWxH).

Marking can be executed on a large amount of components with or without fixtures.

Text height & Code dimensions can be varied from 0.5 mm x 0.5 mm to 200 x 600 mm.

3D Marking:

Linear Y and Z axis for pre-programmed markings along different components with variable dimensions.

A C-axis for circular markings on rotated objects is also available.



Our tailored Vision Management system, Östling Codevision is a standard option in many medical applications

Simply place all components to be marked inside MiniMax or LaseMax and push "start". The vision system will locate all the objects, validate all intended markings, send ID and position for each object to the laser and the marking then starts directly using prestored specific marking instructions for each and every individual component.

The marking is then read & verified by CodeVision and finally stored with all data for future tracking.



Special machines tailored for your particular application

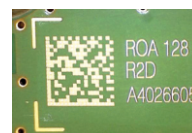
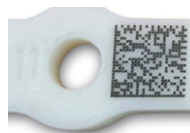
To fully realise the potential of all our different Lasers and Marking Programs we are more than happy to design unique solutions for your particular applications. As an example, our XLP boxes are often used by medical sub-contractors to mark plastic components of highly variable sizes. A vast volume of space is available here - 1200 x 400 x 400 mm (LxWxH) is a minimum, but other dimensions can be tailored. Round tables are also available for safe, fast loading during marking.

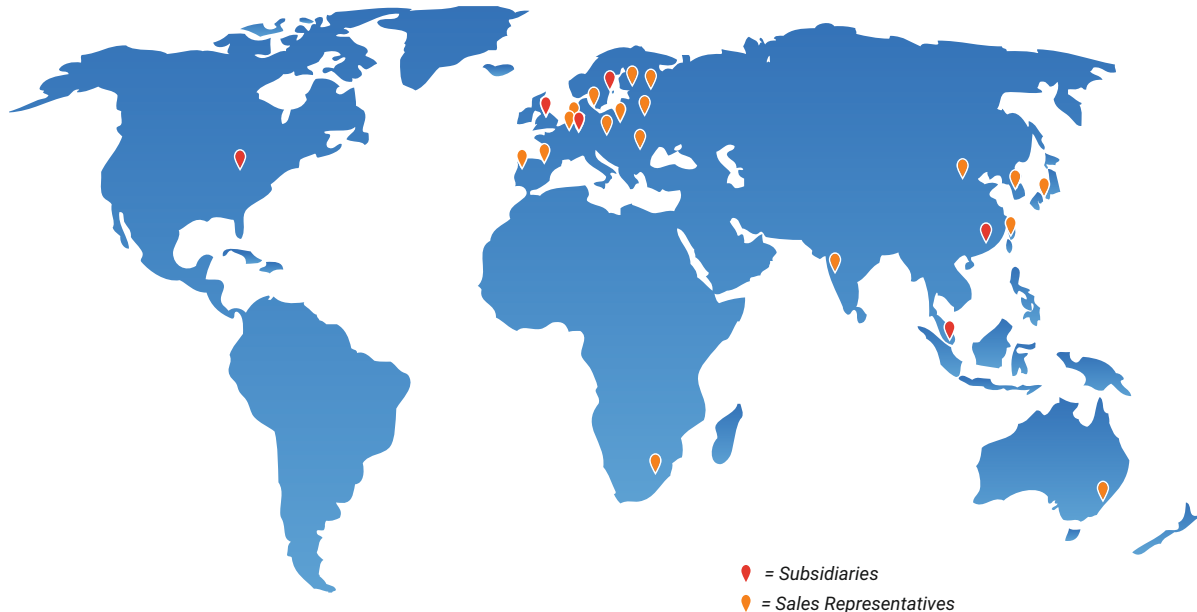
AIO Medical M-Series & Industrial Lasers: Technical Data

Please note: Where a range is indicated, specific values will depend on model chosen

Laser-Systems	AIO Medical Lasers	XS Vanadate Lasers	FS Fiber Lasers
Laser Source	Nd: YVO . diode-pumped	Nd: YVO . diode-pumped	Yb: fiber. diode-pumped
Wavelength	1064 nm / 532 nm	1064 nm	1064 nm
Average Power	6W, 20W, 30W / 5,10	5W, 10W, 20W, 30W, 40W	20W, 50W
Beam Quality	M <1.2 – 2.	M <1.5 – 2.5	M <1.5 – 1.8
Peak Power (Max)	20 – 400 kW	58 – 200 kW	-
Pulse Energy (Max)	-	-	1 mJ
Pulse Repetition Freq. (PRF)	10 kHz – 100 kHz	10 kHz – 150 kHz	20 kHz – 100 kHz
Spot Size (1/e ²)	36 – 62 / 18-31 µm	36 – 62 µm	36 – 48 µm
Pilot Laser	Integrated Red Laser-Diode; λ=635nm, 3mW (Beam class 2M) Indicates zero-point; marking area selection; marking simulation		
Cooling	Integrated Air Cooling		
Power Supply	24 V		
Operating Temperature	+10 till +35 °C		
Humidity	< 90% non-condensing		
Dimensions, Marking Head:	400 x 200 x 190 mm	245 x 145 x 100 mm	327 x 96.5 x 124.2 mm
Weight, Marking Head	12 kg	4.5 kg	3 kg
Dimensions - Control Unit	No Control Unit: All-In-One	435 x 175 x 405 mm	420 x 280 x 420 mm
Weight - Control Unit	No Control Unit: All-In-One	15 kg	14 kg
User Interface (hardware)	USB, Ethernet, Pronet, Drivers for 3 stepping motors, User-dened IO:s 2 separate security channels (PLC), as specied in EN-ISO 13849-1		
User Interface (software)	VB Script, Active X with a comprehensive application library		
Laser Marking Software	XS Designer – easy to tailor and truly user-friendly		
Operating System	Windows 10		
Fonts	Compatible with all True-Type Fonts (lled/unlled); single-line-fonts Orientation and character distance: free user dened Arc text: scalable and adjustable		
Graphics	Elements: Line, rectangle, circle, ellipse (lled/unlled) ; Gray-Step Formats: Vector-based: HPGL/DXF, PLT; Bitmap: BMP,JPG,GIF		
Coding Facilities	Barcodes: Codes 2/5, 3/9, 128 ; EAN 8/13, UPC, GS1 2D: Datamatrix (GS1, HIBC, ECC 200), QR Code , PDF 417, Code 16K		
Misc. Features	Flexible serialization, date & time functions User programmable VB script interface for variable data & sub routines' integration Text- and data exchange with data base systems (ODBC) ; Excel User-dened masks / HMI: Large library of application & help functions		
Options	Programmable X,Y,Z- & rotation-Axis (up to 3 simultaneously) Additional Pilot-laser for beam focusing; Extraction Systems, Remote control/ Robot-cell): External command box (Start/Stop, Emergency-Stop)		
Std Option: Östling CodeVision	Search & Identify Unlimited Quantity of Medical Devices Send positional Data for marking to Laser Validate Marking before & Check Quality of Laser Marking after Read & Transmit Content of OCR text, Barcode, Datamatrix & QR Codes		

Your All-In-One Supplier
for every Mark





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