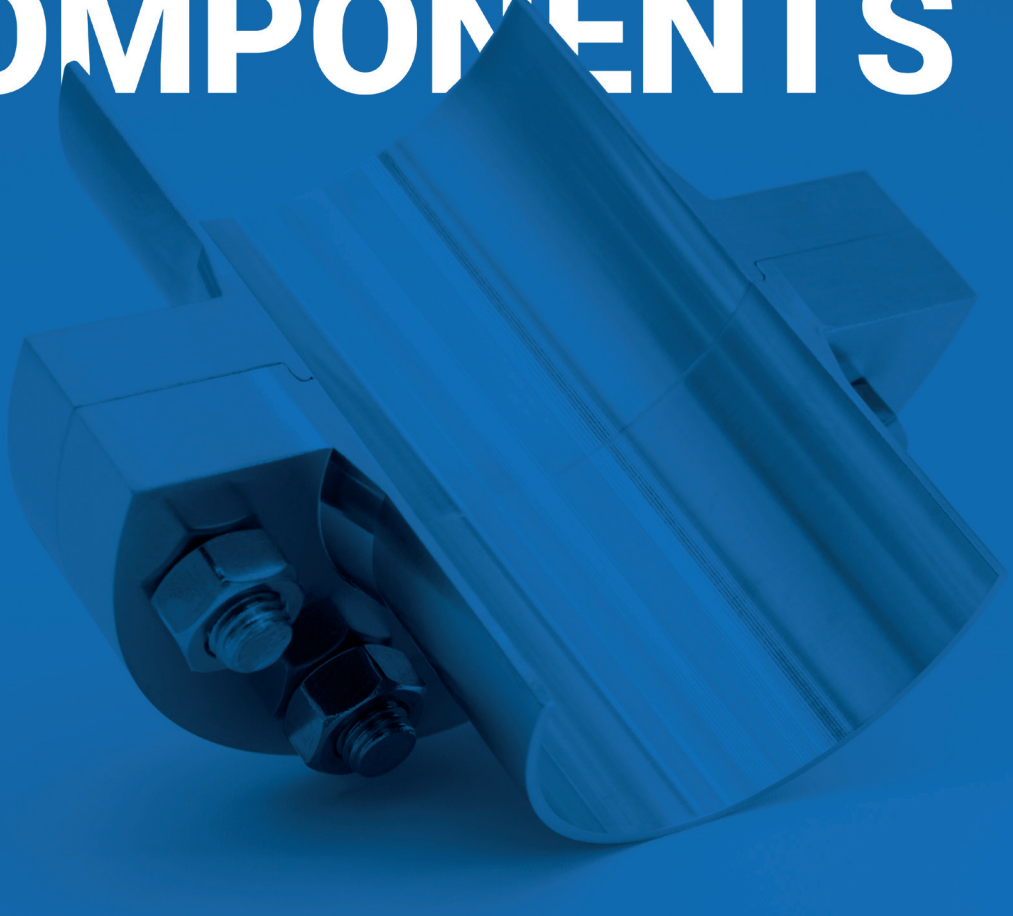
NEUMO

ELASTOMERFREE COMPONENTS



NEUMO
NEUMO Ehrenberg Group

OUR ELASTOMER-FREE PORTFOLIO

Elastomers have provided reliable sealing for decades, but their time is, in a sense, running out. Not only do elastomers have a limited service life, but they are increasingly reaching their limits due to aggressive media, high temperatures and demanding cleaning cycles. In addition, fluorinated sealing materials are coming under pressure from several directions: the upcoming PFAS restrictions at EU level, the tightened requirements in Annex 1 of the EU GMP guidelines, and the specifications of the German TA Luft 2021 for contamination control. What is still standard practice today may lead to problems in plant approval or during regulatory inspections tomorrow. For operators of, for example, pharmaceutical, biotech, chemical and food processing plants, this means that taking action is becoming a necessity rather than a voluntary option.

Gaskets are used wherever tubes are connected, valves are installed, or sight glasses and instrumentation are fitted. In most cases, these are made of elastomers or fluoropolymers – both representing potential vulnerabilities. Whether PTFE and other fluoropolymers are banned or strictly regulated as part of PFAS restrictions, or elastomeric seals come under increasing scrutiny under Annex 1: particle abrasion, uncertain service life and reactive “replace-on-demand” approaches are no longer a viable strategy. The earlier you identify and implement suitable alternatives, the better and more future-proof your planning will be. Choose solutions that are sustainable, future-proof and unique worldwide – with elastomer-free technology from NEUMO.

