

- Le Marquage UDI et le 'Black Marking'

- UDI Marking and 'Black Marking'



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TRUMPF



e·micronora

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TRUMPF Business areas:

Machines outils pour le travail de la tôle



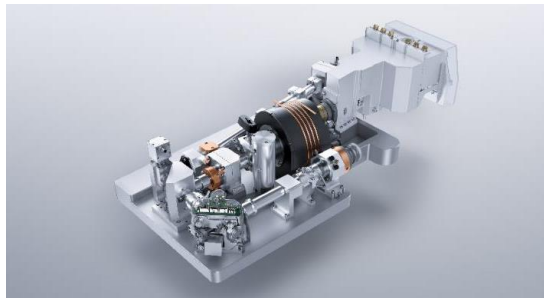
Découpe laser

Poinçonnage

Pliage

Soudage laser

Technologie laser



CO2 and solid state lasers

Systèmes laser

Marquage

RF générateurs pour applications industrielles

Nouveaux domaines d'activité



High power laser systems for EUV lithography

Fabrication additive

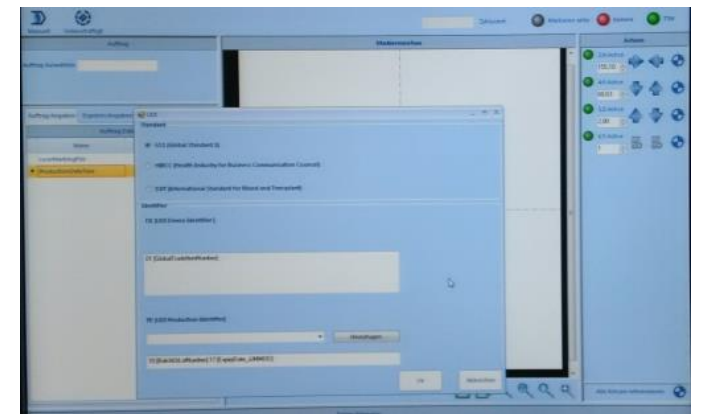
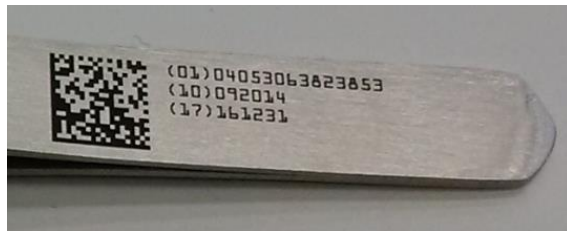
Laser diodes for photonics and digital products

European Standardization for medical traceability

- FDA-Regulation Unique Device Identification (UDI) for traceability

What is **U**nique **D**evice **I**dentification?

- Medical devices has to be marked durable
- Traceability is compulsory throughout the whole production and supply chain for the whole Lifecycle – latest until 2020
- All relevant information has to be implemented in the code (producer, production date, date of expiry, charge number, serial number, ...) free available in online data base
- Code can produced by three Standards (GS1, HIBC, ISBT 128)
- Marking must be machine and human readable



European Standardization for medical traceability

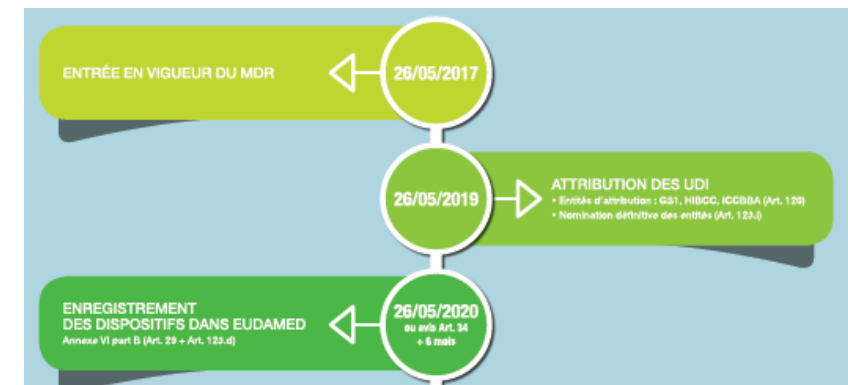
- Standard EN-13485:2016

Medical devices –
Quality management systems –
Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009);
German version EN ISO 13485:2012 + AC:2012

EN ISO 13485

ISO 13485:2016 sets out the requirements for the quality management system when an organization must demonstrate its ability to regularly provide medical devices and associated services that meet customer requirements and applicable regulatory requirements.

