Ultrapharma bv

Company Profile
Perfil de Empresa
Unternehmen

PHARMA

Introduction

Ultrapharma BV was founded in 2002 in the Netherlands, starting as Master Distributor for Rubberfab Technologies Group, a leading company in the development of Sanitary Seals for the Pharmaceutical industry.
One decennia later 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®, Tri-Bond® and engineered HNBR, Silicone, FKM and other elastomers. 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 manufacturing capabilities for European pipe standards such as DIN32676, ISO1127, DIN11864, SMS3017, BS4825 and DIN11851.

Ultrapharma BV
Heemskerk
The Netherlands

Chapters

Standard Gaskets

Pharmaceutical Grade

Our standard process gaskets are Tri-Clamp versions in several standards; OD tube also known as ASME BPE, DIN32676, SMS 3017, ISO1127 and BS4825. The Tri-Clamp gasket is made in several types of elastomers.

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

High performance plastics are:

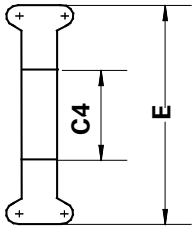
PTFE	PolyTetraFluoroEthylene
TFM	Modified PolyTetraFluoroEthylene
Tuf-Steel®	Blend of non pigmented PTFE and 316L powder
Tuf-Flex®	Bonded PTFE with EPDM substrate
Tri-Bond®	Bonded PTFE with FKM substrate, DIN & ISO only

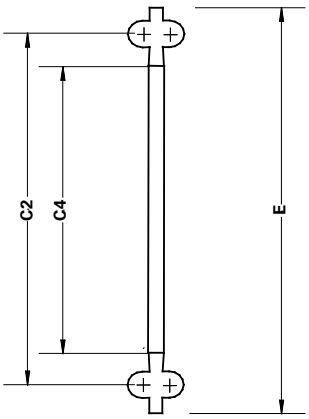
Typical Gasket Guidelines

	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*
Tuf-Flex®	1	1	1	1	1	1	1	-20°C to 150°C
Tri-Bond®	1	1	1	1	1	1	1	-30°C to 175°C
Food-Flex	X	2	1	2	1	2	2	-35°C to 122°C
Tuf-Steel®	1	1	1	1	1	1	1	-212°C to 288°C
PTFE Solid	1	1	1	1	1	1	3	-74°C to 260°C
PTFE Envelope (EPDM)	2	2	1	1	1	1	3	-30°C to 150°C
PTFE Envelope (FKM)	2	1	1	1	1	1	3	-30°C to 170°C
Silicone Platinum cured	2	2	2	2	2	2	1	-40°C to 230°C
FKM Fluoroelastomer	2	2	2	2	2	2	2	-30°C to 205°C
EPDM Peroxide cured	3	3	3	3	3	3	3	-20°C to 150°C
								*recommended