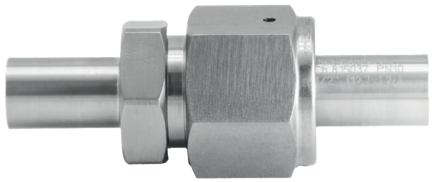
CONNECTS®
YOUR PLANT DESERVES THE CLEANEST CONNECTION

ConnectS® is NEUMO’s answer to one of the most pressing questions in the process industry: how can tubes be connected safely, hygienically and without elastomers? The product family includes flange, clamp and screw-type connections, thereby fully covering the most common connection types in pharmaceutical, biotech, chemical and food processing plants. All three variants provide a metal-to-metal seal, are entirely free from PFAS-containing materials and elastomers, and meet the highest purity requirements. ConnectS® offers the right, future-proof and maintenance-free detachable connection for every application. In addition, this connection is TA Luft certified and meets the requirements of Annex 1.

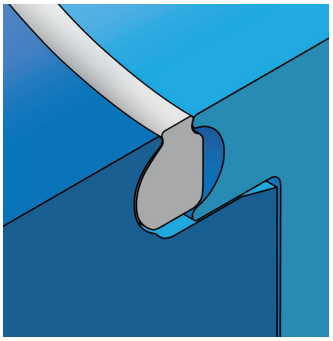
FLANGE CONNECTION

CLAMP CONNECTION

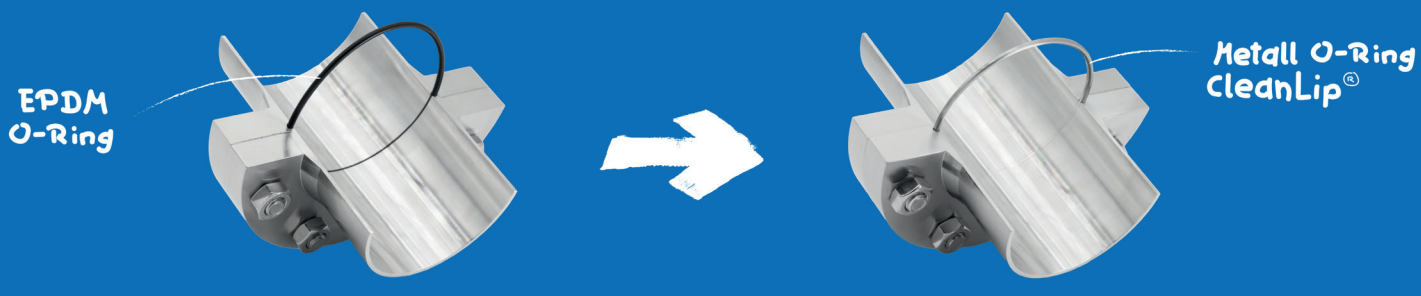
SCREW CONNECTION



BIOCONNECT® WITH CLEANLIP®
ARE YOU ALREADY USING BIOCONNECT® UNIONS?

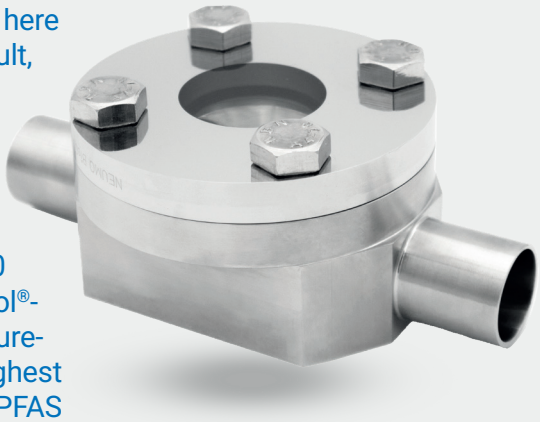


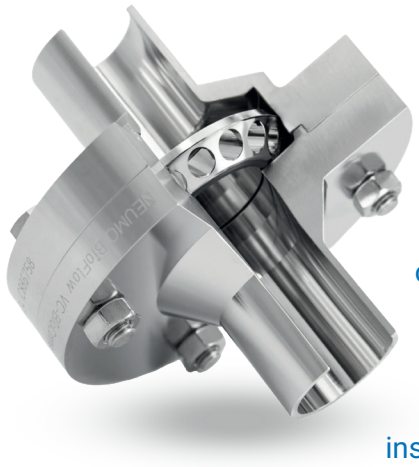
If you have already chosen BioConnect®, that was an excellent decision. With CleanLip®, you do not have to abandon this investment – it can simply be upgraded. CleanLip® is the metal sealing ring (1.4435/316L) that replaces the conventional O-ring in your existing BioConnect® flange and clamp connections without modification or significant effort. What would previously have required a complex retrofit is now a quick and cost-effective measure with CleanLip®: your system becomes PFAS-free, remains TA Luft certified, meets the requirements of Annex 1 for metal-sealing, particle-free connections – and is also completely maintenance-free.



