60th ANNIVERSARY 1962-2022

FLUITEN

Mechanical seals

FOR THE PHARMACEUTICAL INDUSTRY

The processes and equipment found in the pharmaceutical industry differ substantially from those used in other industries due to the requirements they have to meet.

The Food and Drug Administration (FDA) aims to protect public health through regulations that govern how certain products are placed on the market, including drugs, foods, food supplements and additives, veterinary feeds and drugs, and cosmetics.

Bioprocessing through mixing can greatly affect the purity of final products.

The manufacturing choices made regarding equipment and the sealing systems used on rotating shafts significantly affect process efficiency and quality.

DIRECTIVES AND GUIDELINES	
Food and Drug Administration (FDA)	The Food and Drug Administration is a US government agency, under the US Department of Health and Human Services, responsible for regulating food and pharmaceutical products.
GMP Regulation	The Good Manufacturing Practice regulations, or good preparation standards, are a set of rules, procedures and guidelines to be observed when producing drugs, foods and pharmacologically active substances.
3A Sanitary Standard	The 3-A Sanitary Standards are US standards that govern the design and manufacture of equipment that meets food. 3-A aims to protect the public from risks relating to potential food contamination.
EHEDG	This is a European non-governmental organization devoted to the advancement of hygienic design and food engineering.
1935/2004	1935/2004/EC is a European Parliament and European Council directive issued on 27 October 2004 which applies to materials and objects that come into contact with food.
Eu 2014/34/EU (ATEX) 95 EX 94/9/ec	The ATEX directive sets common, EU-wide standards for the sale and commissioning of equipment and protection systems intended for use in potentially explosive atmospheres. It aims to make sure products meet certain requirements to ensure a high level of health and safety protection.

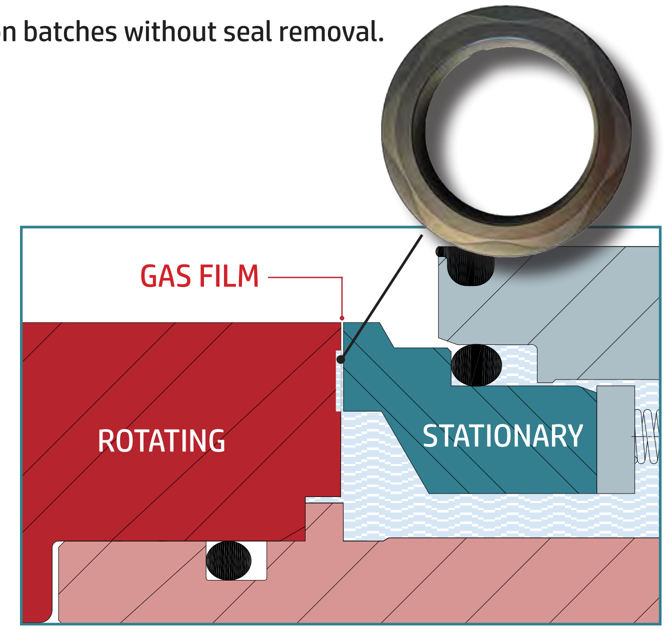
Agitators, dryers and fermenters with top, bottom, rotating shafts, should be designed to prevent the growth of undesirable micro-organisms.

Besides preventing process contamination from the external atmosphere or from double seal lubrication and cooling liquids, the mechanical seals installed on the rotating shafts of this kind of equipment should also ensure a constant positive pressure or vacuum inside the tank and prevent wear of the contact material that might cause the product to be rejected, especially if it is in the process of being finished. Seal design should consider two key aspects:

• Avoid contamination of both the process fluid and the atmosphere when the substances are hazardous to people and the environment. If the process takes place in a vacuum, no atmospheric infiltration is allowed.

• Allow cleaning and sterilization between production batches without seal removal.