- Evolution of the regulation
- Already done



-Source : snitem

European Standardization for medical traceability

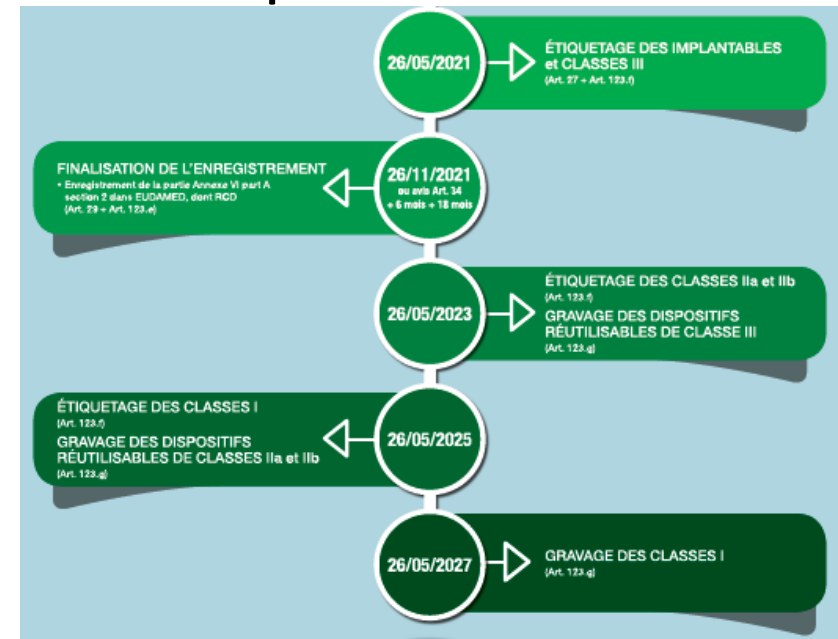
- Standard EN-13485:2016

EN ISO 13485

Medical devices –