BIOCONTROL® - CS

Sensors, measuring instruments and sight glasses must be reliably and hygienically integrated into pipework or vessels – and it is precisely here that conventional solutions always incorporate gaskets. As a result, typical vulnerabilities arise from an Annex 1 perspective: particle generation, dead legs behind seals and uncertain resistance to CIP/SIP media. BioControl®-CS is the elastomer-free variant of the modular NEUMO BioControl® system and consistently closes this gap. The housing connects sensors and measuring instruments without a single gasket being used in the product-contact area. More than 40 leading measuring instrument manufacturers already offer BioControl®-compatible instruments, which significantly simplifies planning, procurement and validation. The result is an interface that meets today's highest hygiene and cleanability requirements and is fully prepared for both PFAS regulations and Annex 1 – completely maintenance-free.





BIOFLOW®

Check valves are installed in virtually all process plants and therefore represent a key starting point on the path to an elastomer-free plant. BioFlow® from NEUMO is the check valve for aseptic and ultra-pure applications. In the version featuring the ConnectS® body sealing contour and a FLOWstop made of pure stainless steel, it is completely elastomer-free and therefore PFAS-compliant, without compromising on hygiene, pressure resistance or cleanability. Instead of using springs, diaphragms or magnets, the FLOWstop shut-off element operates solely based on gravity and the product flow. It is therefore completely maintenance-free and CIP/SIP-compatible, which is unique worldwide and provides a clear advantage under Annex 1, as no dynamic elastomer seals are installed in the product-contact area. In addition, the valve is TA Luft certified.

YOU SAVE

DOWNTIMES · ENERGY · CLEANING WATER · CHEMICALS · TIME

YOUR PROFIT

COST · PRODUCTION TIME · PROCESS RELIABILITY · ENVIRONMENTAL PROTECTION

PLANNED EU RESTRICTION OF PER- AND POLYFLUORINATED CHEMICALS, INCREASINGLY DRIVING OUT FLUORINATED SEALING MATERIALS SUCH AS PTFE AND FKM.

Under the REACH regulation, the EU is planning a far-reaching restriction of per- and polyfluoroalkyl substances (PFAS), a group of more than 10,000 substances that also includes commonly used sealing materials such as PTFE, FKM and FFKM. The reason for this is the extreme persistence of these substances in the environment and in living organisms ("forever chemicals"). For operators of process plants, this means that materials considered standard today may no longer be available tomorrow, could be banned or only usable under strict conditions – with direct implications for procurement, maintenance and plant approval.

- Affects an entire group of substances, not just individual chemicals
- Direct impact on O-rings, gaskets and coatings made of PTFE, FKM and FFKM
- Transition periods are planned – long-term planning reliability requires early substitution

PFAS BAN READY?

GERMAN REGULATION ON AIR POLLUTION CONTROL WITH TIGHTENED LEAKAGE REQUIREMENTS FOR FLANGES AND VALVES.

The Technical Instructions on Air Quality Control (TA Luft) are a German administrative regulation which, since its revision in 2021, has introduced significantly stricter requirements for installations requiring approval. The focus is on fugitive emissions from leaking flange connections, valves and pumps. Connections must be demonstrably "highly leak-tight," verified through standardized test procedures and corresponding certifications. Non-compliance may result in conditions being imposed during approval procedures or retrofitting requirements during operation.

- Mandatory for installations requiring approval under the German Federal Immission Control Act (BImSchG)
- Proof of certified leak-tightness required (e.g. according to VDI 2440, ISO 15848-1)
- Applies to both new installations and significant modifications to existing plants

TA-LUFT APPROVED?

GMP STANDARD FOR STERILE DRUG MANUFACTURING WITH CLEAR REQUIREMENTS FOR CONTAMINATION CONTROL – LEGALLY BINDING DURING REGULATORY INSPECTIONS.

The EU GMP guidelines define the requirements for the manufacture of sterile medicinal products in Annex 1 and were fundamentally revised in the version published in 2022. The core requirement is a holistic contamination control strategy (CCS) that reliably prevents microbial, particulate and pyrogenic contamination throughout the entire process. Seals play a key role in this context: they must not generate particles, must be resistant to cleaning and sterilization media, and must have a defined service life. During regulatory inspections by the EMA, FDA or national authorities, Annex 1 is legally binding. Observations or deficiencies can lead directly to regulatory requirements or, in the worst case, to production shutdowns.

- Mandatory contamination control strategy across the entire process
- Strict material requirements: no particle generation, CIP/SIP resistance, defined service life
- Legally binding during inspections – deficiencies have immediate consequences for production

ANNEX 1 COMPATIBLE?

WE ARE READY.
ARE YOU?

neumo.de