NOVOPLAST SCHLAUCHTECHNIK

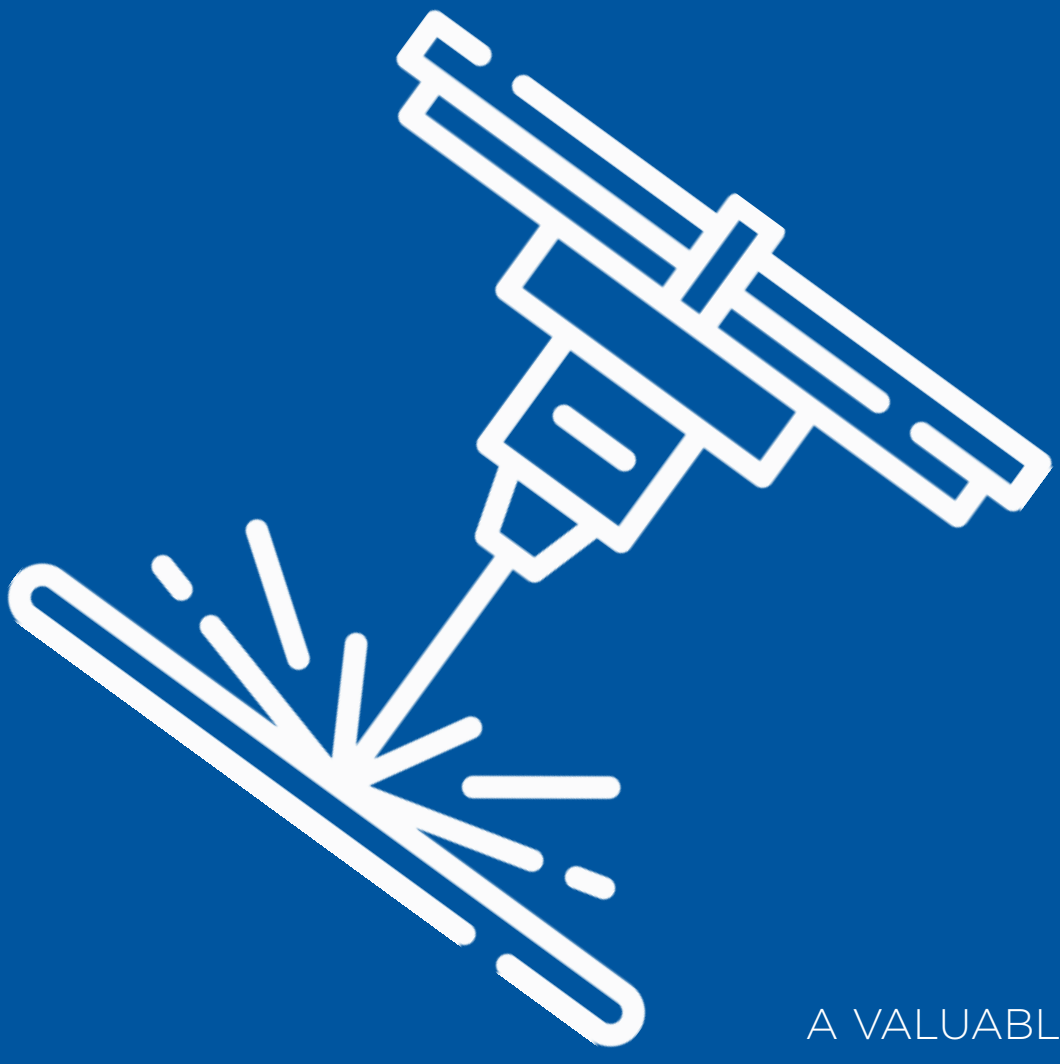
FLEIMA-PLASTIC

WHITE PAPER

As unique as a fingerprint

Laser labelling of plastic components in medical technology

How innovative laser technology is solving special challenges in the labelling of plastic products in medical technology