Dimensional Chart

DIN32676	BS4825	ISO1127	SMS 3017	OD-BPE ISO2852	SCH 5	E	C4 PTFE	C4 ELASTOMER	C2
DN06				1/4"		22	4	4,2	
DN08						22	6	6,2	
DN10				3/8"		22	8	8,2	
DN12						22	10	10,2	
	1/2"			1/2"		22	9,6	10,8	
DN14						22	12	12,2	
DN16						22	14	14,2	
DN18	3/4"		DN18	3/4"		22	16	16,2	
DN08						34	8		27,5
DN10						34	10	10,2	27,5
		DN08				34	10,3	10,5	27,5
		DN10				34	14	14,2	27,5
DN15						34	16	16,2	27,5
		DN15				34	18,1	18,2	27,5
DN20						34	20	20,2	27,5
DN10						50,5	10	10,2	43,5
		DN10				50,5	14	14,2	43,5
DN15						50,5	16	16,2	43,5
DN20						50,5	20	20,2	43,5
		DN15				50,5	18,1	18,4	43,5
	1"		DN25	1"		50,5	22,1	22,5	43,5
		DN20				50,5	23,7	23,9	43,5
DN25						50,5	26	26,2	43,5
		DN25				50,5	29,7	29,9	43,5
					1"	50,5	30,3	30,5	43,5
			DN33,7			50,5	31,3	31,5	43,5
DN32						50,5	32	32,2	43,5
	1,5"			1.5"		50,5	35,1	35,3	43,5
			DN38			50,5	35,6	35,8	43,5
DN40						50,5	38	38,2	43,5
		DN32				50,5	38,4	38,6	43,5
		DN32				64	38,4	38,6	56,5
		DN40				64	44,3	44,5	56,5
					1,5"	64	45,1	45,3	56,5
			DN51			64	48,6	48,8	56,5
	2"			2"		64	47,4	47,8	56,5
DN50						64	50	50,2	56,5
		DN50				77,5	56,3	56,5	70,5
					2"	77,5	57,2	57,4	70,5
	2,5"		DN63,5	2.5"		77,5	60,5	61	70,5
DN65						91	66	66,2	83,5
					2,5"	91	68,8	69	83,5
		DN65				91	72,1	72,3	83,5
	3"		DN76,1	3"		91	73,2	73,5	83,5
DN80						106	81	81,2	97
		DN80	DN89		3"	106	84,3	85,1	97
	4"		DN101,6	4"	3.5"	119	97,5	98,2	110
DN100						119	100	100,2	110
DN115		DN100		4.5"	4"	130	109,7	110,5	122
				5"		144	125	125,4	134,5
DN125						155	125	125,4	146
		DN125				155	134,5	134,7	146
	5,525"			5.5"	5"	155		135,9	146
				6"		167	146,9	147,2	156,5
DN150						183	150	150,4	174
	6,625"	DN150			6"	183	163,2	163,3	174
				8"		217,4	197,8	198	207
DN200						233,5	200	200,2	225
	8,625"	DN200			8"	233,5	213,9	214,2	225
DN250				10"		268	250	250,2	257
	10,625"	DN250			10"	286	268	268,2	276
DN300				12"		319	300	300,2	309
	12,625"	DN300			12"	338	319	319,2	328





Screens

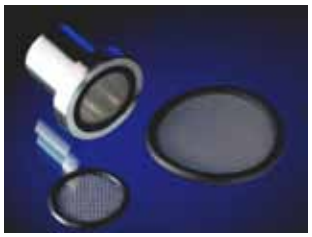
Our screens are not used the same way as filters, although it can be considered a filter. These screens are most of the time a single layer wire filter, with a rectangular opening. Retention vary from 6000 µm down to 10 µm, ranging from thick wire to thin filter cloth.
Most of the time we use screens as a safety measure. Either to protect a pump in a startup phase or to take out the last potential particles in a filling machine.

Screens can be supplied with 3.1B certificates. Flat screens are available from ½" through 6" in TC connections.

Ultrapharma is introducing a full screen line for DIN32676, DIN11864 and ISO1127 standards.

Sock screens offers up to 300% more open area and more soil collection capabilities than conventional flat screens. Available from 1,5" through 4" TC connections.

DIN11864 screens



Screen Reference Chart

Approx. Retention in Microns	Opening in mm	Mesh (wire/inch)	Open Area %	Filter Cloth	Filter Cloth Thickness in mm
5156	5,156	4x4	65,9		
3340	2,794	6x6	62,4		
2464	2,464	8x8	60,2		
1905	1,905	10x10	56,3		
1532	1,524	12x12	52,4		
1306	1,295	14x14	51,8		
1130	1,143	16x16	50,7		
979	0,991	18x18	48,2		
864	0,864	20x20	46,2		
703	0,711	24x24	44,1		
516	0,508	30x30	37,2		
381	0,381	40x40	36		
318	0,330	50x50	30,3		
233	0,229	60x60	30,3		
160	0,178	80x80	31,4		
140	0,152	100x100	30,3		
118	0,127	120x120	30,9		
103	0,102	150x150	37,2		
96		-	-	20x200	0,838
80	0,076	180x180	34,3		
74	0,051	200x200	33,6		
70			-	120x180	0,254
65			-	120x200	0,229
61	0,051	250x250	36		
50			-	120x330	0,254
43	0,025	325x325	-	-	
40	-		-	120x400	0,229
35	-		-	120x500	0,229
30	-			120x600	0,229
25	-			200x600	0,152
21	-			200x830	0,152
10	-			200x1150	0,152

Orifice plates

Ultrapharma offers a very wide range of Orifice Plates, used to modify flow patterns in critical systems. Orifice plates are made in 316L stainless steel and can be electro polished as an option. Standard plates are delivered without hole. We offer custom drilled holes either eccentric or concentric.