Quality management systems –
Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009);
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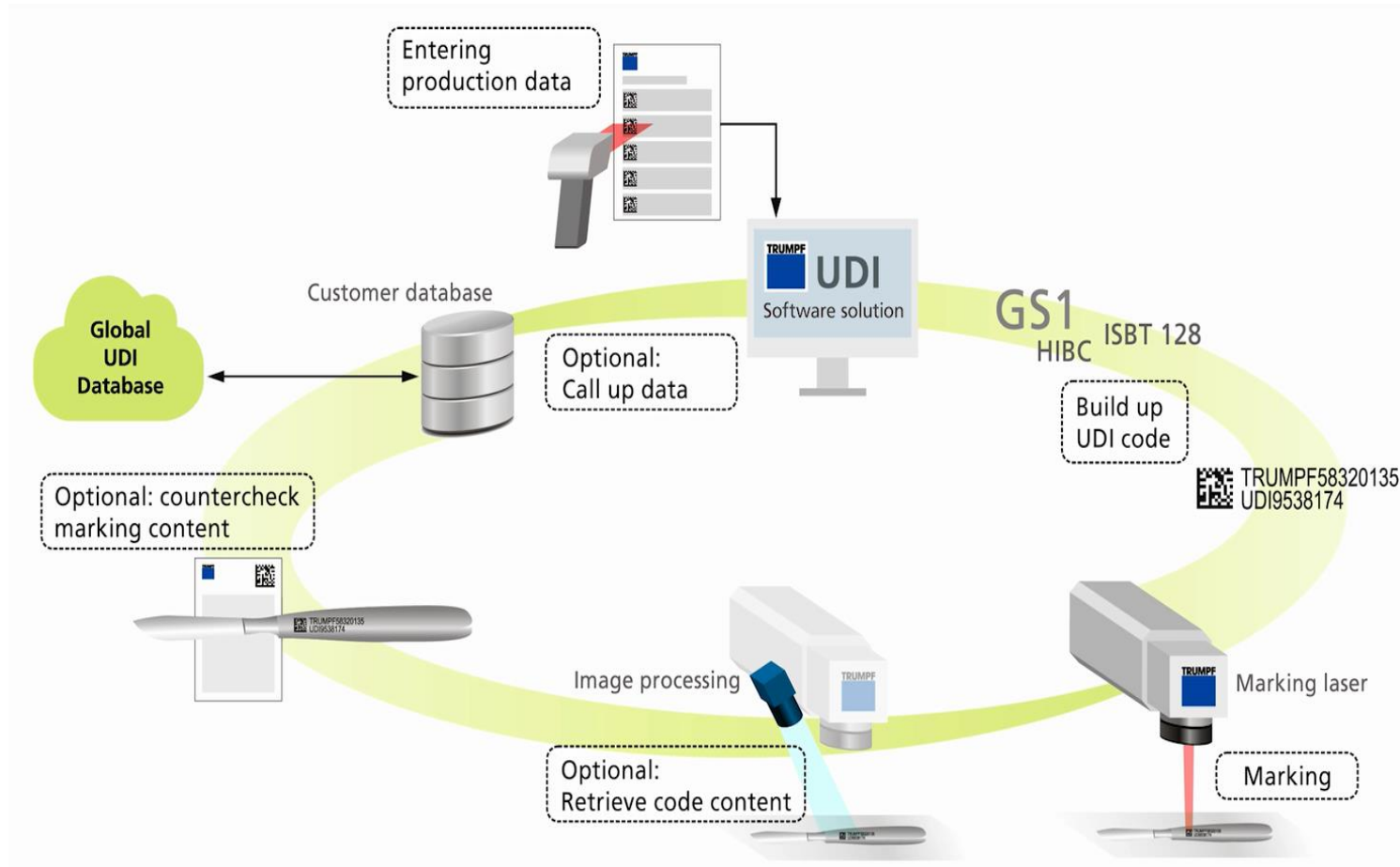
- Evolution of the regulation