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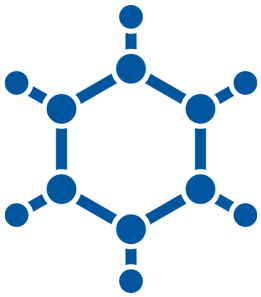
Abstract

In medical technology, safety is paramount. This applies not only to complete medical devices, but also to individual components. With the entry into force of the new MDR, the regulations to improve the health and safety of patients or users have been tightened up once more. Among other things, to ensure transparency and traceability, each product must be labelled in a uniform manner using the global UDI system. This clear labelling not only protects patients and users, but also manufacturers (e.g. against product piracy) and ensures quality. Laser marking technology, with its many unbeatable advantages, has become the accepted method for labelling.

Our white paper deals with the labelling requirements of plastic components in medical technology and how this can be safely covered by various technologies, but especially laser marking.

Plastics as materials

Plastics are used in many sectors. Their versatility and the constant new developments (e.g. increasingly also of bio-based plastics) make them universal and powerful materials.



An outstanding feature of plastics is that their technical properties, such as **formability, hardness, elasticity, breaking strength, temperature, heat resistance and chemical resistance**, can be varied by the choice of starting material, manufacturing process or the addition of additives.

In addition, plastics have a much lower weight compared to other materials such as metal or ceramics.

Plastics in medicine

Plastics are therefore one of the most widely used materials in medicine. Whether for intubation tubes, disposable syringes or needles: More than half of all medical devices manufactured worldwide are now made of plastics.

In many areas, they cannot be replaced by other materials.

The type of plastic used depends mainly on its special properties. In principle, any polymer material can be used as long as it meets the requirements of national and international regulatory requirements.

Due to their versatility and good processing characteristics, thermoplastics in particular are frequently used in medical technology.

Thermoplastics, thermosetting plastics, elastomers

Thermoplastics are plastics that can be easily deformed (thermoplastically) within a certain temperature range. This process is reversible, that is, it can be repeated as often as required by cooling and reheating up to the melting liquid state, as long as so-called thermal decomposition of the material does not occur due to overheating.

Thermoplastics differ from thermosetting polymers and elastomers.

Injection moulding and extrusion are the most commonly used processes for processing plastics in medical technology.

Injection moulding versus extrusion

While injection moulding is a cyclic process for the production of workpieces with a certain geometry, extrusion is a continuous process for the production of endless profiles. During extrusion, the plastic is not injected into a closed mould, but is pressed through a die instead.

High quality standards in medical technology

Apart from the pharmaceutical and aviation industries, medical technology is one of the most regulated sectors.

This is unsurprising, because medical devices are used on and in humans.

And also why state and supranational institutions repeatedly intervene in legislation. Quality assurance concerns both the procedures for certification and approval as well as the quality management of the production and processes themselves.

The establishment and maintenance of quality management systems (QM systems) was originally based on the **DIN EN ISO 9001** standard . ISO 9001 is a widely used quality management standard. It is not unusual for even small artisanal producers to have an ISO 9001 certificate on their wall.

However, medical devices are subject to a separate industry-specific and harmonised standard **DIN EN ISO 13485:2016**, commissioned by the EU Commission ("Medical devices - quality management systems - requirements for regulatory purposes").

ISO 13485 is an important standard and certification for medical device developers, manufacturers and distributors. Suppliers and service providers can also improve their competitiveness through ISO 13485 certification. At the same time, more and more manufacturers expect such certification as a basic prerequisite for business relationships.

The QM systems of medical device manufacturers are audited and certified in Germany and the European Economic Area by so-called "notified bodies" (e.g. TÜV Süd).

Product labelling: Greater quality and safety

Whether it is a minimum shelf life, a textile label or a quality label – labels on products are common and can be found on almost all products.

In addition to providing information regarding certain properties of the product and associated warning notices, they also contain information on manufacture, use, disposal, price or manufacturer.