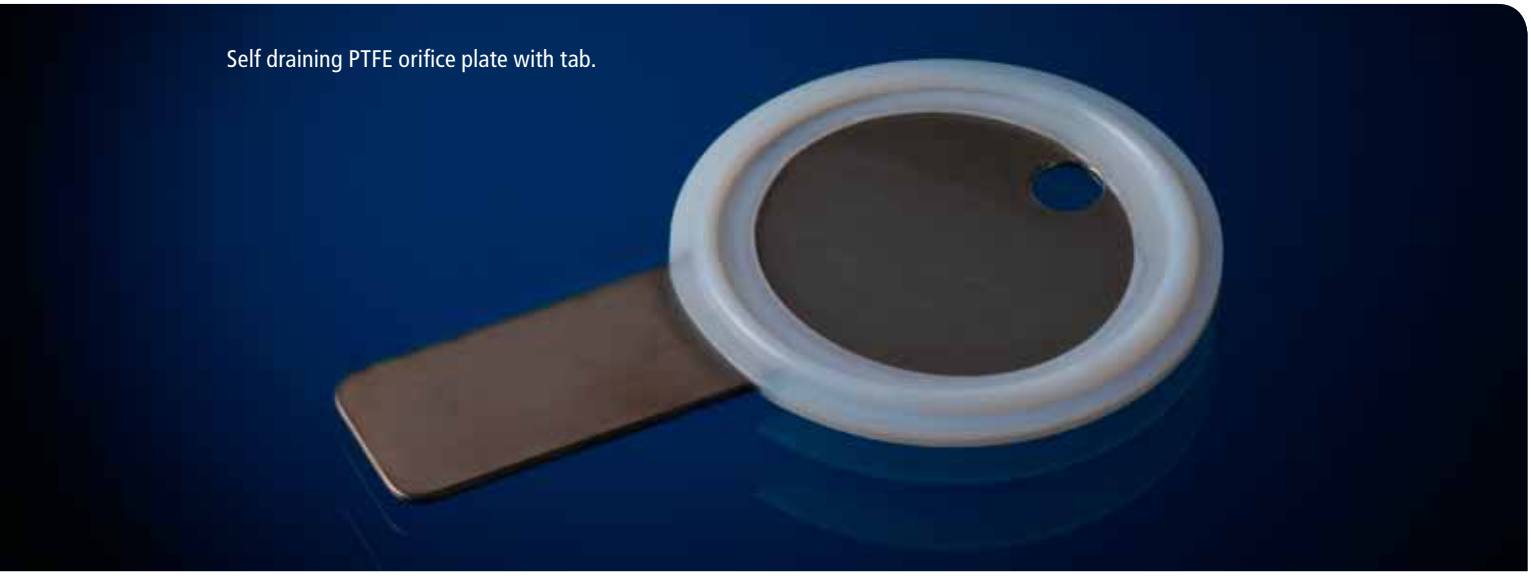
A new innovation in the range of plates are the plates used in vertical pipelines. A flat plate horizontal is not self draining, a conical plate is self draining.

Available from ½" through 6"
Sealing material:
EPDM, FKM, Silicone, PTFE, Tuf-Steel.

Tabs help to visualize the presence of an orifice plate "in line" easy to see from the outside. Extra text can be laser engraved on the tab indicating hole size for example.

DIN32676 DN10 orifice plate´s

Vertical piping orifice plate´s for full drainage



Self draining PTFE orifice plate with tab.

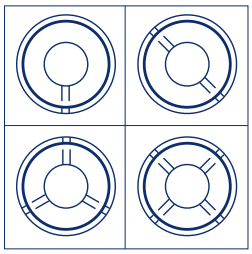
Smart Gaskets

The Rubberfab Smart Gaskets® have become a standard tool for Validation Engineers. Thermal mapping is an easy task with the Smart Gasket®, a reliable tool for a temperature probe.

