

 **Ultrapharma**_{by}



Company Profile
Unternehmen

FOOD

Introduction

Ultrapharma BV was founded in 2002 in the Netherlands, starting as European Master Distributor for Rubberfab Technologies Group, a leading company in the development of Sanitary Seals for the Pharmaceutical industry.

Well passed our 12,5 year anniversary Ultrapharma BV has become a recognized partner for many companies that are involved with daily processing challenges in this industry in Europe. Innovation is our drive for success, smart solutions that will help resolve many in-field problems.

A well balanced inventory is a security for fast shipments with an emphasis on the full product range.

Ultrapharma BV offers a very wide spectrum of products for fluid handling systems for the pharmaceutical industry as well as the Food & Beverage. Unique sealing materials such as Tuf-Steel®, Tuf-Flex®, Steam-Flon®, Tri-Bond® and standard elastomers such as Platinum Silicone, Peroxide Silicone, FKM, EPDM and many more. Popular material such as PTFE or TFM are standard among the many validated materials we offer. We have capabilities to develop specific compounds with unique properties.

Ultrapharma BV has developed gasket manufacturing capabilities for European pipe standards such as DIN32676, ISO1127, DIN11864, SMS3017, BS4825 and DIN11851.

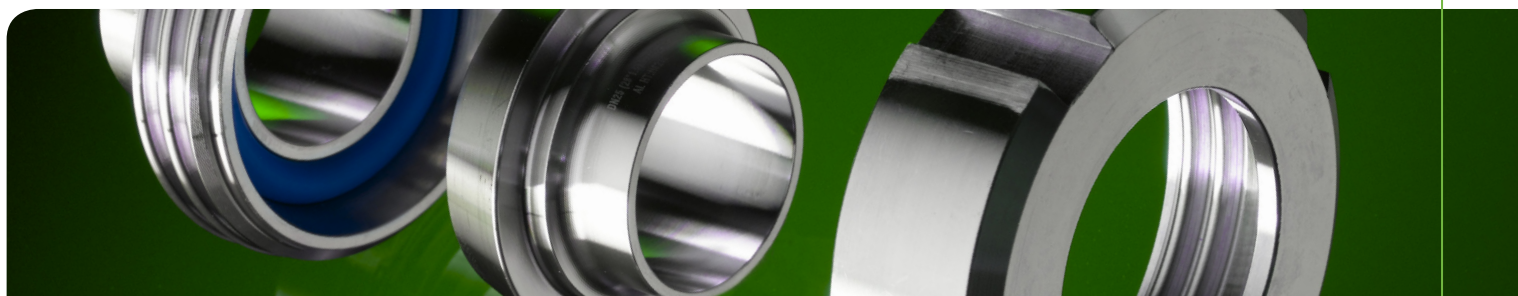
Ultrapharma BV is **ISO-9001** certified (August 2015)

Ultrapharma BV
Heemskerk
The Netherlands



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Certification

FDA

Food and Drugs Administration is a US government agency within the Department of Health and Human Services. FDA is the federal agency responsible for ensuring that foods are safe, wholesome and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe. FDA has written codes (CFR's) to ensure that seals that we make conform to certain standards when in contact with food or pharmaceutical processing systems. Many companies in the EU are using this standard.

Examples:

FDA CFR 177.1550 Perfluorocarbon resins. A detailed description of methods of processing and substances that can be safely used.

FDA CFR 177.2600 Rubber articles intended for repeated use may be safely used in producing, manufacturing, packaging, processing, preparing, treating, transporting or holding food, subject to the provisions of this section. It also describes a test for impurities from elastomeric closures. The purpose of the study is to analyze total extractables.

TSE

TSE also known as BSE (Bovine Spongiform Encephalopathy) has been addressed by FDA and the European Union. The use of animal derived ingredients in the production of medicine and other related products has in the past lead to the transmit of TSE disease. TSE disease is a central nervous disease.

The European Union has written a journal (EMA/410/01) in which they give guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medical products.