There are **legally prescribed items of information**, such as the CE marking, energy label or certain hazard warnings, but also **voluntary markings**, which are intended to make statements about the quality of the product, such as the GS mark for tested safety, the use of which is voluntary.

In addition, there are also manufacturer's identification numbers (e.g. part numbers) or commonly used in the sector (e.g. global article number, GTIN, formerly EAN), which enable identification of the product.

The main objective of product labelling is the traceability of the individual product and the delimitation from other products.

Labelling for medical devices: A special challenge

The labelling of medical devices is a particular challenge - especially plastic components. Not only from a regulatory point of view, but also from a technical point of view.

The basis for the labelling of products in medical technology is the new **Medical devices Ordinance (2017/745/EU) – MDR for short**. It replaces the Medical Devices Directive and the Directive on Active Implantable Medical Devices and aims to further increase the safety of medical devices throughout their entire life cycle.

More stringent requirements for medical devices are the response to a whole series of scandal cases, for example involving the use of inferior or defective materials. The central objective is patient and user safety as well as transparency and traceability.

The MDR focuses on: Traceability

Essentially, the new MDR involves a re-classification of certain products, as well as stricter specifications for the content of technical documentation and clinical evaluation.

The monitoring of products and the **clear identification of products** after placing them on the market are becoming even more important.

The MDR differs significantly in several respects from the current EU directives for medical devices and active implantable medical devices. The most important changes include the **implementation of the system of the unique product number** that each product is to receive.

This requirement is intended to create the necessary transparency, facilitate traceability of certain products within the supply chain for manufacturers and authorities and, if necessary, enable rapid and efficient recall of medical devices with a safety risk.

In addition, the European Medical Device Database (EUDAMED) will be enlarged to facilitate access to information on approved medical devices as a whole.

EUDAMED

The European Medical Device Database is a database operated by the European Commission and the EU member states for the central management of medical products.

Specifically, the MDR provides for **"improved identification and traceability of medical devices by means of a unique ID number"**.

The concept of product traceability refers to the possibility of determining the origin and the different phases of a product, which it passes through within the entire production process and subsequent logistics distribution to the end user.

In addition to requirements from standards, such as

- Product identification,
- Compliance with regulations and standards,
- Traceability,
- Improving patient safety,
- Simplifying product recalls and
- Quality assurance in general

there are other advantages of the clear labelling of medical devices.

These include:

- Trademark protection: Protection against counterfeit products, e.g. by applying an encrypted letter or numerical code.
- Branding: Application of logos, with which identification is possible, e.g. in surgical documentation.
- Measurement accuracy: Graduations on medical measuring devices such as depth gauges or rulers, which assist in the precise determination of screw lengths in surgical technology, for example.

In addition, version labels or icons can be applied.

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Uniform standards through UDI

In order to ensure complete traceability, there are now strict rules for product labelling, which mean more safety for the patient. Manufacturers are obliged to label medical devices of all classes with the so-called **Unique Device Identification (UDI)** for the customer.

Unique Device Identification (UDI)

Is a global system for uniform product labelling for medical devices developed in the USA.

In order to be able to accurately identify and track the individual components, from production to distribution to their later location of use, the labelling of the product must consist of two parts:

- a **machine-readable barcode or data matrix code** and
- a **unique product number - a combination of numbers and letters** that can be deciphered by humans, meaning that they are clearly legible.

Deadlines for labelling on the product

The following deadlines apply for labelling on the product itself:

- For **Class III** medical products and implants: 26th May 2021
- For **Class IIa** and **IIb** products: 26th May 2023
- For **Class I** products: 26th May 2025

For reusable products in which the UDI carrier must be applied to the product itself: two years after the specified date for the relevant product class.

Overview of medical device risk classes

Class III	Implantable pacemakers, pulse generators, HIV tests, automated external defibrillators, breast implants and contact lenses for long-term use.
Class II a/b	Acupuncture needles, daily contact lenses, electric wheelchairs, infusion pumps, surgical cover sheets and implantable high-frequency transponders for the acquisition of patient and health data.
Class I	Elastic bandages, examination gloves and hand-guided surgical instruments.

