

INDUSTRY

Medical Technology

Components for implants and medical technology are subject to special requirements in terms of manufacturing processes, process monitoring and quality assurance. BEUTTER has decades of experience with these highly sensitive products.

■ We manufacture components for medical devices and implants.

Osteosynthesis and endoprosthesis

Active implants

Artificial hearts

Cardiac support systems

Incontinence valves

Port systems

Surgical instruments

■ We machine all machinable materials.

We are particularly familiar with high-alloy steels, titanium and special materials. In medical technology, these include for example:

Implant alloys 1.4441, CoCr28Mo6, Rex 734

Titanium to ASTM-F 67, ASTM-F 136, DIN ISO 5832

Pt-Ir as well as precious and pure metals

Implantable plastics to ISO 10993, PEEK

■ We document the entire manufacturing process.

This includes unbroken traceability from the raw material to the finished product, as well as process validation. Our quality management certificate DIN EN ISO 13485 covers implants up to risk class III.

■ Fine machining, cleaning and cleanroom in-house.

We use blasting systems for the fine machining of surfaces that are reserved exclusively for medical components. Various washing systems ensure product cleanliness and low particle counts in preparation for physical or chemical product sterilisation and sterile packaging. A cleanroom to DIN EN ISO 14644 class 7 is available for inspection, assembly and packaging tasks.

■ We manufacture to customer drawings and take part in development.

Together with medical technology companies and end users, we provide support through prototype production and contribute our manufacturing experience to series design. We are a member of associations and working groups dealing with medical technology topics.

CERTIFICATIONS

DIN EN ISO 13485

Medical devices, risk class III

DIN EN ISO 9001

Quality management

DIN EN ISO 14644 cl. 7

Cleanroom