Whereas many of our products are used in human or veterinary medicine production plants, it is important to know if any of our products have been in contact or are produced with animal derived ingredients.

The only product (compound) that is made manufactured with animal derived ingredients is NBR (buna). All other products such as EPDM, FKM, PTFE and Silicone are Animal Derived Ingredient free. (ADIF).

EC1935/2004

Is a standard that looks at extractable levels when rubber is exposed to 4 different simulant, water, acetic acid, ethanol and iso-octane. Migration should be <10mg/dm², for each simulant. A difficult standard to interpret, for example we don't recommend Silicone rubber in an oil or grease environment, but yet we test it against iso-octane, a substitute for olive oil. Silicone did not pass this test, not strange, a paradox.



Standard Gaskets

The standard food process gasket in Europe is DIN11851 in several elastomeric materials.

EPDM	Ethylene Propylene Diene Monomer
FKM	(Viton®) Fluoroelastomer
Silicone	Silicone Rubber
BUNA	Acrylonitrile Butadiene Rubber
HNBR	Hydrognated Nitrile Butadiene Rubber

High performance plastics are:

PTFE	PolyTetraFluoroEthylene
TFM	Modified PolyTetraFluoroEthylene
Tuf-Steel®	Blend of non pigmented PTFE and 316L powder
Tuf-Flex®	Bonded PTFE with EPDM substrate
Food-Flex®	Bonded PTFE with Nitrile substrate (Tri-Clamp only)
Tri-Bond®	Bonded PTFE with FKM substrate (DIN32676 & ISO1127 only)
Steam-Flon®	Blend of non pigmented PTFE and 316L powder DIN & ISO

Typical Gasket Guidelines

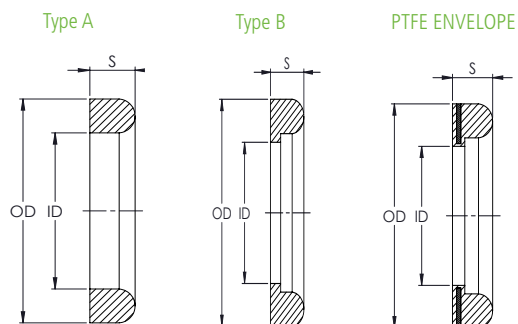
	1=Excellent	2=Good	3=Acceptable	4=Marginal	5=Poor	X=do not use			
Gasket type	Continuous Steam	Intermittent Steam	Pure Water Ambient	Pure Water Hot	Process Fluids Ambient	Process Fluids Hot	Process Fluids Variable ΔT	Temperature Range*	Torque Value in Nm*
Tuf-Flex®	1	1	1	1	1	1	1	-20°C to 150°C	2 Nm
Tri-Bond®	1	1	1	1	1	1	1	-30°C to 175°C	2 Nm
Tuf-Steel®	1	1	1	1	1	1	1	-212°C to 288°C	4 Nm
Steam-Flon®	1	1	1	1	1	1	1	-212°C to 288°C	4 Nm
PTFE Solid	1	1	1	1	1	1	3	-74°C to 260°C	3 Nm
PTFE Envelope (FKM)	2	1	1	1	1	1	3	-30°C to 170°C	3 Nm
Silicone Platinum cured	2	2	2	2	2	2	1	-40°C to 230°C	1,5 Nm
FKM Fluoroelastomer	2	2	2	2	2	2	2	-30°C to 205°C	1,5 Nm
EPDM Peroxide cured	3	3	3	3	3	3	3	-20°C to 150°C	1,5 Nm
NBR (Nitrile)	5	5	3	3	3	4	3	-20°C to 110°C	1,5 Nm
HNBR (hydrognated Nitrile)	2	2	3	2	2	2	1	-40°C to 165°C	1,5 Nm

