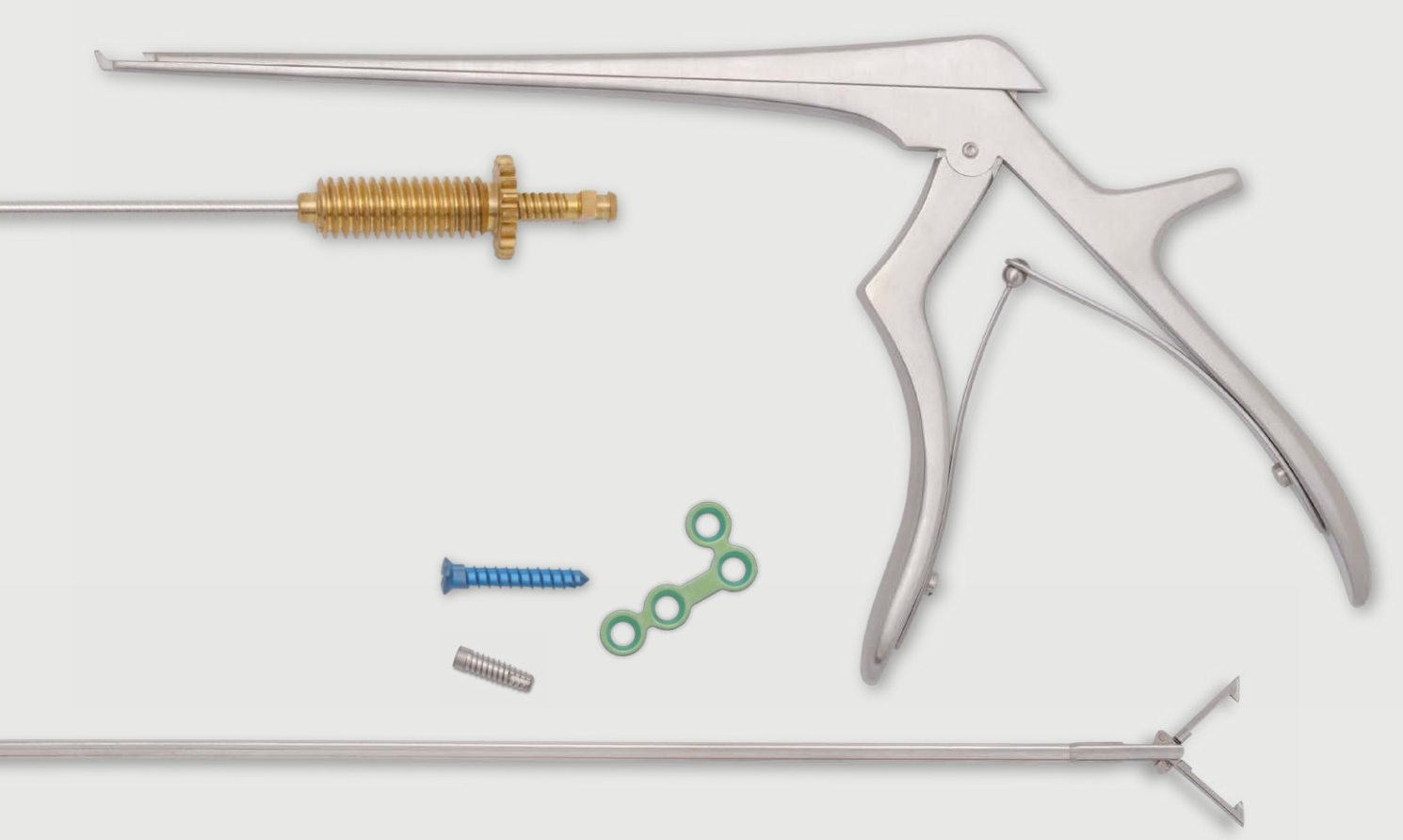
Highest cleanliness requirements.
Validated processes.

Ultrasonic cleaning in medical technology



www.elma-ultrasonic.com

Elma ultrasonic cleaning systems are equipped with modern systems technology for demanding cleaning tasks, highest cleanliness requirements and are therefore also ready for integration into valdiated processes.

Since process requirements vary greatly, a tailor-cut cleaning process with process guarantee can be developed in the Elma process laboratory. This process is then transferred in system technology including suitable product carriers and complementary Elma MedTech Clean cleaning and passivation agents. Elma's certification to DIN EN ISO 13485 reflects our high quality standards in process development and system manufacture.

Project-accompanying documentation - from detailed specifications to IQ and OQ documents - completes our range of services.

