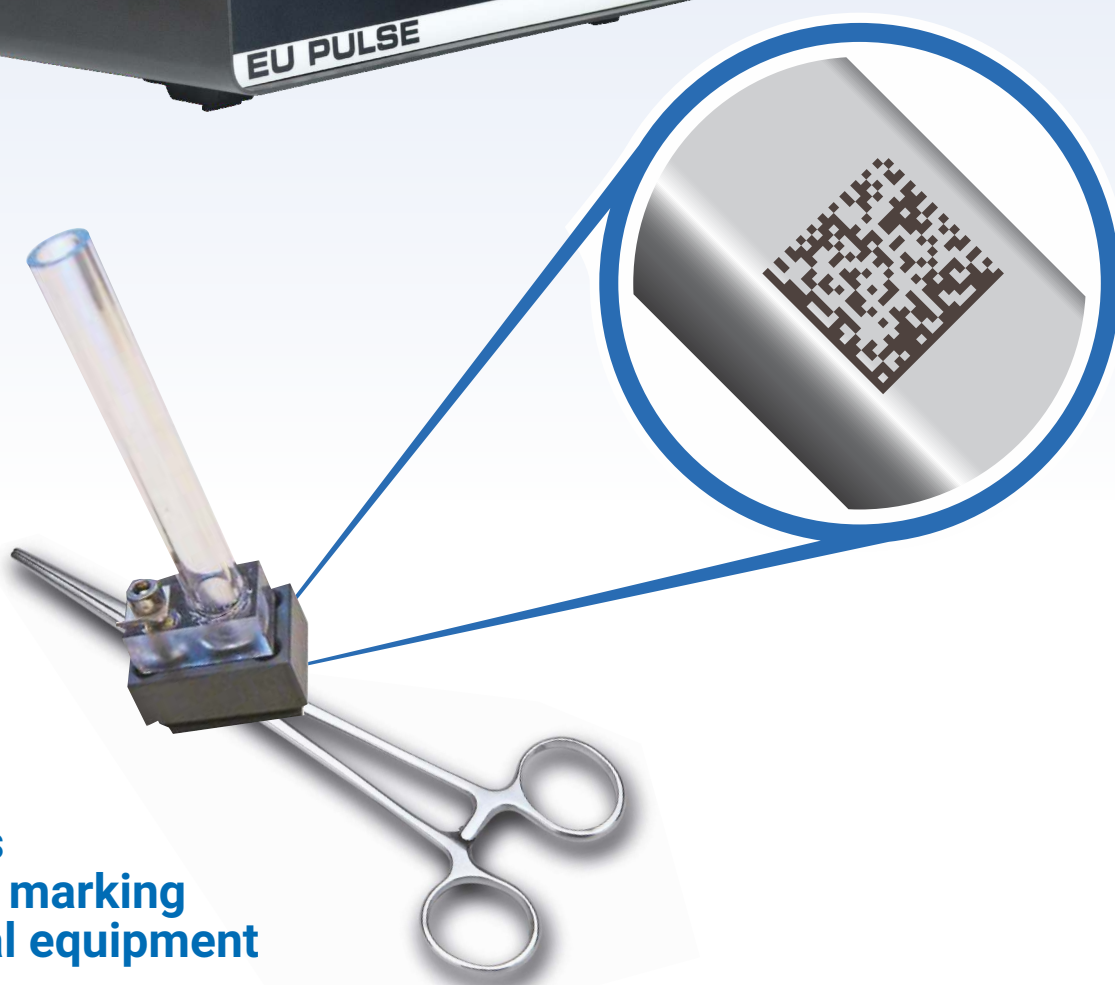


MARKING MEDICAL DEVICES



**Permanent marking
for your devices**



**New rules
regarding marking
of medical equipment**

www.etchmark.co.uk

ÖSLING
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.

How do you make sure to conform to these standards and regulations?

You are welcome to contact us for further information about the correct marking method for UDIs!

Permanent Marking

What type of marking methods and marking systems conform to the main FDA and MDR requirements for 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 limited group of marking methods 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 and indentations comprising potential bacterial sites are definite no-no's!

Electrolytic Etching

This marking method provides a smooth, black & permanent marking without affecting the surface of the device marked. No bacterial sites are created and the risk of rusting is minimised.



Cost-effective and durable

All materials with conductive surfaces can be electrolytically marked. The marking method is similar to screen-printing, but an electrolyte is used instead of colors. The electrolyte is a slightly acidic to neutral saline solution. Electrolytic marking is based on an electrochemical etching process where the image of a stencil is transferred to an electrically conductive product by the action of ions and electricity.

Chemically speaking, electrolytic marking will oxidize the surface of the metal in question down to a maximum depth of 10 µm. A marking consists of several layers of oxides and is durable and resistant to abrasion.

Electrolytic marking is easy and user-friendly!

A template of the required marking is clamped onto the marking head or placed directly on the workpiece. The marking head is connected to the positive terminal of an electrical supply, the workpiece to the negative pole. Once the marking head, soaked with electrolyte, is placed on the metal, current flows, creating the desired marking in seconds.



Project:

Marking Medical Devices made of stainless steel of the highest quality. The device has to sustain all autoclaves required during its 30 years lifecycle.



The Solution:

Electrolytic etching using EU Pulse with an electrolyte optimised by ÖSTLING for durable, black marking.