DIN11851 series

DIN11851	Type A	Type B	PTFE ENVELOPE
	OD X ID X S		
DN10	12 x 20 x 4,5	10,5 x 20 x 5	10,5 x 20 x 5
DN15	18 x 26 x 4,5	16,5 x 26 x 5	16,5 x 26 x 5
DN20	23 x 33 x 4,5	20,5 x 33 x 5	20,5 x 33 x 5
DN25/1"	30 x 40 x 5	26,5 x 40 x 6	26,5 x 40 x 6
DN32/1.25"	36 x 46 x 5	32,5 x 46 x 6	32,5 x 46 x 6
DN40/1.5"	42 x 52 x 5	38,5 x 52 x 6	38,5 x 52 x 6
DN50/2"	54 x 64 x 5	50,5 x 64 x 6	50,5 x 64 x 6
DN65/2.5"	71 x 81 x 5	66,5 x 81 x 6	66,5 x 81 x 6
DN75/3"	78 x 88 x 5		
DN80	85 x 95 x 5	81,5 x 95 x 6	81,5 x 95 x 6
DN90	94 x 104 x 5		
DN100/4"	104 x 114 x 6	100,5 x 114 x 6	100,5 x 114 x 6
DN125	130 x 142 x 7	125 x 142 x 7	125 x 142 x 7
DN150	155 x 167 x 7	150,5 x 167 x 7	150,5 x 167 x 7

The "Milchrohrverschraubung" or Milk threaded fitting DIN11851 is still a popular fitting in the food industry. There are two types available as indicated in above table. Type B is the most sanitary version because the inside lip closes the gap between the two metal parts. Recently we have introduced the PTFE envelope gasket with lip (Type B), this envelope gasket seals better than its solid version because of its rubber (FKM) insert.

See page 8 for in-line filter solutions for DIN11851.

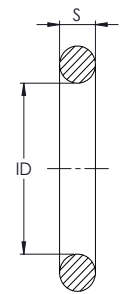


DIN11864 Fitting

NEW Fitting

In the food processing industry there is a drive to design systems in a more aseptic way. The DIN11851 fitting is not a hygienic standard although still utilized in new equipment. There is an alternative fitting the DIN11864 available in 3 executions, Flanged with bolts, Tri-Clamp and in a threaded Nut version.

DIN11864	DIN11850	ISO1127	BPE	
	ID X S	ID X S		ID X S
DN08		12 x 3,5	DN1/2"	12 x 3,5
DN10	12 x 3,5	16 x 3,5	DN3/4"	18 x 3,5
DN15	18 x 3,5	20 x 3,5	DN1"	24 x 3,5
DN20	22 x 3,5	26 x 3,5	DN1.5"	37 x 5
DN25	28 x 3,5	32 x 5	DN2"	50 x 5
DN32	34 x 5	40,5 x 5	DN2.5"	62 x 5
DN40	40 x 5	46,5 x 5	DN3"	75 x 5
DN50	52 x 5	58,5 x 5	DN4"	100 x 5
DN65	68 x 5	73,5 x 5		
DN80	83 x 5	86,5 x 5		
DN100	102 x 5	111 x 5		
DN125	127 x 5			
DN150	152 x 5			



SECTION A-A

FEP/FKM



EPDM or FKM



Peroxide Silicone

O-ring seal DIN11864 available in many interesting materials:

EPDM

FKM Fluoroelastomer

Silicone

PTFE

Steam-Flon®

FEP/FKM

Meets: FDA CFR 177.2600

FDA CFR 177.1550

EC1935/2004

TSE/BSE free

Screens

With our experience in the pharmaceutical industry we learned that there is a need for in-line coarse screen (filter) products for the food industry as well. Our screens are not used the same way as filters, although it can be considered a filter. These screens are most of the time a single layer stainless steel wire filter, with a rectangular opening. Retention vary from 11 mm down to 10 µm, ranging from thick wire to thin stainless filter cloth.

Most of the time we use screens as a safety measure. Either to protect a pump in a startup phase or to take out the last potential particles in a filling station.