The classification of all medical devices can be found in Annex VIII and Annex XVI to the EU Directive 2017/745.

Only components that are properly labelled can be sold in the United States and Europe.

Since the FDA introduced its Medical Device Labelling guideline, the majority of all medical products, components, and devices imported into or sold in the United States have to be labelled with the UDI.

FDA – U.S. Food and Drug Administration

The FDA is the USA's food safety and drug administration. As such, it is subordinate to the American Department of Health. The FDA was founded in 1927 and is based in White Oak, Maryland. Its mission is to protect public health in the United States. The FDA controls the safety and efficacy of human and veterinary medicines, biological products, medical devices, food and radiation-emitting devices. This applies to products manufactured in the USA as well as imported products. All medicines approved in the USA must be manufactured by pharmaceutical manufacturers, which have been inspected by the FDA and whose manufacturing facilities comply with the regulations. The same applies to manufacturers of medical devices. As early as 2011, the American health authorities (FDA) adopted a regulatory requirement for unique product identification and labelling for medical devices, the so-called UDI rules (Unique Device Identification).

But it is not only in the USA that strict regulations apply. The high labelling standards are also implemented in the EU, Canada, Japan and many other countries.

The markings themselves must be durable and traceable, legible and clear, high-contrast, tamper-proof, resistant to sterilisation and cleaning procedures, hygienic and clean.

Counterfeit products: This is also an issue in medical technology

Product piracy is also a problem for medical technology. Product plagiarism and counterfeiting often undermine the high standards within the industry, as they are manufactured outside the legal controls or without the necessary expertise. Not only can they lead to a loss of sales, but also to a loss of consumer confidence in the brand. Above all, counterfeit or cheaply manufactured products can endanger the health of patients. In the worst case, counterfeits may even threaten the life of the user.

The manufacturer is responsible for the correct labelling of the goods and products and is therefore responsible for the implementation of the MDR (including the entry of all UDI-related data into the European medical device database EUDAMED).

Violations of these laws have serious consequences.

Manufacturers will no longer be able to deliver their products to all EU Member States if they fail to comply. this is because insurance carriers and healthcare providers will not accept products without appropriate labelling.

As a result, manufacturers must now become familiar with the precise legal requirements and ensure that they have a coding and marking system in place that meets the legal requirements in good time before the deadline.

Requirements pose major challenges for manufacturers

Medical technology components are often designed in such a way that labelling is extremely challenging: They are often very small and therefore there is very little space for marking. It should also be remembered that medical devices and parts undergo various surface treatments and a large proportion of them are sterilised repeatedly.

Nevertheless, the labelling must be applied in a high contrast and clearly visible way so that it can be recognised and read by both a scanner and by humans. And it must be particularly resistant and durable.

Stamp, label, ink jet or laser labelling?

Medical devices can be marked by various processes: Stamping, labelling, labelling by inkjet printer or labelling by laser are some of the possibilities.

The various methods have disadvantages: Stamps can easily smudge, labels fade over time, ink printing is vulnerable to chemicals and friction. Only laser technology offers key advantages when the labelling is exposed to strong mechanical loads or when it is a question of forgery or manipulation security.

> *Laser marking is clearly superior to other printing methods, as these often require the application of additional material to the tube and therefore additional validation processes.*

Andreas Hankel, Senior Sales Manager Medical Products at Novoplast Schlauchtechnik GmbH

The laser marking is permanent and cannot be removed or altered without being noticed.

Laser dots are also used wherever there is little space available for labelling, with extremely fine, yet super-sharp markings. During laser labelling and laser marking, the material is permanently changed. The laser coding is extremely resistant to abrasion, heat and acid and is very difficult to remove or modify. It offers consistently high quality and precision.

Even extremely small fonts and detailed graphics are clearly legible and sharp.