A standard sanitary flange utilizing the Smart Gasket® Thermocouple Gasket obtains the critical thermal mapping information needed during the validation process without interference due to incorrect assembly.

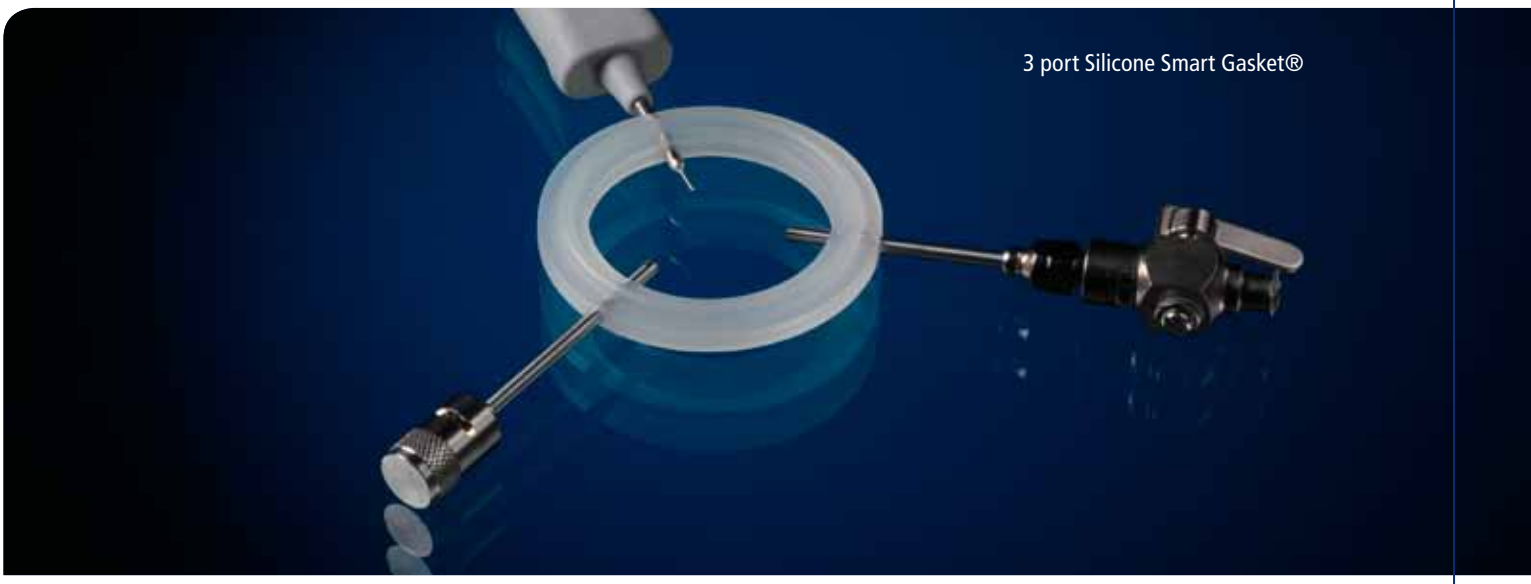
Available in ASME BPE ½" - 4"
DIN32676 DN20 (34 mm flange)
ISO1127 DN50 (77,5 mm flange)

Materials:
EPDM
Platinum Silicone
FKM Fluoroelastomer



1, 2, 3 or 4 ports are available

The Smart Gasket® is 2x as thick as a standard gaskets and therefore they requires a special stainless steel clamp. The clamp is available with the same amount of slots/ports as the gasket itself.



3 port Silicone Smart Gasket®

Tuf-flex®

Tuf-Flex® the ultimate pharmaceutical sanitary gasket, is setting new standards for purity, performance, flexibility and is the world's first unitized gasket. A Tuf-Flex® gasket's contact surface is PTFE unitized to an EPDM rubber inner core. This totally bonded construction provides the inert, non-stick benefits of PTFE with the memory of an elastomeric gasket without fear or risk of pigmentation or spalling. Designed to meet critical requirements in biopharmaceutical, ultra-pure water, WFI and difficult aseptic processing applications. Tuf-Flex® extended service life increases up-time by outperforming other gaskets by eliminating costly process interruptions.