We designed screens for DIN11851

Available materials: EPDM and Steam-Flon®

EPDM meets:

FDA CFR 177.2600

Is TSE/BSE free

Meets EC1935/2004 for Water and Acid only

Removable screen for DIN11851

Steam-Flon® meets:

FDA CFR 177.1550

Is TSE/BSE free

Meets EC 1935/2004

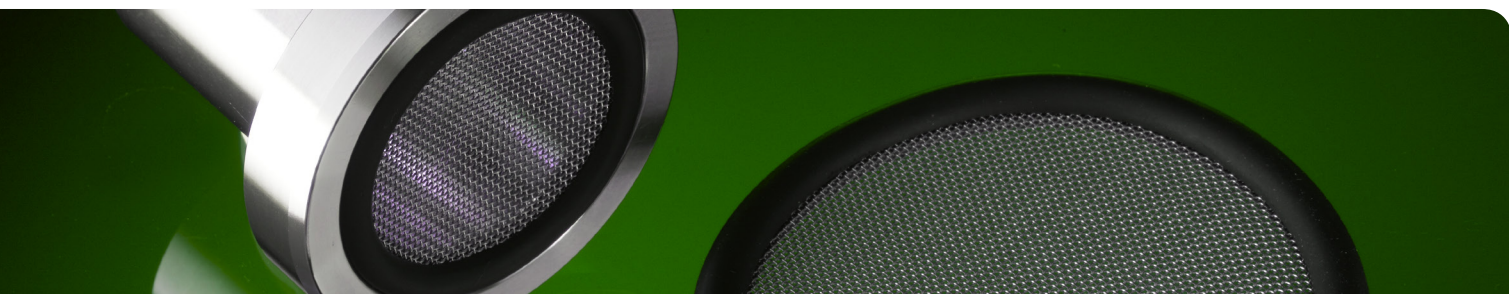
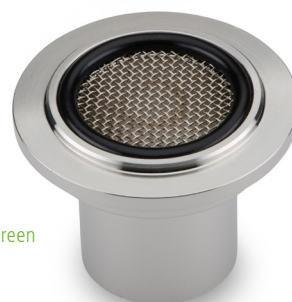
Common Mesh Sizes

Mesh	Wire Ø	Opening	Open area	Material
(warp)	(mm)	(mm)	(%)	
10	0,60	1,95	58	AISI 316
20	0,34	0,95	54	AISI 316
40	0,22	0,42	43	AISI 316
60	0,19	0,23	30	AISI 316
80	0,17	0,15	22	AISI 316
100	0,11	0,14	31	AISI 316

DIN11851 screen



DIN11864 screen

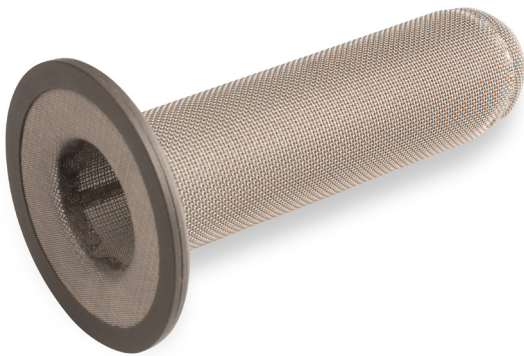


Steam-Flon®

Steam-Flon® is an alternative for white virgin PTFE. It is a mix of white PTFE with 316 stainless steel powder as a filler. This 316 stainless filler enhances the compound to become more stable and outperforms standard PTFE. With hardly no dimensional change under pressure it maintains a seal even under high temperature exposure, no leaks. The ability to hold its shape during service is something we utilize for our Removable gasket.

Removable gaskets can be used for screens, sock screens and orifice plates. The gasket is a two part unit that can be pressed together with a screen or plate in between. It can be taken apart, cleaned and reused.