FLUILIFT TECHNOLOGY Using a pressurized inert gas - normally nitrogen - as a barrier fluid between the process and the atmosphere prevents product leakage and contamination from the atmosphere or seal lubrication barrier fluid. The rotating ring of the mechanical seal has microscopic grooves. If they are appropriately sized, they provide a small lift from the stationary ring caused by the pressurized barrier gas.



FLUIDIAMOND A chemical deposition on silicon carbide rings can improve the tribological properties of the material which otherwise would not tolerate even transient 'contact operation' in the absence of liquid. A diamond coating allows the seal to tolerate the start-up stage, or in the case of mechanical stresses on the rotating shaft, contact between the rotating and stationary rings, while keeping friction and overheating down to acceptable limits.

USE BENEFITS

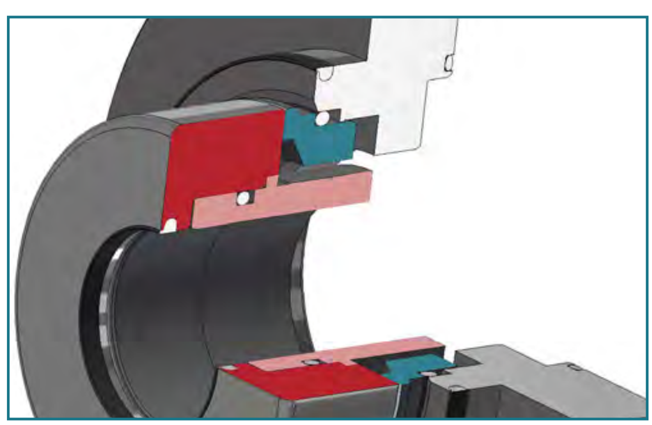
• Extremely low coefficient of friction
• High hardness and abrasion resistance
• Excellent conductivity
• Broad compatibility with chemical aggression
• High corrosion resistance

GAPLESS PART IN CONTACT WITH THE PROCESS

The parts of the mechanical seal in contact with the process should be cleanable in place (CIP) and sterilizable in place (SIP). The design should:

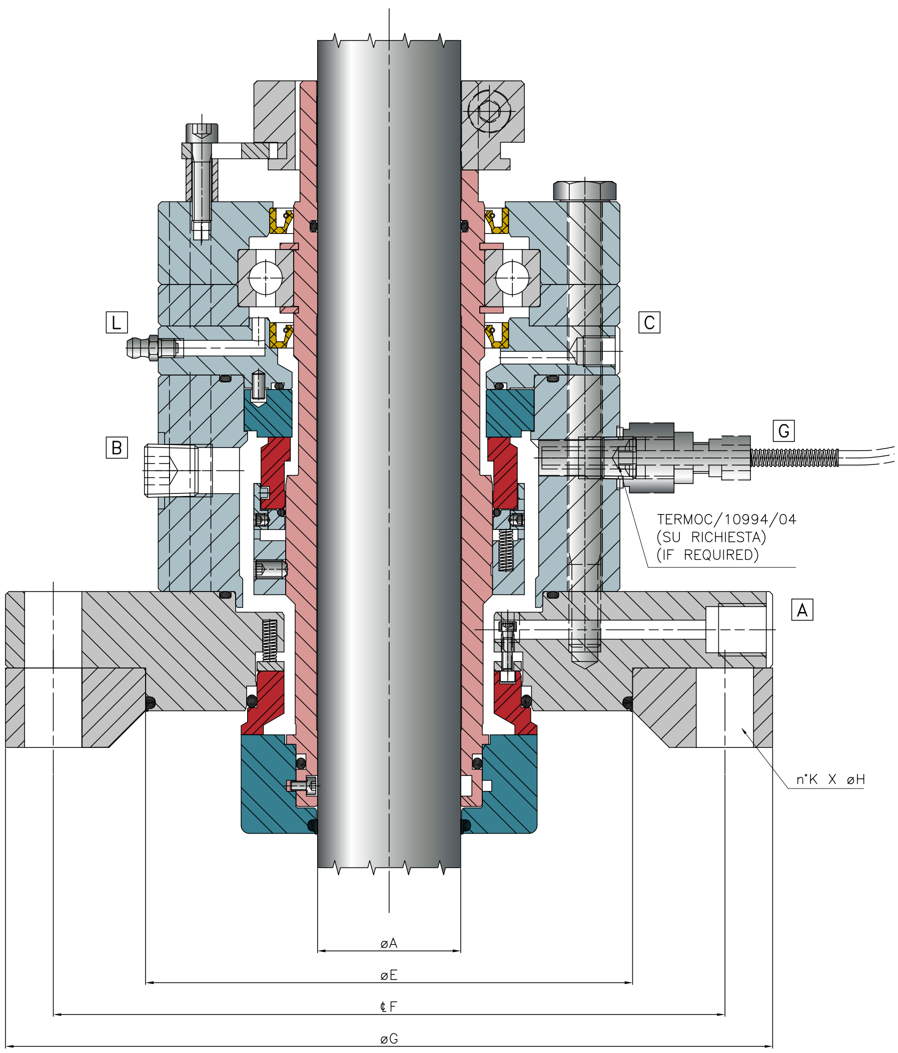
• Have no recesses where the process liquid can become stagnant and difficult to remove.