By the way, did you know that you can even label food by laser?

The "Smart labelling" process uses laser technology to mark the food with a logo and other information. The bundled light beam removes pigments from the outermost layer of the shell and burns the labelling into the fruit, so to speak. This "natural" labelling does not affect taste, quality or durability.

In addition, laser marking is a cost-effective and economical method because no consumables such as adhesive labels, stickers or films are required. Devices and systems for laser coding are generally robust and extremely low maintenance, so that usually only low service costs are incurred.

No wonder, then, that laser marking has become the dominant technology for **Direct Part Marking** of medical devices and components.

Direct Part Marking

Direct marking is the direct marking of a product without the use of type plates or labels. The process allows certain identification features to be applied to finished products, so that not only the final product but also the individual parts of the product can be traced over their lifetime. And they allow the separation of the product and the original packaging. The UDI code is not lost under any circumstances. Devices that need to be permanently labelled include, for example, pacemakers and surgical instruments. Here, the UDI code must be as durable as the device itself.

Laser Technology - A Wide Range of Possibilities

The laser technology offers many possibilities of marking. Laser marking is a non-contact optical method.

"LASER" is an acronym and stands for "light amplification by stimulated emission of radiation". Put simply: Light particles excited by current (photons) emit energy in the form of light. This light is bundled into a beam. This produces the laser beam.

All lasers consist of three components:

1. an external pump source
2. an active laser medium
3. a so-called resonator

The pump source supplies external energy to the laser.

The active laser medium is located inside the laser. Depending on the design, the laser medium may consist of a gas mixture (CO_2 laser), a crystal body (YAG laser) or glass fibres (fibre laser). When the laser medium is supplied with energy by the pump source, it emits energy in the form of radiation.

The active laser medium is located between two mirrors, the "resonator". One of these mirrors is semi-transparent. In the resonator, the radiation of the active laser medium is amplified. At the same time, only a certain type radiation can leave the resonator through the semi-transparent mirror.

This bundled radiation is laser radiation.

The most suitable laser system depends on the following factors:

- Surface to be labelled
- Type of labelling
- Marking field size
- Marking and production speed
- Required power

Process of laser labelling

The term laser labelling summarises various methods. The method used depends in particular on the material of the product or workpiece and the desired quality of the labelling.

Plastics can be marked with different laser types and in different ways.

There are basically three types of laser labelling for plastics:

Foaming

During foaming, the material is foamed and then solidifies. A "raised" mark is created. The marking result is always a little brighter than the colour of the base material, which makes it more suitable for darker materials.

Carbonisation

During carbonisation, colour pigments change due to the heating effect of the laser on the material. The process is more likely to be used with lighter or transparent plastics, as the marking result is relatively dark.

Engraving

Here, the laser melts the material from the plastic surface. It evaporates and produces a clearly noticeable indentation. The surface is effectively removed (engraved).

A change of colour occurs during both foaming and carbonisation.

By selectively destroying colour pigments, a bright colour change can also be achieved in dark plastics. In this process, the pigments contained in the plastic are deliberately destroyed and the corresponding areas become faded. The markings stand out in colour from the base material and are therefore easy to recognise.

The common laser types

Depending on which materials are to be marked, different laser types are used. These differ primarily in the laser sources they are used for and can be divided into two categories: **Gas and solid state lasers.**

When it comes to labelling, CO2 lasers (these are gas lasers) and **fibre and YAG lasers** (these are solid-state lasers) are usually used.

CO_2 laser	CO_2 lasers work with a **gas mixture** that is stimulated to produce the laser beam. They mark paper and cardboard, plastic, rubber, wood, anodised surfaces as well as glass and ceramics without any problems.
Fibre laser	Fibre lasers are solid-state lasers in which the doped core of a **glass fibre** is the laser medium. They are particularly suitable for marking harder materials such as stainless steel and plastic (ABS), but also fine films.
YAG laser	Solid-state lasers in which the laser-active medium is a **YAG crystal**. The diode-pumped lasers are efficient solutions for labelling materials such as plastic, foil, metal and ceramic with very easy to read and high-contrast results.