Available sizes: ½" through 6"
Material: PTFE/EPDM
Temperature range -20°C to 150°C
Meets: USP Class VI-121°C
Meets: FDA CFR 177.1550

RUBBER FAB technologies group

Solid PTFE | Envelope PTFE | Tuf-Flex® | Tri-Bond®

Tri-Bond®

Ultrapharma has developed Tri-Bond® an identical product as Tuf-Flex® but for DIN32676 and ISO1127. The contact surface is PTFE and the core is FKM. It also has the lip build in for easier installation.

Available sizes: DN10 through DN100
DIN32676 & ISO1127
Material: PTFE/FKM
Temperature range -30°C to 175°C
Meets: USP Class VI-121°C
Meets: FDA CFR 177.1550

Tuf-Steel®

Tuf-Steel® a Rubberfab market innovation, is composed of a unique proprietary blend of non-pigmented PTFE and 316L passivated and atomized stainless steel. Testing and many years of documented application usage has demonstrated that Tuf-Steel® is the choice for perfect surface performance, outstanding durability, extended service life and increased up-time in both SIP and WFI applications. Tuf-Steel® is ideal for sanitary steam and extreme temperature processes. Especially when large temperature fluctuations are present Tuf-Steel® will eliminate the need for re-torque clamps. The gasket will move with the temperature and will maintain sealing capabilities, no leaks. The superior strength of Tuf-Steel® eliminates creep and cold flow providing a leak-free seal.

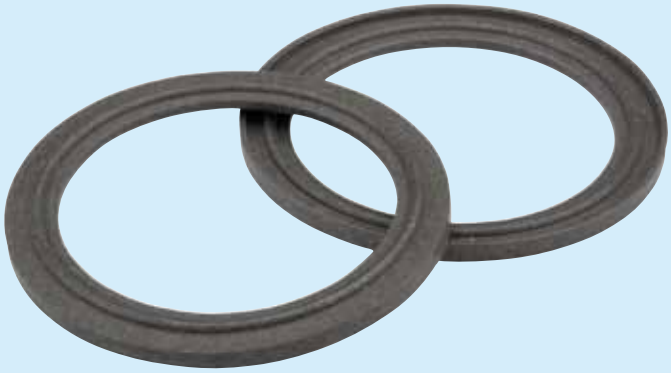
Available sizes: ½" through 12"
Material: PTFE/316SS powder
Temperature range -212°C to 288°C
Meets: USP Class VI-121°C
Meets: FDA CFR 177.1550

RUBBER FAB
technologies group

Tuf-Steel®

Ultrapharma has developed an identical product as Tuf-Steel® but for DIN32676 and ISO1127. It also has the lip build in for easier installation.

Available sizes: DN10 through DN100
DIN32676 & ISO1127
Material: PTFE/316SS
Temperature range -212°C to 288°C
Meets: USP Class VI-121°C
Meets: FDA CFR 177.1550



Special Gaskets

Removable Tuf-Steel gaskets

Tuf-Steel DN32 removable orifice plate

A new innovation for orifice plates in DIN32676 and ISO1127. We all know the good things that Tuf-Steel brings. We developed a system that will allow you to easily install orifice plates with different centre holes. Very useful in testing conditions.

Tuf-Steel®

Assembly

Installation is easy. Place the 316L orifice plate in one of the Tuf-Steel gasket halves and place the other Tuf-Steel part as a lid on top. Use two Stainless Steel ferrules and press them together until you hear 'KLICK'

Tuf-Steel®

Tuf-Steel removable Rupture disc Seal

Rupture disc seals are normally not replaceable because of the tabbed information label. These are factory installed. By using the same principle as above with an orifice plate you are now able to place a new gasket around your valuable Rupture Disc.

Tuf-Steel®

Tuf-Steel removable Screen Gasket Seal

It is also possible to use the removable Tuf-Steel gasket in combination with screens. From 10 mesh to 80 mesh it is possible to use this system. Finer filters will break out as they have no strength.

Available up to 64 mm TC flange diameters
(2" BPE or DN50 DIN32676)

With our validated compounds whether PTFE or an elastomeric version we can make virtual any product for you. On the side some examples of custom made parts.