• Involve materials that do not contaminate the process. Non-metals must be FDA approved while AISI 316L steel or higher quality is normally acceptable for components.



GT1960F

GT1960F seal meets all the requirements laid down by the pharmaceutical industry. Its special shape allows perfect cleaning and sterilization in place (CIP and SIP). So it can be installed in aseptic environments. Double sealing involves pressurization with a barrier gas that separates the process from the atmosphere, thus preventing process contamination and equipment leakage. The materials are FDA-certified, and the cartridge version with built-in bearing keeps maintenance and operating costs to a minimum. The dimensions of the connecting flange comply with DIN 28138, but can be engineered according to the dimensions of the equipment.



MATERIALS

PRODUCT SIDE
- *U51/U51:* pressurized gas lift-off
- *U31/U31*: pressurized wet

ATMOSPHERIC SIDE
- U51/U51: pressurized gas lift-off
- Z51/U31: pressurized wet
- U31/U31: pressurized wet

FDA APPROVED SECONDARY GASI
- *V4*; *D3*; *G731 or G718*

METAL PARTS
- *AISI316*; others on request

MATERIALS DESCRIPTION

U51: Fluidiamond

U31: Alpha sintered silicon carbide

Z51: FDA carbon - wet application

ZD51: FDA carbon - gas dry running

V4: FKM, FDA approved fluoroelastor

D3: EPDM, FDA approved

G731 or G718: FFKM, Perfluoroelasto

T33: PTFE energized FDA approved fo

ØA h8	ø	E e8	F	G	K	H ø
40	50	110	145	175	4	18
50	60	176	210	240	8	18
60	70	176	210	240	8	18
80	95	204	240	275	8	22
100	120	234	270	305	8	22
125	140	260	295	330	8	22
140	160	313	350	395	12	22
160	180	313	350	395	12	22

OPERATIONAL LIMITS

Speed (m/s): 10

Temperature (˚C): -40°÷ -200°

Process pressure (bar): V÷6

Barrier pressure: 2 bar > process

GT1961F

GT1961F seal boasts all the special properties developed for the GT1960A range with the peculiarity that it can be installed on equipment with glass-lined vessels. The enamelled flange connecting the cartridge to the equipment complies with DIN 28137, while the other parts in contact with the process are made of sintered silicon carbide as standard to ensure complete resistance to chemical attack. The dimensions and materials can be engineered differently on request.