// Electrolytic Marking Devices

EU 80

Art. E-1101 1010



Power: 100 VA
Output voltage: 8, 16 and 24 V, AC
Input voltage: 115 or 230 V, AC
Dimensions (H x W x D): 155 x 200 x 150 mm

EU 100

Art. E-1101 1030



Power: 100 VA
Output voltage: 0 - 24 V, AC or DC
Input voltage: 115 or 230 V, AC
Dimensions (H x W x D): 155 x 200 x 150 mm

EU PULSE

Art. E-1101 1122



Power: 510 VA
Output voltage: 0 - 30 V, AC or DC
Input voltage: 115 or 230 V, AC
Dimensions (H x W x D): 170 x 300 x 260 mm

EU Pulse has been developed to modulate the AC pulse as desired. Quality, contrast and durability can be optimized and make the marking highly corrosion resistant.

Stencils of many different types

FIBRE Stencils - Suitable for a limited amount of markings per stencil.

Available as rolls or separate sheets to be printed by a matrix printer.

Small holes on the surface of the stencil will allow current to flow through to create the desired image.

PT-Stencils - Suitable for a limited amount of markings per stencil.

With the PT-Printer it is easy to produce your own templates. Thermal stencil material, available in cassettes or rolls of various sizes, are loaded into the printer. Using a very user-friendly software program, the desired stencil is designed and then printed in the amount of copies desired.

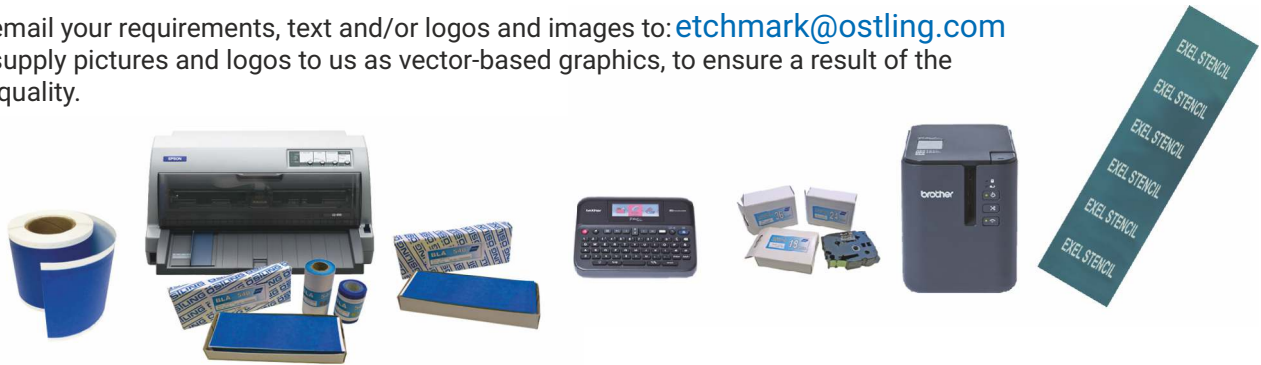
Exel Stencils - Suitable for a very large amount of markings of the highest quality.

These long-life stencils are templates we produce ourselves in accordance with your requirements. The Exel Stencils will last for thousands of etchings. Even for a limited quantity of markings per stencil - the result will be of a higher quality with a much finer and sharper definition of details.

They are available in sizes ranging from 50 x 50 mm to 350 x 450 mm.

Simply email your requirements, text and/or logos and images to: etchmark@ostling.com

Please supply pictures and logos to us as vector-based graphics, to ensure a result of the highest quality.



// ÖSTLING WORLDWIDE



Germany

ÖSTLING Marking Systems GmbH
Broßhauser Strasse 27
42697 Solingen
Germany
Tel.: +49 (0) 212 2696-0
Fax: +49 (0) 212 2696-199
Mail: info@ostling.com
Web: www.ostling-markiersysteme.de

USA

OSTLING Technologies Inc.
640 Lakeview Plaza Blvd Suite C
Worthington, OH 43085
United States of America
614-231-3559 office
614-436-4898 fax
Mail: sales@ostling-markingusa.com
www.ostling-markingsystems.com

Sweden

ÖSTLING Märksystem AB
Prästkragens väg 40
S-13245 Saltsjö-Boo
SVERIGE
Tel.: +46 851 4905-10
Fax: +46 851 4905-29
Mail: info.se@ostling.com
www.ostlingmarksystem.se

China

OSTLING Shenzhen Ltd.
Room 606, Building 1
Zhongtai Electronic Science & Technology Park
Donghuan No. 1 Road,
Longhua District Shenzhen,
518000, P.R.China
广东省深圳市龙华新区东环一路中泰电子科技园1栋606室
Tel.: +86-755-2533 1491
Fax: +86-755-8291 0651
Mail: info.cn@ostling.com
<http://cn.ostling-markingsystems.com>

England

OSTLING Etchmark Ltd.
Unit 5 Romford Road
Astonfields Industrial Estate
Stafford, ST16 3DZ
ENGLAND, United Kingdom
Tel.: +44 1785 253143
Mail: etchmark@ostling.com
www.etchmark.co.uk

Singapore

OSTLING Marking Systems (SEA) Pte. Ltd.
101, Kitchener Road #01-01
Jalan Besar Plaza, SGP-208511
Tel.: +65 6298 8173
Fax: +65 6298 4486
Mail: info.sg@ostling.com
<http://www.ostling-markingsystems.com>