- Next steps

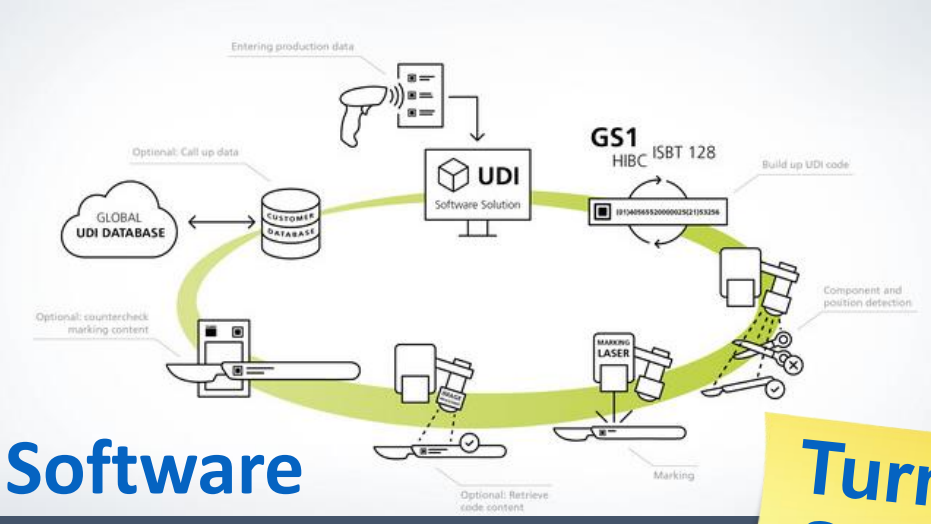


- Source : snitem

corrosion-resistant UDI marking solution



TruMark Port-Folio



Software

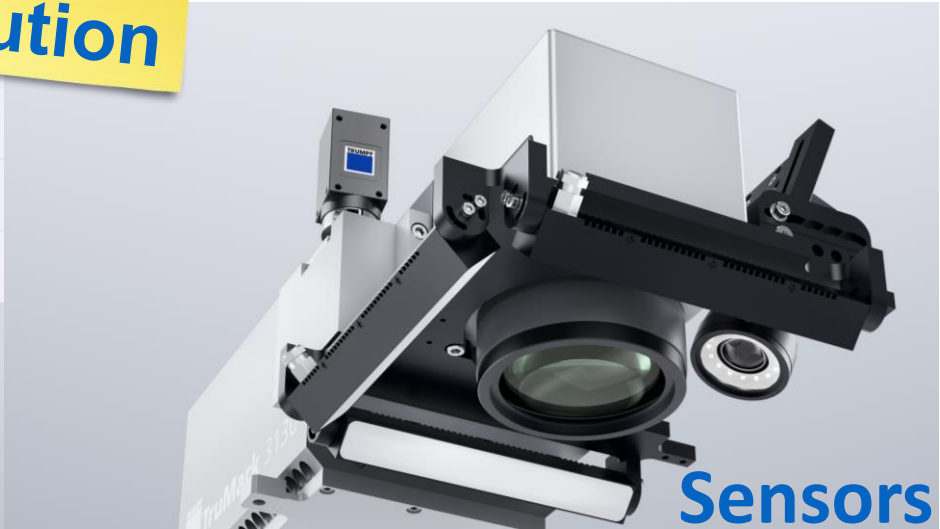


Laser

Turn-key
Solution



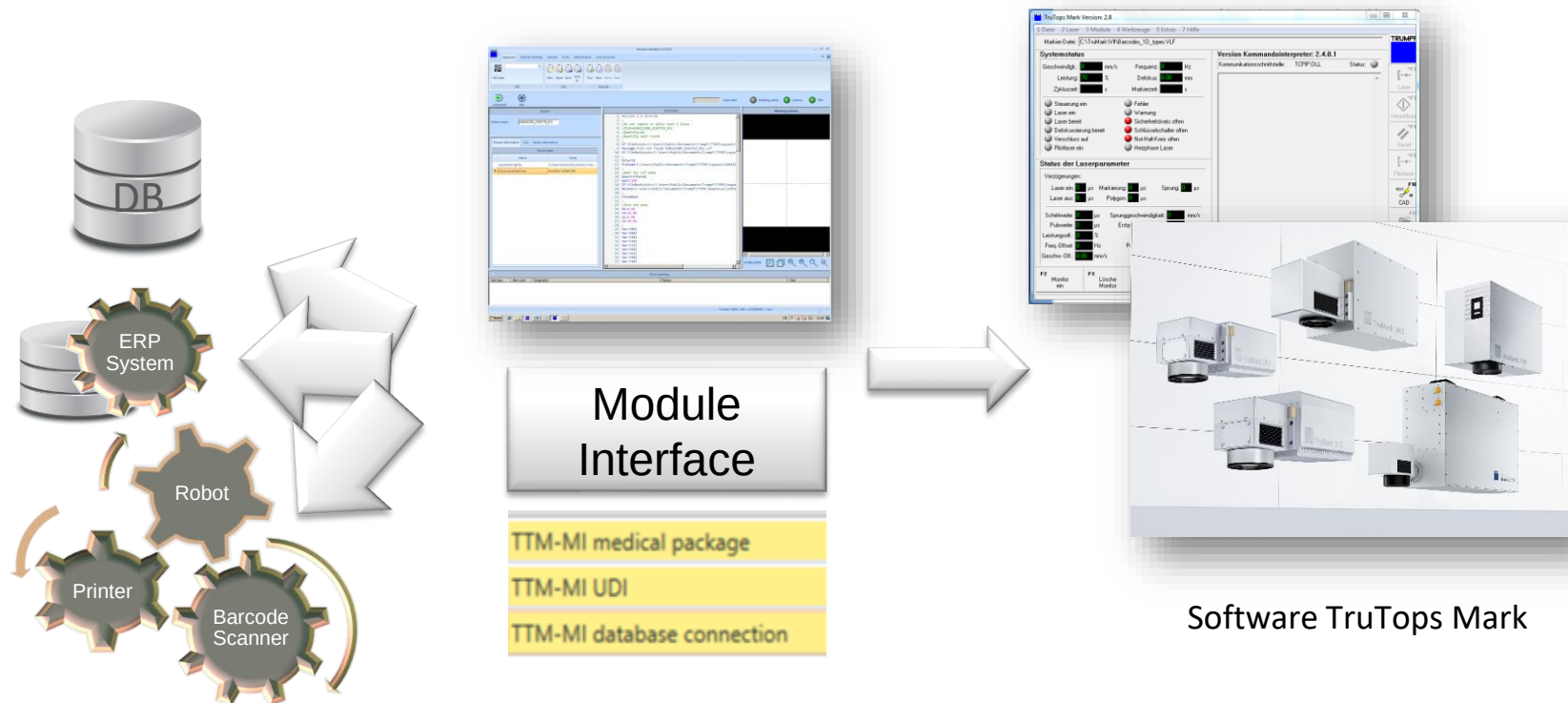
Stations



Sensors

1. Software

TTM-MI Module : TRUMPF Software solution



2. Lasers

TruMark Portfolio – Marking Laser OEM

**TruMark
Series 1000**

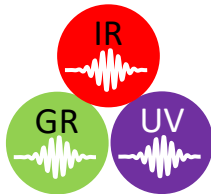


DPSS

Nd:YO₄

TruMark 1110

**TruMark
Series 3000**

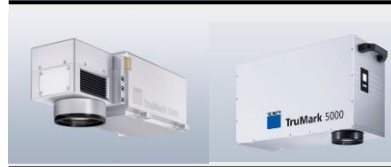


DPSS

Nd:YAG, Nd:YO₄

TruMark 3020
3130, 3230, 3330

**TruMark
Series 5000**



Fiber

Yb:Fiber

TruMark 5020, 5040,
5050, 5070

TruMark 5010

**TruMark
Series 6000**



DPSS

Nd:YAG, Nd:YVO₄

TruMark 6030 (L026),
6020, 6130, 6350

**TruMicro Mark
Series 2000**



Fiber

UKP

TruMicro Mark 2020,