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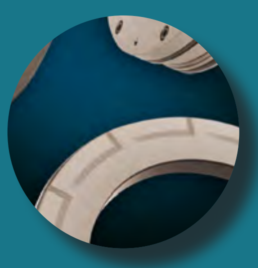
/ GASKETS



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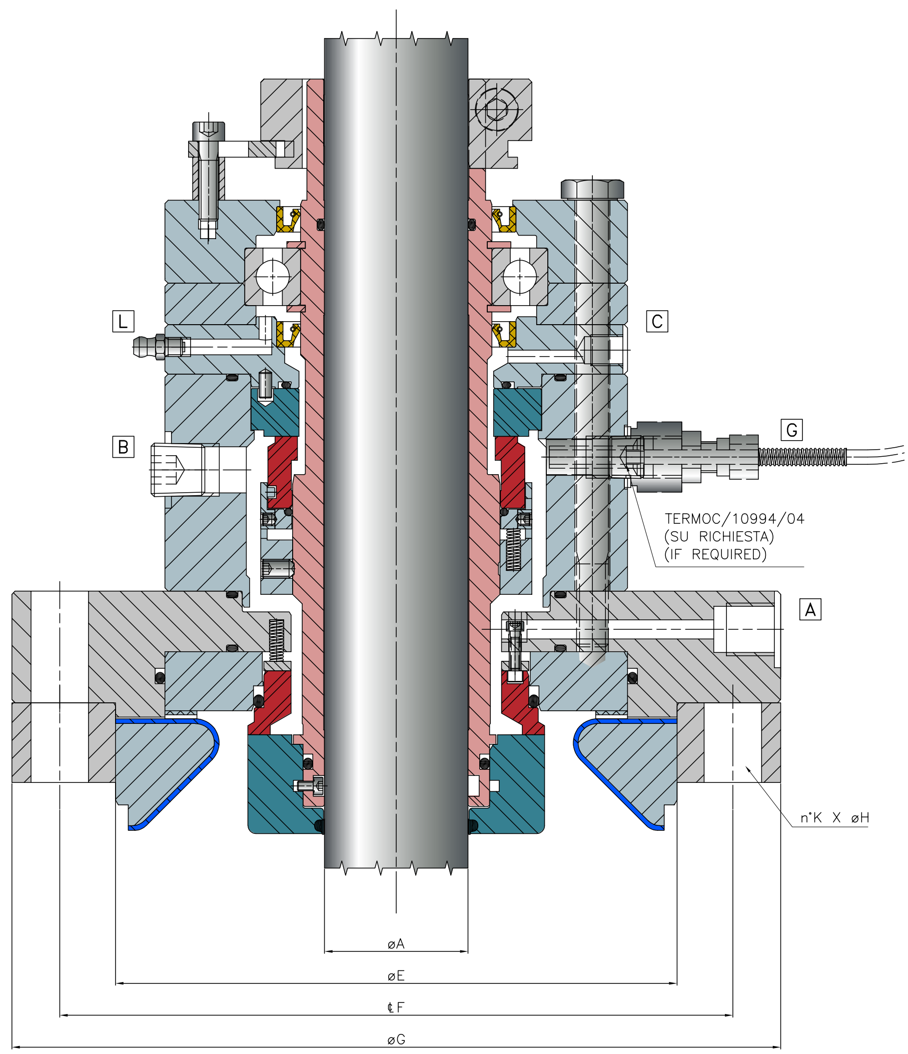
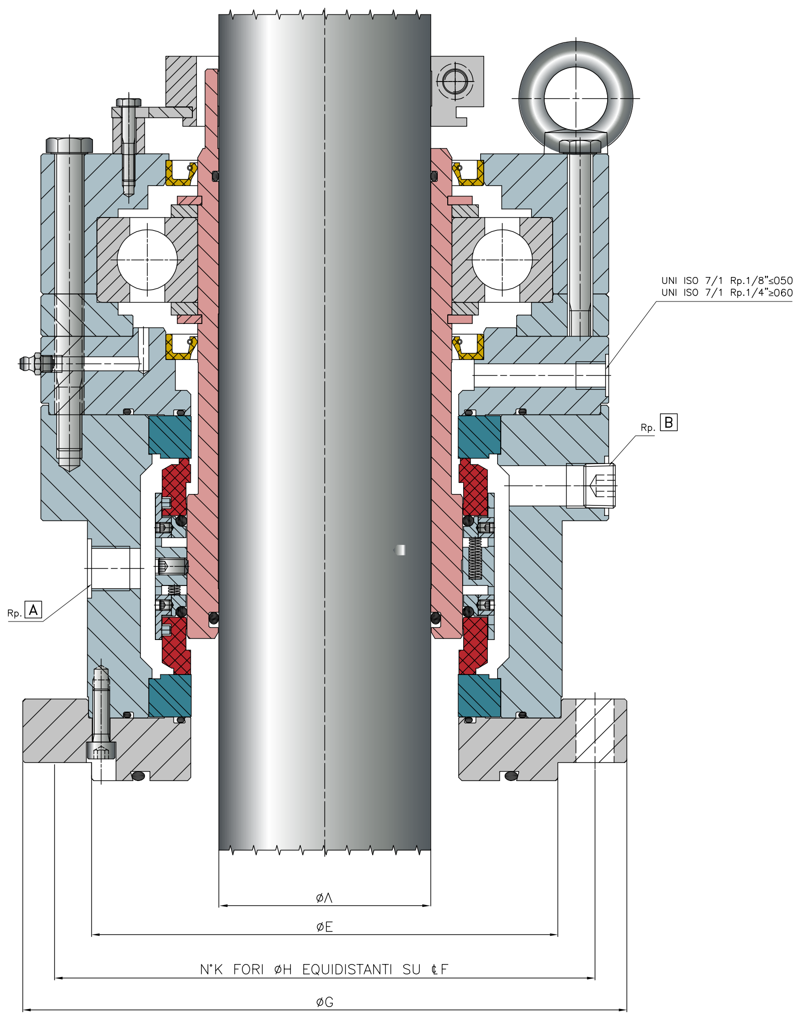