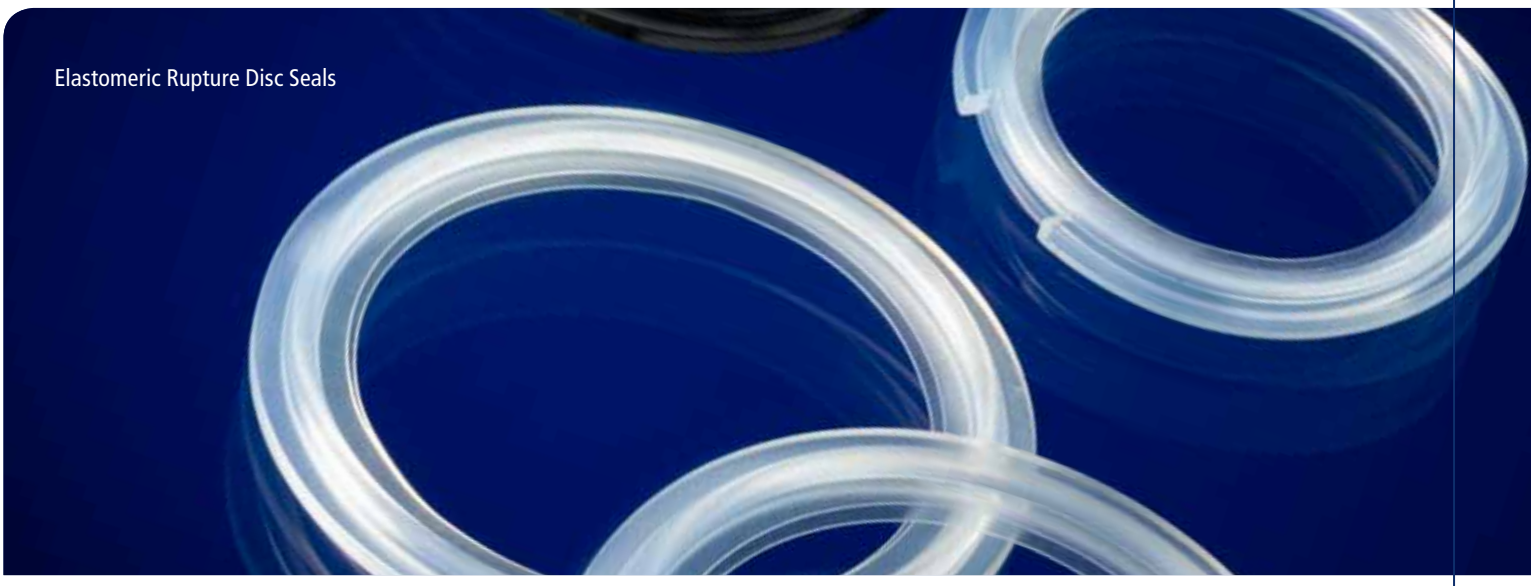
Validated materials:

EPDM	PTFE
Platinum Silicone	TFM
FKM (Viton®)	Tuf-Steel®

Tuf-Steel washers

Tuf-Steel sheets allow us to water jet cut custom seals for example heat exchangers

EPDM and Silicone Sample port septum



Elastomeric Rupture Disc Seals

Identification Gaskets

Identification is a hot item in many processes today. Engineers need to be certain that all gaskets are replaced with new seals, difficult task if all gaskets have the same color. We are now introducing EPDM compound in several colors, Green, Yellow, Blue, Gray, White, Red and the well known Black version. EPDM gaskets are still one of the most common used seals.

- Identify dedicated product lines
- Identify specific process lines
- Color code change out program

Meets FDA CFR 177.2600
Passes USP Cytotoxicity testing
USP Class VI (under testing)

Tuf-Steel can be color coded as well, ASME BPE Standard only.

Traceability

Another way of Identification is to laser an unique lot number on the side of the gaskets. This way you will have, and maintain, full traceability of material in contact with media.

This feature is possible on any type of gasket.

O-ring Seals

The O-ring is an exceptionally versatile sealing device. Countless applications make it the world's most popular seal.

