Life Sciences & Medical

Engineered sealing solutions
for Life Sciences & Medical applications

ceetak SEALING SOLUTIONS

The Life Sciences and Medical industry is one of the most demanding and stringently regulated. Supplying seals into critical devices and equipment means we have to meet the strictest demands in product integrity and meet the highest specifications of hygiene and cleanliness in production conditions.

Extensive product range suitable for all application conditions.

Cleanroom Class 7 (10,000) and Class 8 (100,000) manufacturing, inspection, cleaning and packaging.

Broad material range compliant with FDA, USP Class VI, ISO 10993, UHP, BAM & BfR standards.

Complete seal design service from experienced application engineers.

Product overview

O-Rings

Standard size ranges include; AS568, DIN 3771, ISO 3601 and JIS B2401. Customer sizes available on request.

Moulded Seals & Gaskets

Available in virtually any range of shape and cross section. We design and manufacture engineered elastomeric shapes, both homogenous and inserted, for sealing systems and isolation applications.

Precision Elastomer Seals

Bio-compatible precision-elastomeric medical components manufactured in USP Class VI and ISO 10993 compliant materials.

PTFE Seals

Our full line of spring-energised PTFE lip seals are used in rod, piston, face and rotary sealing applications.

2-Shot mouldings

Allows integration of several functional aspects to give cost, ease of assembly and product reliability advantages. Material combinations are optimised to meet application demands.

Composite Seals

Rubber-to-metal or rubber-to-plastic custom engineered sealing solutions allow for the integration of multiple components with unique sealing geometries.

Diagnostics

Supporting patients with accurate results for the safe management of health conditions is vital. Diagnostic devices and systems are now developed with accuracy and speed of response to enable targeted analysis and therapy. We support your engineers with efficient design and project management of optimised sealing components for both clinical and patient self diagnosis. Examples include seals for In-vitro devices, analytical laboratory equipment, x-ray, and CT's/MRI's.

Patient Management

Repeatable and reliable control of equipment for patient care is paramount. Typical demands include; optimised working friction and wear life, critical features function & tolerance control and gas, liquid or solid media management at accurate rates.
Our seals are manufactured according to FDA, BfR, BAM, USP Class VI and ISO10993. Examples include seals for ventilators, anaesthesia pumps, respiratory therapy, monitoring equipment, minimally invasive surgery equipment and metered dose aerosols (such as inhalers).

Biotech & Pharmaceutical

With continued development of complex and expensive drugs and research control media, the demand for high performance interactive components within the biotechnology process industry is crucial. We provide support on recommending Ultra High Purity (UHP) compounds for application working extremes combined with sensitive media, and seal design recommendations for dead space and entrapment elimination within applications. Examples include seals for analytical equipment, pumps, valves & actuators, monitoring & control equipment, storage equipment & vessels.

Specialist materials

Regulatory control	Definition	Nitrile/Hydrogenated Nitrile (NBR/HNBR)	Ethylene Propylene (EPDM)	Fluorocarbon (FKM)
		Good mechanical properties and wear resistance. Temp range -40°C to 120°C -35°C to 150°C (HNBR)	Good ozone, water and radiation resistance. Organic and polar solvent resistant. Temp range -50°C to 120°C	Good high temperature & chemical resistance, Suitable for aromatic hydrocarbons, vacuum & ozone. Temp range -25°C to 200°C
USP VI	United States Pharmacopeia		✓	✓
FDA	Food & Drug Administration	✓	✓	✓
UHP	Ultra High Purity			✓
BAM	German Federal Ins. for Material Research & Testing			✓
BfR	German Federal Ins. for Risk Assessment		✓	
ISO10993-1	International Standards Organisation		✓	✓