DIN11851 DN65 Sock screen 200 mesh



DIN11851 DN50 Orifice plate

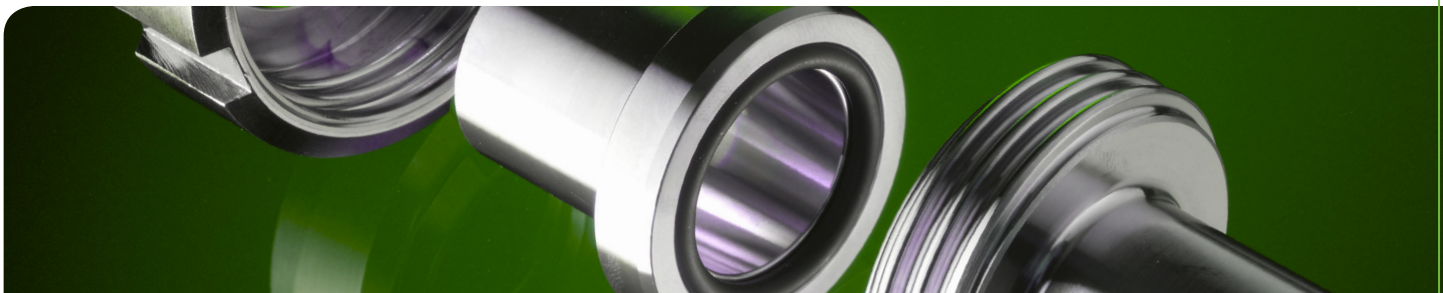


Steam-Flon meets:

FDA CFR 177,1550

Is TSE/BSE free

Meets EC 1935/2004



Orifice plates DIN11851

Innovative Orifice plates are used to modify flow patterns in critical systems. Orifice plates can advance your system's performance, adjusting flow rates, balance backflow and equalize back pressure during SIP or CIP (Steaming In Place SIP or Cleaning in Place CIP) procedures. Currently available in HNBR.

Meets: FDA CFR 177.2600
3.1B certificate for metal parts
Is TSE/BSE free

Available materials: EPDM and Steam-Flon® + HNBR

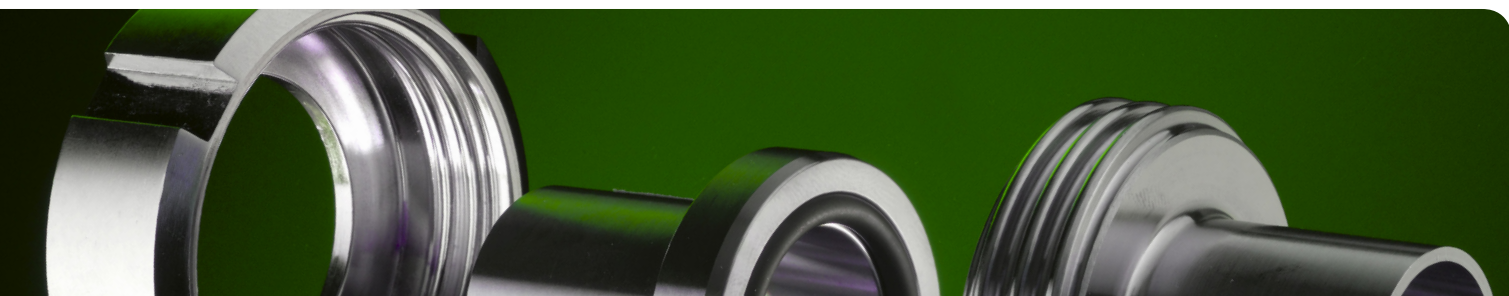
EPDM meets:
FDA CFR 177.2600
Is TSE/BSE free
Meets EC1935/2004 for Water and Acid only

Steam-Flon® meets:
FDA CFR 177.1550
Is TSE/BSE free
Meets EC 1935/2004

HNBR elastomer



Self draining Orifice plate in DIN11851 DN50
With eccentric Ø4,0mm hole



SMS1149

The SMS1149 is a Scandinavian standard and is used in other countries as well. The SMS-L is a better sanitary design than the SMS-R because the L-type has a lip on the inside, securing a smooth transition from pipe to pipe without a crevice.