2030

**TruMark
Series 7000**



Fiber

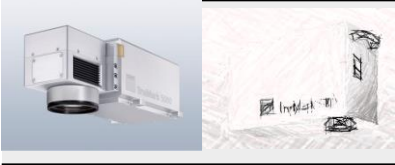
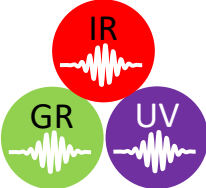
Yb:Fiber

TruMark 7010, 7050

- For every application there is the right wavelength, power class and pulse duration

2. Lasers

TruMark Portfolio – Marking Laser dedicated for medical application

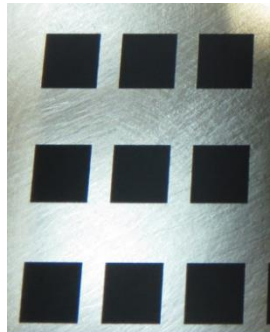
TruMark Series 1000	TruMark Series 3000	TruMark Series 5000	TruMark Series 6000	TruMicro Mark Series 2000	TruMark Series 7000
					
					
					
DPSS Nd:YO ₄	DPSS Nd:YAG, Nd:YO ₄	Fiber Yb:Fiber	DPSS Nd:YAG, Nd:YVO ₄	Fiber Ultra-Short Pulse	Fiber Yb:Fiber
	2D - Marking	2D - Marking	3D - Marking	2D - Marking	
	Stainless Steel Co-Cr – Ti PEHD – POM –PEEK..	Stainless Steel Co-Cr – Ti PEHD – POM –PEEK..	Stainless Steel Co-Cr – Ti PEHD – POM –PEEK..	Stainless Steel Co-Cr – Ti PEHD – POM –PEEK..	