Used for	Pre-, intermediate and final cleaning • Passivation • Final cleaning with connection to clean rooms before sterile packaging
Cleans	Implants and instruments - conventionally manufactured or 3-D-printed, made of metal, plastic or ceramic • Endoscopes • mechanical and optical components • contact lenses • Components for medical devices such as computer tomographs
Equipped with	Reproducible and energy-efficient processes • Complementary, application-specific cleaning and passivation agents • Modular product carrier systems for gentle product transport • Modern cleaning bath monitoring and care systems

Validation and service support

Creation of project accompanying documents like

- functional, hardware and software design specifications,
- installation qualification IQ,
- operational qualification OQ, etc.

in addition to technical documentation and calibration and welding certificates

Support in validation and revalidation of the cleaning process

User-friendly system visualisation and quality assurance through

- data logger
- error prevention with barcode and RFID systems
- connection to ERP and MES systems
- user adminstration and audit trail according to FDA CFR 21, Part 11

Ensuring the system function by

- short reaction times
- regular maintenance
- customised spart part packages

as well as by

- cavitation measurements acc. to IEC TS 63001:2019

Acceptance criteria

Over 20 years of experience in process-safe compliance with specific cleanliness requirements, such as

In-vitro cytotoxicity test
acc. to DIN EN ISO 10993-5

Bioburden determination
acc. to DIN EN ISO 11737-1

Endotoxins
acc. to LAL test USP 85

Compliance with the limit values for filmic contamination - organic and inorganic

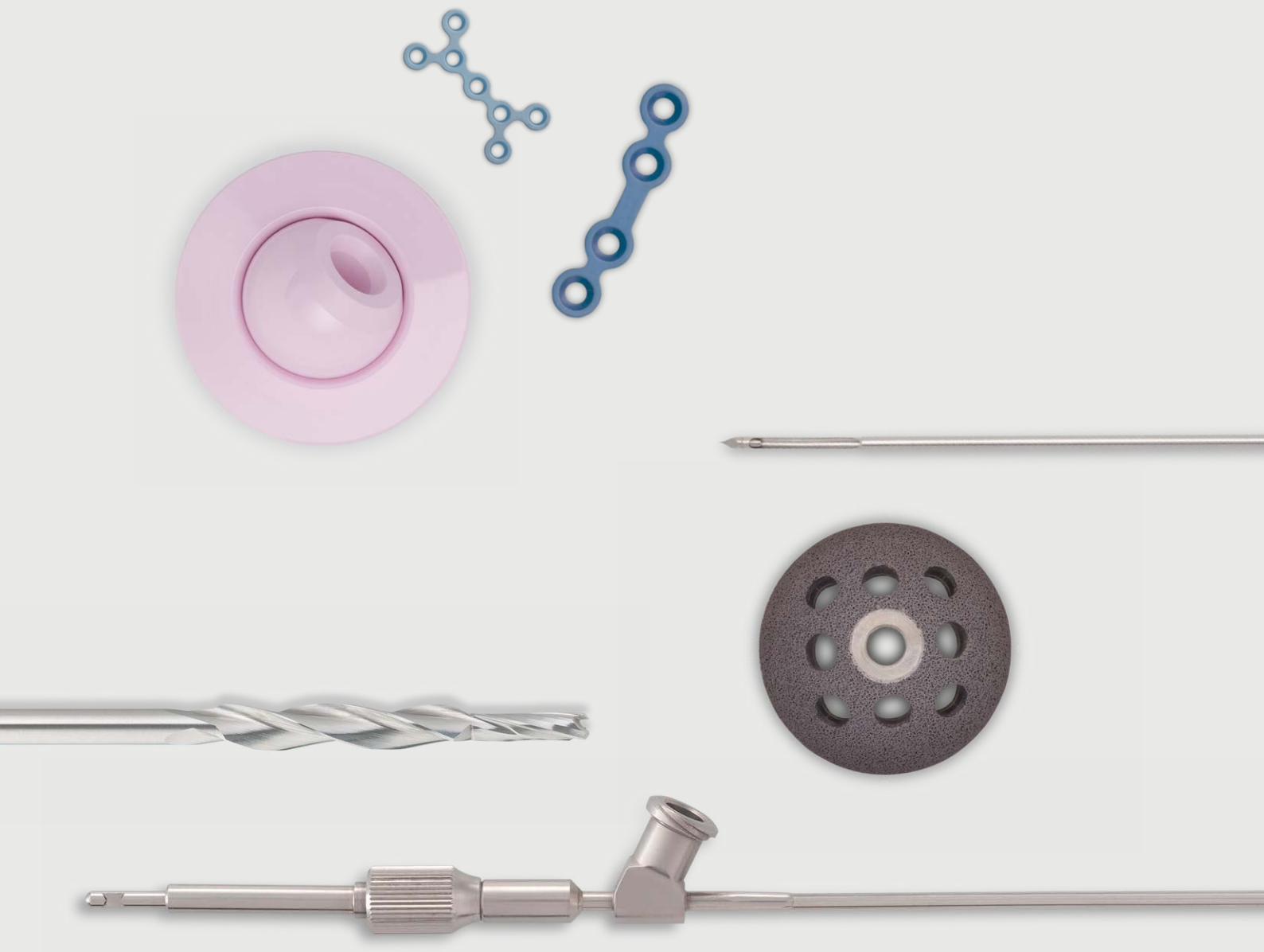
- e. g. of Total Organic Carbon - TOC acc. to DIN EN 1484
- or Total Hydrocarbon - THC acc. to DIN EN 14039

Achievement fo particulate cleanliness

e. g. acc. to DIN ISO SCP Klassen ISO 14644-9 or VDI guideline 2083 sheet 21

Implementation and testing of the passivity of stainless steel surfaces

e. g. acc. to ASTM A0967



Elma Schmidbauer GmbH
Gottlieb-Daimler-Str. 17
78224 Singen (Germany)

www.elma-ultrasonic.com

Subject to technical and optical changes.
Medical Technology_EN_09_20

*Medical Products Class 1 according to MDR (EU) 2017/745. Please observe the laws and legal regulations applicable in your country.