Which laser for which plastic?

All plastics can be engraved with a CO_2 laser. However, the contrast is not always optimal, as it is defined only by the shadow of the indentation created by the engraving. Greater contrast, on the other hand, is a produced with the change of colour caused by carbonising or foaming.

Solid-state lasers are normally used for a colour change on plastics. There are exceptions for PET and PVC: Here, CO_2 lasers also create a highly visible marking.

CO_2 or fibre lasers reach their limits in some plastics. In such cases, a fine, clear colour change is often produced with a YAG laser instead.

Fundamentally, we can say:

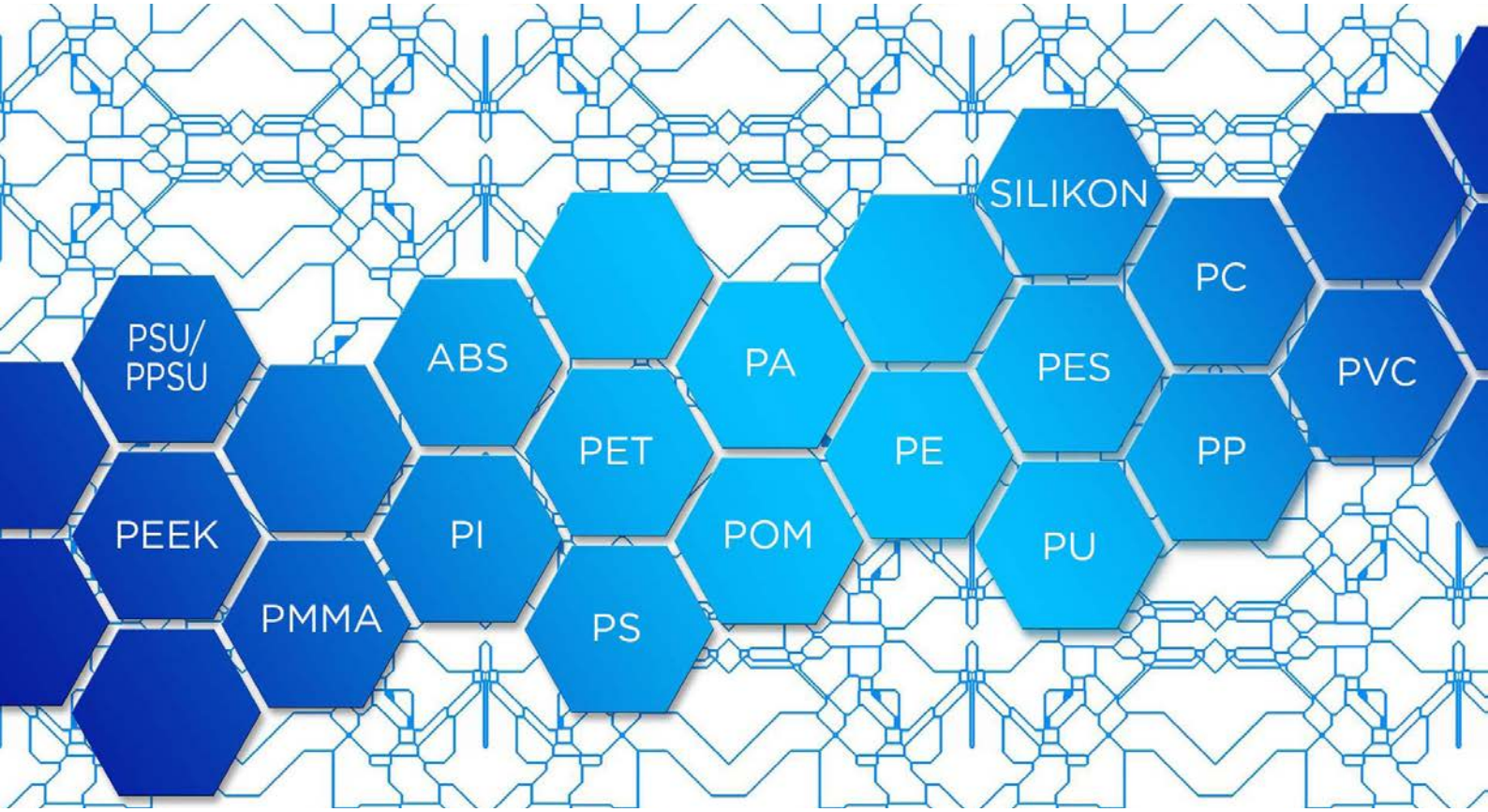
Harder materials – including plastics such as PE, PP, PVC, PS, PU/PUR, PET, polyester, silicone or ABS among others are suitable for labelling with **fibre lasers**.