- The right laser, for the right medical application

2. Lasers

TruMark Portfolio – Marking Laser dedicated for Black Marking: TruMicro Mark 2020

- From nano-second to pico-femto second laser to improve black marking quality and durability



- Highest corrosion resistance
- Highest contrast
- Possible without passivation

3. Working stations

TruMark laser protection class 1 – for safe laser marking



4. Sensors

Traceability and safe marking processes

- Presentation



1 Modular Construction

Optimally adaptable to your specific needs

2 Integrated solution

Compact solution for affordable standard solution

3 intuitive operation

Systematic user guidance by the individual work steps

4. Sensors

Reading back from surface

- Customized grading - qualitative assessment of the marking results (1D / 2D) regarding marking content and marking quality for better traceability and documentation

 1 234567 891231	1D Code	 (01)5102222233336 (11)141231(17)150707 (10)A213B1(21)1234	Exemple : Code UDI selon GS1
	2D Codes	{ (01)5102222233336: GTIN (11)141231: Production date (17)150707: Expiration date (10)A213B1: Numéro de Batch/LOT (21)1234: Numéro de série	
	DM Code		
	QR-Code		
		 (01)5102222233336(11)141231(17)150707(10)A213B1(21)1234	



4. Sensors

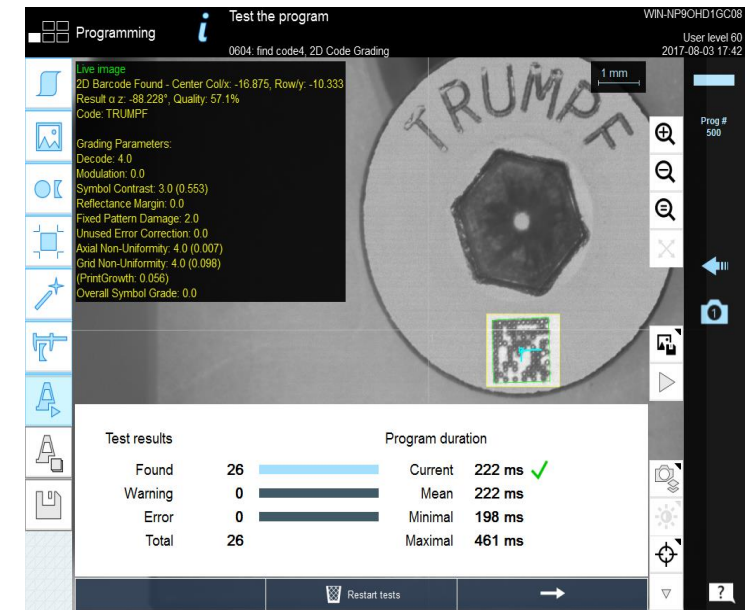
Presence control & Repositioning

- Presence detection of parts and optical repositioning of marking on parts of different dimensions
- Versatile system suitable for different customer configurations combining external camera vision with laser and/or lens vision.



Available modules

- ✓ Adjust
- ✓ Detect
- ✓ Trace
- ✓ Trace Pro



4. Sensors- Auto-Focus Sensor

- The Autofocus Sensor guarantees accurate control of working distance between the laser and the marking part to ensure :
- Same marking quality
- Same marking size and positioning



TRUMPF, Turn-key complete packages on medical applications

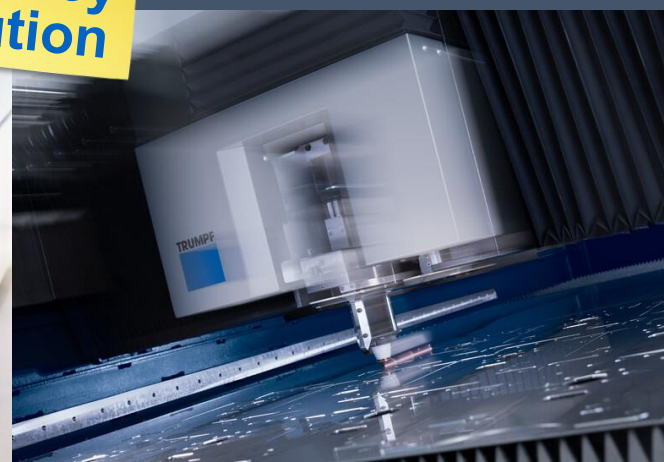
Marking laser



Laser Welding



**Turn-key
Solution**



Additive Manufacturing

Laser Cutting



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