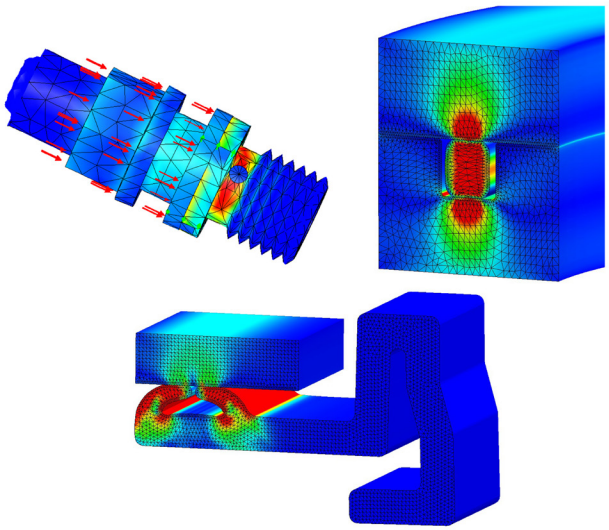
Regulatory control	Definition	Perfluoroelastomers (FFKM)	Silicone (MVQ)	Thermoplastic Elastomers (TPE)
		Excellent chemical & high temperature resistance. Suitable for steam, low weight vacuum loss. Temp range -10°C to 320°C	Heat age resistant, low temperature, ozone, weather and toxicologically stable. Temp range -50°C to 230°C	Good ozone, weather and mechanical properties, good co-polymerisation. Temp range -40°C to 100°C
USP VI	United States Pharmacopeia	✓	✓	✓
FDA	Food & Drug Administration	✓	✓	✓
UHP	Ultra High Purity	✓	✓	
BAM	German Federal Ins. for Material Research & Testing			
BfR	German Federal Ins. for Risk Assessment		✓	
ISO10993-1	International Standards Organisation		✓	✓

Regulatory control	Definition	Polyurethane (TPU)	Polytetrafluorethylene (TFE/PTFE)	Polyetheretherketone (PEEK)
		Excellent tear and wear resistant properties. Oxygen and ozone resistance. Aliphatic hydrocarbon resistant. Temp range -45° to 120°C	Excellent chemical resistance, low friction and wide temperature range. Creep strength (with fillers). Temp range -269°C to 320°C	Excellent temperature, chemical and pressure resistance. Low friction, dimensional stability. Temp range -120°C to 250°C
USP VI	United States Pharmacopeia	✓	✓	✓
FDA	Food & Drug Administration	✓	✓	✓
UHP	Ultra High Purity			
BAM	German Federal Ins. for Material Research & Testing	✓		
BfR	German Federal Ins. for Risk Assessment			
ISO10993-1	International Standards Organisation			

Design & Development

Unrivalled technical and engineering support means our customers benefit from the best possible seal performance at optimum cost.

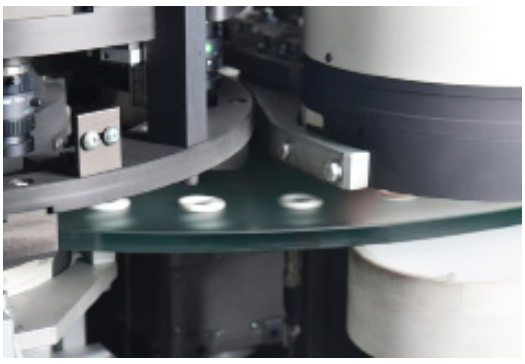
- Experienced application engineers support every project; from concept to approval ✓
- Complete seal design service ✓
- Seal geometry and profile choice ✓
- Material selection and development ✓
- 3D CAD modelling and FEA Simulation ✓
- 3D printing for concept testing ✓
- Prototyping through to final production ✓
- Online Technical Hub and interactive tools ✓



Quality Assurance

Strict quality procedures at all stages of our design, development and manufacturing processes.

- We are ISO9001:2015, ISO13485:2016 and ISO14001:2015 approved ✓
- Manufacturing approved to IATF16949:2016 & AS9100 ✓
- ISO14644 accredited cleanroom production ✓
- Worldwide network of global manufacturing facilities ✓
- Advanced product quality planning ✓
- Proactive and preventative expertise ✓



Cleanroom Capabilities

Production step	FS209E	ISO14644
	Cleanroom Class	
Vulcanisation	100 000	8
Deflashing	100 000	8
Washing and Cleaning	10 000	7
Inspection	10 000	7
Packaging & special inspection	10 000	7

We have a complete ISO 13485 accredited cleanroom production process. From material blank production through to inspection and packaging, using controlled materials within state of the art cleanrooms.

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