Labelling lasers can mark virtually all plastics used in industry. These include, for example:

Plastics such as PE, PP, PVC, PS, PU/PUR, PET, rubber as well as thermosetting polymers (BR, NBR, IIR, EPDM, CR and IR) as well as silicones (MQ, VMQ, PVMQ, PMQ, FMQ, FVMQ) are suitable for marking with **CO_2 lasers**.

Plastics such as PE, PP, PVC, PS, PU/PUR , PET, polyester, silicone, ABS are used for marking with the **YAG laser**.

However, plastics often consist of multiple materials, which react differently when processed with a laser. Not only the raw material plays a role, but also individual colour pigments or other mixed components contained in the material, e.g. additives, fillers or protective substances influence the laser result.

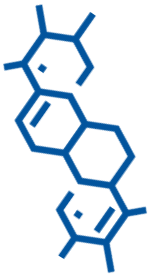


Colour-control with additives and pigments

Most plastics can be labelled very well with the laser, some however are only possible with the addition of certain additives or pigments, with which plastics are effectively "laser-optimised".

Additives and pigments change the absorption behaviour of the material, so that a colour change is possible. Only if the material absorbs enough laser light, i.e. absorbs it and does not reflect, is a clearly visible marking produced.

As a rule, a **dye concentrate (masterbatch)** is used or the effect is achieved by **using an already optimised plastic (compound).**



Additives and pigments in plastics increase the contour sharpness and contrast and thus the readability of the labelling. With transparent and semi-transparent materials, these additives result in a more even contrast distribution.

The addition of additives and pigments also enables a wider range of product colours and is crucial for the labelling of some materials. This is because the pigments in the base material contain metal ions. The laser beams change the crystal structure of the ions, as well as the amount of water in the crystal. As a result, the chemical composition of the element itself changes, so that colour is produced as a result of the greater intensity of the pigment.

Good labelling results without additives	ABS, PC, PPSU, PBT, PBTP, styrene (SAN), PEEK, UREA
Acceptable labelling results without additives, but good labelling results with laser additive (colour-dependent behaviour)	PS, PI, PETP, POM, PPS, ASA
	PES, PEI, PES, PE, PA, PVC, TPE
Not possible to label or only with special additives	Polyester, PU, polyolefins, (PEHD, PP), PMMA, PTFE

Source: TRUMPF

Advantages of laser labelling

Laser marking has numerous advantages over conventional marking methods, which are based on either colour, chemical reactions or mechanical pressure:

- Flexible in terms of the geometry of the label
- High quality of labelling (very sharp edges)
- High reproducibility
- No tool wear due to non-contact processing
- Heat input has little influence on the material
- Easy integration into fully automatic production processes
- Pre- and post-work is not necessary
- Wide range of laser-capable materials (ceramics, metals, plastics, etc.)
- Fine structures and small markings are possible
- Processing of large surfaces is possible

> *The information is wipe- and scratch-resistant, long-lasting, scalable and can be automated.*

Ismail Dogru, Key Account Consultant Medical Products at FLEIMA-PLASTIC GmbH

- Hard to reach places
- High marking speed
- No need for expensive, potentially environmentally harmful consumables such as ink
- Environmentally friendly and waste-free

(According to TRUMPF)

Limits of laser labelling

In order to achieve an optimal result in laser labelling, the plastic type, process and laser type must be perfectly matched. Otherwise, for example, the marking may be difficult to read. Therefore, each application must be considered and analysed individually.