Materials:

NBR/EPDM

FKM

PTFE Solid

PTFE/FKM Envelope

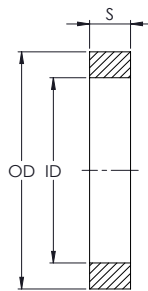
Meets: FDA CFR 177.2600

FDA CFR 177.1550

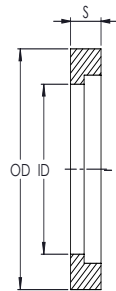
EC1935/2004

Is TSE/BSE free

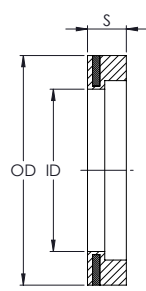
SMS-R



SMS-L



PTFE/FKM Envelop



SMS-R		SMS-L	
	ID x OD x S		ID x OD x S
DN25	25 X 32 X 5,5	DN25	22,6 X 31,6 X 5,5
DN32	32 X 40 X 5,5	DN32	29,8 x 38,8 x 5,5
DN38	38 X 48 X 5,5	DN38	35,5 X 47,5 X 5,5
DN51	51 X 61 X 5,5	DN51	48,6 X 60,6 X 5,5
DN63	63,5 X 73,5 X 5,5	DN63	60,6 X 73 X 5,5
DN76	76 X 86 X 5,5	DN76	73,1 X 85,5 X 5,5
DN89	89 X 101 X 5,5		
DN100	101,6 X 113,5 X 5,5		
DN104	104 x 116 x 5,5	DN104	99,8 x 115 x 5,5
DN108	108 X 120 X 5,5		

SMS-3008 pipe	
	OD x ID x w all
DN25	25 X 22,6 X 1,2
DN32	32 x 35,6 x 1,2
DN38	38 x 35,6 x 1,2
DN51	51 x 48,6 x 1,2
DN63	63,5 x 60,3 x 1,6
DN76	76 x 72,9 x 1,6
DN89	89 x 84,9 x 2,0
DN100	101,6 x 97,6 x 2,0



Metal detectable

The need for metal detectable gaskets in the EU food industry is gradually increasing. Over time and repeated clean-in-place, sterilization and handling during equipment cleaning, component parts used in food and beverage processing equipment and pipe work can degrade. As the elastomer degrades, there is a potential risk of rubber breaking off, resulting in product contamination, product recall, lost of product and down time. Metal detectable gaskets are magnetic and can therefore be isolated from the process by magnetic separators.

