

MEDICAL TECHNOLOGY PRODUCTION



seleon can produce special systems, prototypes, zero and primary series, small series or even larger quantities. We have the expertise, the infrastructure required and the high-performance quality management needed to manufacture your product in a short space of time in the quality you expect. We can manufacture your products, if you wish, so that they are packaged and ready for sale and use a testing protocol specified by you.

We will sign a quality assurance agreement with you in advance. The production process will be documented throughout every step using a Device History Record (DHR), so that traceability is guaranteed at all times.

Final checks, packaging, logistics as well as technical service and support with product care also feature on our extensive spectrum of services.

rock solid
medical
engineering.

SUPPLY CHAIN MANAGEMENT

Maintenance of the article master and the parts lists | Drawing up of required production and testing documentation | Development and construction of production and testing materials | Strategic purchasing, goods inwards checks, warehousing and management of the supplier network | On-demand production of individual items, small, medium and major series (up to around 5,000 products/year) | Series management | Takeover of support and technical service | Worldwide shipping

OUR SPECIALITY

Production of reverse-engineering, redevelopments and new developments, taking account of:

series compatibility | inadequate documentation | component discontinuation or change of supplier | changed requirements resulting from legislation or standards and also optimisation of the 'design to cost' ratio

PROFESSIONAL EXPERTISE

Quality testing at parts level, parts picking, assembly, calibration, testing, batch management, documentation / DHR, logistics, supplier management, production planning, variant management, service processes

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REFERENCES

- » Siemens AG Healthcare Sector, CT division
- » CareFusion Germany 234 GmbH
- » GSI – Helmholtzzentrum für Schwerionenforschung GmbH
- » TNI medical AG
- » Naviscan PET Systems
- » Schwarzer GmbH
- » F. Stephan GmbH
- » Quantel Derma GmbH



EN ISO 9001:2008

EN ISO 13485:2007 (QM systems for medical products)

CFR 820 (FDA Quality System Regulation)

93/42/EEC, Appendix II (EU Medical Devices Directive)

Observance of Good Manufacturing Practice (GMP) guidelines

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OUR EXPERIENCE – YOUR PROFIT

We have outstanding experience in respirator technology for intensive care medicine, home-based care and laser technology. Since the company was first founded in 1998, seleon gmbh has worked as a production and logistics service provider all over the world for major and SME-sector medical technology firms.