It becomes difficult if the colour change during laser marking is not sufficient, but laser additives must not be added and the material composition cannot be changed. This is usually the case for approved products, where a change would have far-reaching effects in risk assessment and biocompatibility studies.

For defined material specifications, it is therefore only possible to proceed on a "best efforts" basis.

Our experts can often assess the possibilities and limits of laser marking very well in advance and identify alternative approaches.

Conclusion

The laser marking process is generally suitable for all types of plastic.

However, in order to achieve the highest possible readability and labelling quality, it is necessary to add laser-sensitive additives for some types of plastics. The properties of the plastics are largely retained.

Laser marking is one of the most durable and reliable marking types - for small series applications with variable data as well as for large series production.

When labelling with bundled light, the necessary information is burned into the surface of the product with a laser beam. The laser beam is so finely adjustable that it produces precisely as much penetration depth and width as is necessary for clear reading of the information.

The non-contact laser marking process guarantees high-quality, smallest and highly precise markings for almost all materials. With appropriate machines, virtually all products and all materials can be reliably marked by laser labelling.

The marking contents can be read (also electronically) even after heavy use and after hundreds of cleaning processes.

This means that medical instruments and components can be clearly traced and assigned.

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Your path to perfect laser marking begins with us!

We will support you with the technology of laser marking in meeting the high requirements with regard to the clear identification, traceability and protection against counterfeit products in medical technology.

Laser marking: flexible, gentle, high quality and long-lasting

Laser marking allows a flexible (text) design (e.g. of serial numbers or data matrix codes according to UDI). Graduations, depth marks, text or logos are also possible.

Almost all media types can be marked.

We do not subcontract laser marking to an external company, quite the opposite: The laser marking is carried out on site with a labelling laser from TRUMPF as a downstream process.

A secondary processing step is no longer necessary.

The laser easily adapts to the relevant conditions and requirements, regardless of which type of marking is to be made, which parts are to be labelled or how many parts need to be marked.

Do you have questions or want to learn more about our products and services?

We look forward to talking to you!

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Our speciality: Plastic components for medical technology

Plastics have always inspired medical technology. As versatile as plastic itself - products can be diverse and individual.

We develop and manufacture high-quality hoses, connectors and applications as well as customer-specific assemblies for demanding applications in medical technology. Our components are used in the fields of infusion, dialysis, endoscopy, enteral nutrition, but also in hearing aids.

For many years, we have successfully combined the two production techniques of extrusion and injection moulding in demanding medical technology projects and thus offer creative solutions from a single source. More and more often, we are also development partners and accompany medical devices from the idea to the finished product.

In Halberstadt, polymer materials are processed into medical tubes in clean rooms of ISO classes 6 to 8 by extrusion, while in Wald-Michelbach suitable connecting parts such as terminals, adapters, connectors or protective caps are manufactured using injection moulding.

On request, we can combine the individual components into custom-tailored and precisely-fitting assemblies – for example by bonding (with solvent adhesives or UV adhesives) or by ultrasonic welding.

We offer all assembly steps in the clean room according to ISO 14644-1 ISO Class 7 according to the purity and quality requirements of the relevant product. We can draw on broad and deep expertise in terms of materials, manufacturing techniques and industry requirements.

Our products are “Made in Germany”.

In addition to the legal framework according to DIN EN ISO 13485:2016, we also meet the requirements of the EU Medical Device Regulation (MDR).

Novoplast Schlauchtechnik and Fleima-Plastic are part of the Masterflex Group.

www.schlauchtechnik.de

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