Materials available

Tuf-Steel®

Steam-Flon® DIN11851 & DIN11864

BUNA

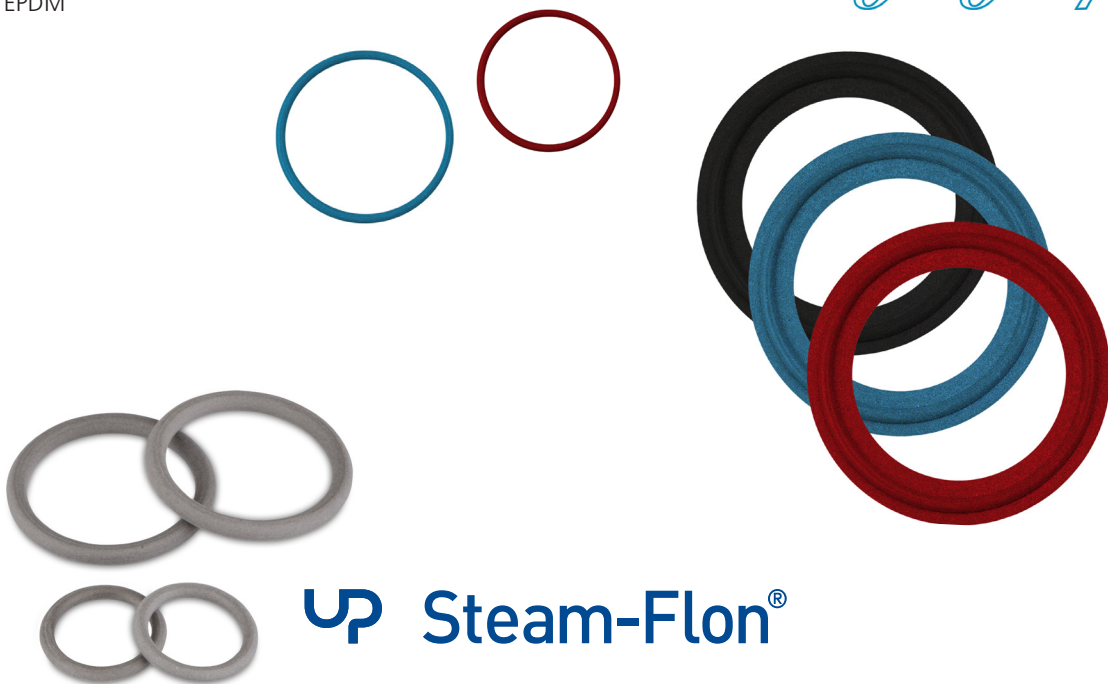
FKM

SILICONE

EPDM



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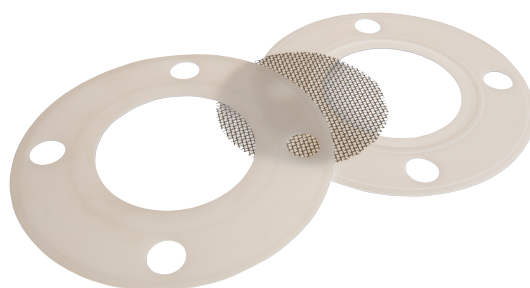
Special parts

Ultrapharma has 3D design capabilities in house to develop special seals or parts for the food industry. Below some examples.

Ball Valve Seat in Steam-Flon®



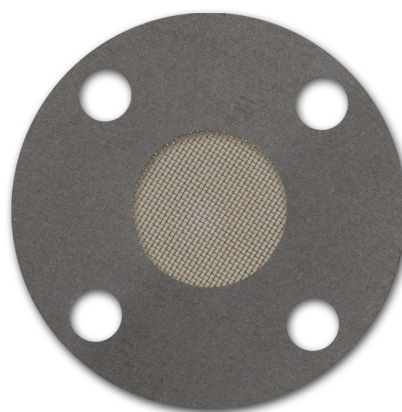
Two Part PTFE DIN2633 PN16 Screen



Blue EPDM in all standards



DIN 2633 PN16 Screen in Tuf-Steel®



Cam Lock

Rubberfab gaskets for Camlock coupling are available in the standard style and Metal Detectable X-ray Inspectable.

Available in the following materials:

BUNA

EPDM

FKM and Silicone

Sizes: ½" – 4"

RUBBER FAB
technologies group

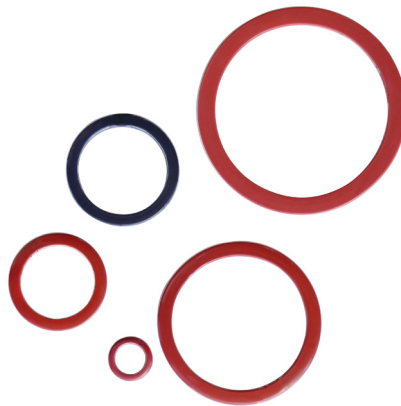
Encapsulated Camlock gaskets in FEP

Available in:

FEP with FKM inside

FEP with Red Silicone inside

Sizes: ½" – 4"



Camlock Screens



0,033" Standard Stock Perforation

Available in wire mesh from 10 to 100 mesh



Notes



Screens (strainers) in DIN11851, DIN11864, SMS1149 (above), SMS3017
Call us for details

Get more information about other Sanitary Solutions on our website

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