ØA		E	F	F1	G	G1	K	K1	H	H1
h8	ø	ø			d9	ø			ø	ø
40	40	102	145		110	175	4		18	
50	50	138	210		176	240	8		18	
60	60	188	240		204	275	8		22	
80	80	212	270		234	305	8		22	
100	100	268	350		313	395	12		22	
125	125	320	350	460	422	505	12	4	22	22
140	140	320	350	460	422	505	12	4	22	22
160	160	320	350	460	422	505	12	4	22	22

GT1910A

The **GT1910A** seal is a double back-to-back pre-assembled cartridge seal with built-in multi-purpose bearing. It is ideal for finished product preparatory stages, but it is also widely installed on aseptic equipment. Standard options include the GT1910D sanitary flange model for cleaning and sterilization in place (CIP & SIP), or with a process-side heating or cooling jacket, and the GT1910C, for products that tend to crystallize or high temperatures. Sealing is achieved through a pressurized barrier gas that separates the process from the atmosphere, thus preventing process contamination and equipment leakage. Their compact size allows them to be fitted on a wide range of equipment.



MATERIALS

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ATMOSPHERIC SIDE
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- Z51/U31: pressurized wet
- U31/U31: pressurized wet

FDA APPROVED SECONDARY GASKETS
- *V4*; *D3*; *G731 or G718*

METAL PARTS
- *AISI316*; others on request

Material description pag 4,5

øA		E	F	G	K	H
h8	ø	e8				ø
40	55	120	145	170	6	13
50	65	130	155	180	6	13
60	75	150	180	210	6	18
80	100	180	210	240	6	18
100	135	220	255	285	8	18
125	145	240	275	305	8	18
140	165	260	295	325	8	18
160	185	280	315	345	10	18