Materials available:

- Platinum Silicone
- EPDM
- FKM Fluoroelastomer
- PTFE
- FEP/FKM encapsulated
- Tuf-Steel®
- NBR

Dimensions available:

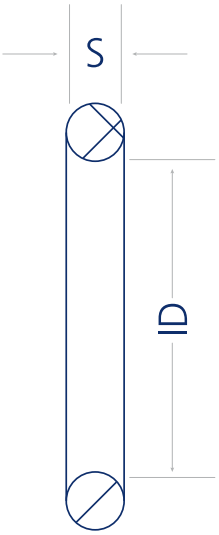
- DIN11864
- AS 568
- Custom sizes

Credentials:

Meets FDA CFR 177.2600
Meets FDA CFR 177.1550
Passes USP Cytotoxicity testing
USP Class VI testing

O-rings can be made in different colors ask us about the possibilities.

DIN11864	IDxS	
	ISO1127 PIPE	**DIN11850 PIPE**
DN10	16 x 3,5	12 x 3,5
DN15	20 x 3,5	18 x 3,5
DN20	26 x 3,5	22 x 3,5
DN25	32 x 5	28 x 5
DN32	40,5 x 5	34 x 5
DN40	46,5 x 5	40 x 5
DN50	58,5 x 5	52 x 5
DN65	73,5 x 5	68 x 5
DN80	86,5 x 5	83 x 5
DN100	111 x 5	102 x 5
DN125		127 x 5
DN150		152 x 5



NEW

Single use Pressure Gauge

Ultrapharma has developed a Single Use Pressure Gauge for the Bio-Pharmaceutical industry. This mini pressure gauge is available in two high purity materials; TPE and PTFE. The PTFE version is made for use in a more chemically aggressive environment, the TPE version is designed for water based applications. The TPE version has a build in seal. The pressure range is from 0-2 Bar (0-30 PSI).
Although designed for the bio-pharmaceutical industry it will find its way in Universities, Laboratories and other industries. The connection is a ¾" Tri-Clamp, 25 mm flange diameter.

Purpose of this gauge is to provide an indication of pressure in a single use environment. The accuracy of the gauge is approximately ± 10%

Sterilization by Autoclave
Dimension is Ø30 mm (W) x 40 mm (H)

PTFE version
Meets USP Class VI
Meets FDA CFR 177.1550
Maximum temperature exposure 125°C
Liquid filled

TPE version (white)
Meets FDA CFR 177.2600
(USP Class VI under evaluation)
Maximum temperature exposure 80°C
Liquid filled
Tri-Clamp seal build in

Certification

USP-NF

The United States Pharmacopoeia and the National Formulary are the official compendia of standards for drug, excipients dietary supplements, and other therapeutic products for the United States and several other countries. It is an independent organisation under one cover. The USP contains legally recognized standards of identity, strength, quality, purity, packaging, and labelling for more than 3400 drug substances, preparations and products. When a standard is published in the USP-NF, federal and state government agencies, such as FDA have the authority to enforce them and to ensure that products comply.

Most important test protocols for elastomer and perfluorocarbon products (seal) are:
USP Class VI testing Part 88, Biological reactivity test, in vivo. It is designed to determine the biological response of animals to elastomerics, plastics and other polymeric material with direct or indirect patient contact, or by the injection of specific extracts prepared from the material under test.

USP Class VI testing Part 87, Cytotoxicity test, Biological reactivity test, in vitro. It is designed to determine the biological reactivity of mammalian cell cultures following contact with the elastomeric plastics and other polymeric materials with direct or indirect patient contact or of specific extracts prepared from the material under test.

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.

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 us may be safely used in producing, manufacturing, packaging, processing, preparing, treating, transporting or holding food, subject to the provisions of this section.

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 (EMEA/410/01) in which they give guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medical products.

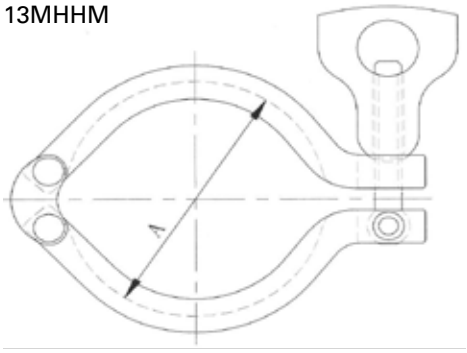
Whereas many of our products are used in human or veterinary medicine production plants, it is important to know if any of our products have been in contact or are produced with animal derived ingredients.