OPERATIONAL LIMITS

Speed (m/s): 10

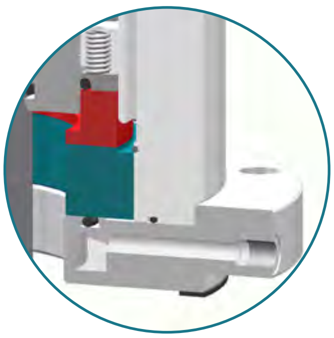
Temperature (˚C): -40°÷ 200°

Process pressure (bar): V÷10

Barrier pressure (bar): 2 > process

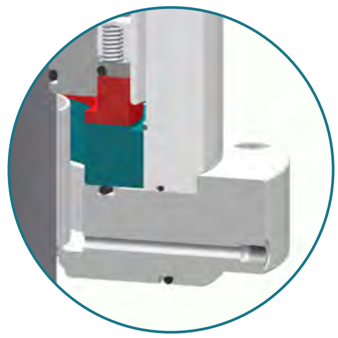
GT1910

Sanitary flange available as an option on the seal cartridge. The GT1910A allows sterilization in the area between the product-side seal and the process.



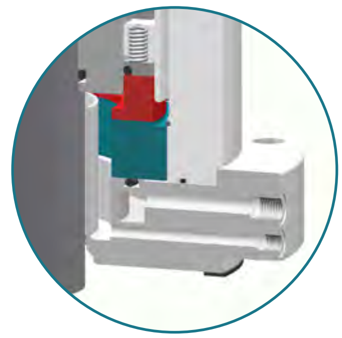
Flange with cooling jacket **(C)**

GT1910C



Sanitary flange **(D)**

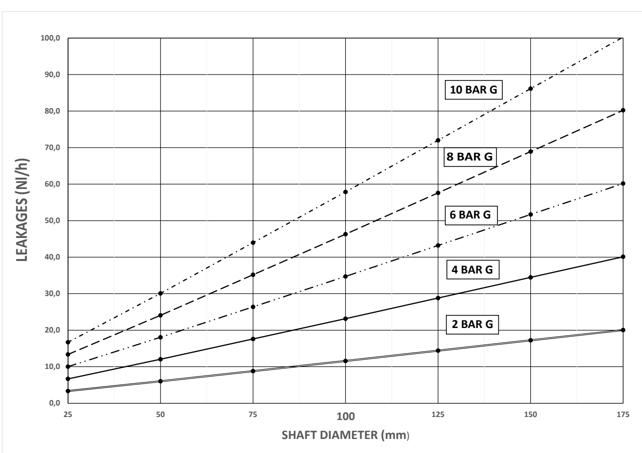
GT1910D



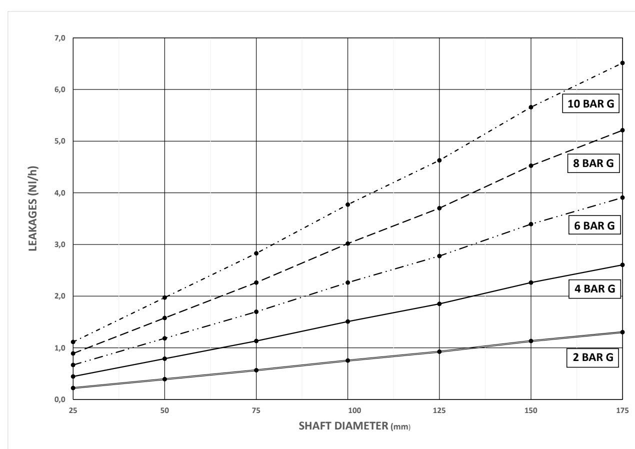
Sanitary flange with cooling jacket **(E)**

GT1910E

Nitrogen **leakage** graph



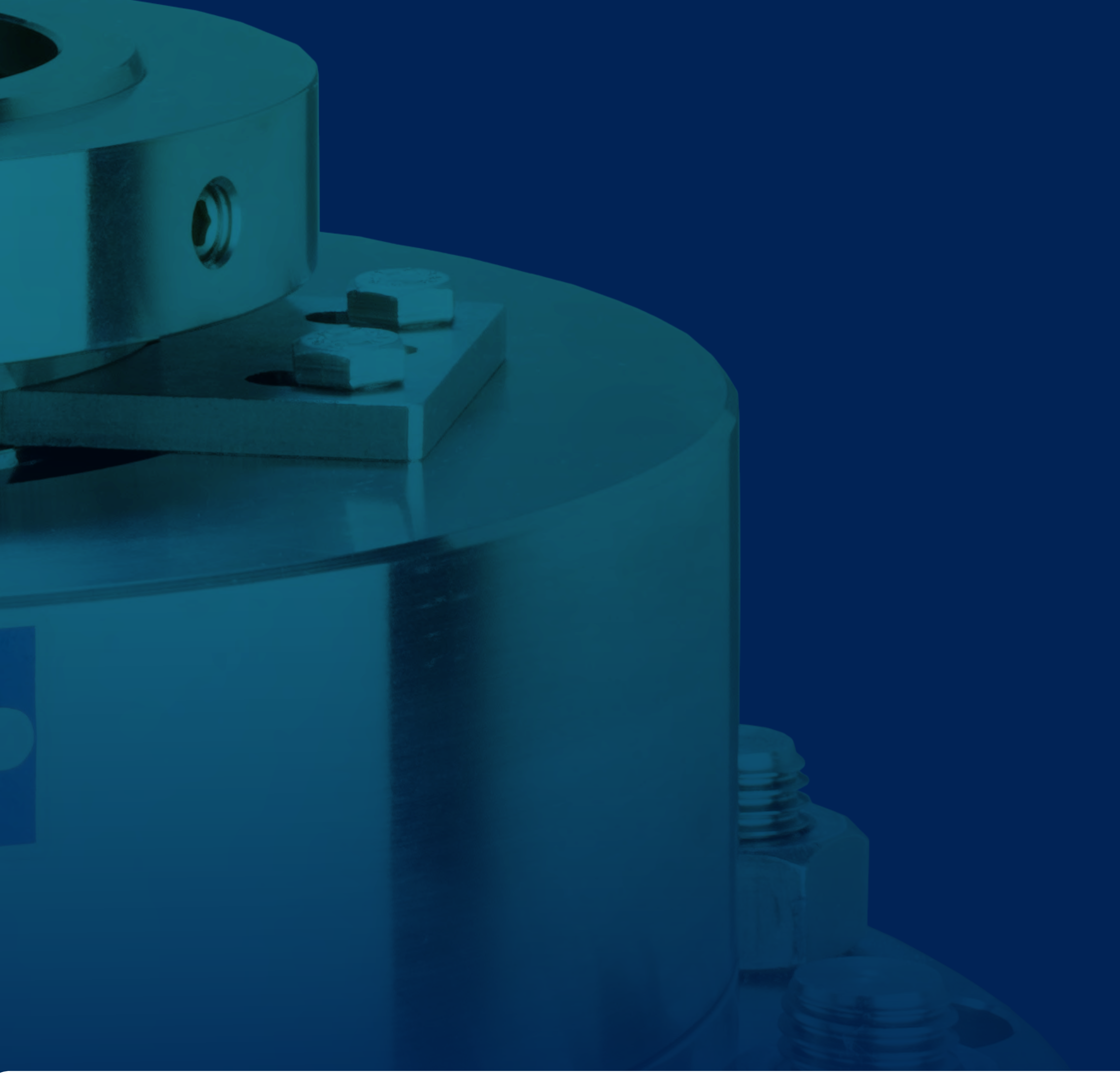
Gas Seal non contacting (PRODUCT SIDE)



Dry Running contacting (ATMOSPHERE SIDE)

PLAN 74 Gas panel control

PLAN 52-53 (12L)
Seal lubrication tank



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