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).

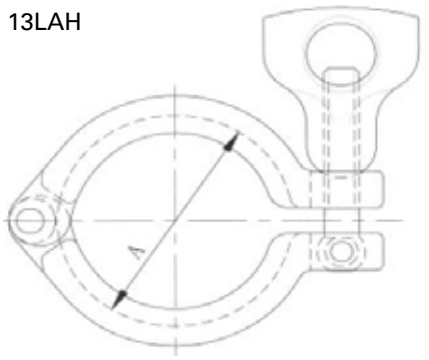
Stainless Clamps

304 (1.4301)	Inch	Flange OD Ø	A mm	PART NO.
DN/NW				
20-32	1 1/2″	50,50	53,59	13MHHM-150
40	2″	64	66,90	13MHHM-200
50	2 1/2″	77,50	80,59	13MHHM-250
65	3″	91	93,98	13MHHM-300
80	3 1/2″	105	108,28	13MHHM-350
100	4′	119	122	13MHHM-400
115	4 1/2″	130	133,68	13MHHM-450
	5″	144,70	148,23	13MHHM-500
	6″	167,10	170,05	13MHHM-600
150	6-5/8″	183	187	13MHHM-6625
	8″	218	220,85	13MHHM-800
200	8-5/6″	233,50	238	13MHHM-8625
250	10″	267,20	272,80	13MHHM-1000
300	12″	319	322,45	13MHHM-1200
DN/NW				
8-20	DIN 34	34	37,7	13LAH-034
	1/2″	25	31,75	13LAH-050
	3/4″	25	31,75	13LAH-075
20-40	1-1/2″	50,50	53,59	13LAH-150
40	2″	64	66,90	13LAH-200
50	2-1/2″	77,50	80,59	13LAH-250
65	3″	91	93,98	13LAH-300
80	3-1/2″	106	110	13LAH-350
100	4″	119	122	13LAH-400
125	5-525″	155	158	13LAH-550
	6″	167,10	170,05	13LAH-600
150	6-5/8″	183	187	13LAH-6625
200	8-5/6″	233,50	238	13LAH-8625

13MHHM



13LAH



Clamp versions

13LAH

13MHHM

13MHHS

13MHP

Different Wing Nuts are available

Clamps are made in 304SS (1.4301) stainless steel.
Clamps carry Heat numbers.

Semi Closed Wing Nut

Ribbed Wing Nut

Butterfly Wing Nut

Closed Wing Nut

Hex Nut

NEW

Smart Clamps

RUBBER FAB technologies group

The "HALF-TURN" Sanitary Smart Clamp is a NEW Rubberfab innovation. It allows to assemble and dismantle a Tri-Clamp connection in only Half a Turn. This dramatically increases production uptime, while reducing hand & finger strain (RSI).
Multiple Torque settings for use with all Sanitary gaskets, eliminating the need for costly compression control gaskets.

Threadless system prevents soil and bacteria entrapment.

Supports ASME-BPE standards as well as DIN32676, BS4825 and ISO1127, made in 304SS.
Available in ½" (25 mm), DIN32676 (34 mm), 1" (50,5 mm) , 2" (64 mm) , 2.5" (77,5 mm), 3" (91 mm), DIN32676 (106 mm), 4" (119 mm) and 6" (167 mm).

"Half-Turn"Clamp

Clamp (position) Identification

Single pin Clamps are also available in colors Gold, Black and Blue. They can be used to identify a position in your system that hides a screen or Orifice plate, which you can normally not see from the outside.

Gold

Black

Blue

Lock-Out tab

The "Lock-Out" tab can be a helpful tool to secure certain piping connections so they are not opened without breaking the seal. The Lock-Out tag is supplied with a sequential unique number and can be documented in validation files. It is now easy to register certain points in a process line. No more homemade tie-raps.

The color of these can also be used to identify a dedicated product line, or you may use it to identify for example a screen with a yellow Lock-out and an Orifice plate with a blue Lock-out.

To take away a Lock-Out tag you need to cut both wires. It is a single use system. Available colors are; Green, White, Yellow, Blue and Red.

Get more information about other Sanitary Solutions on our website

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