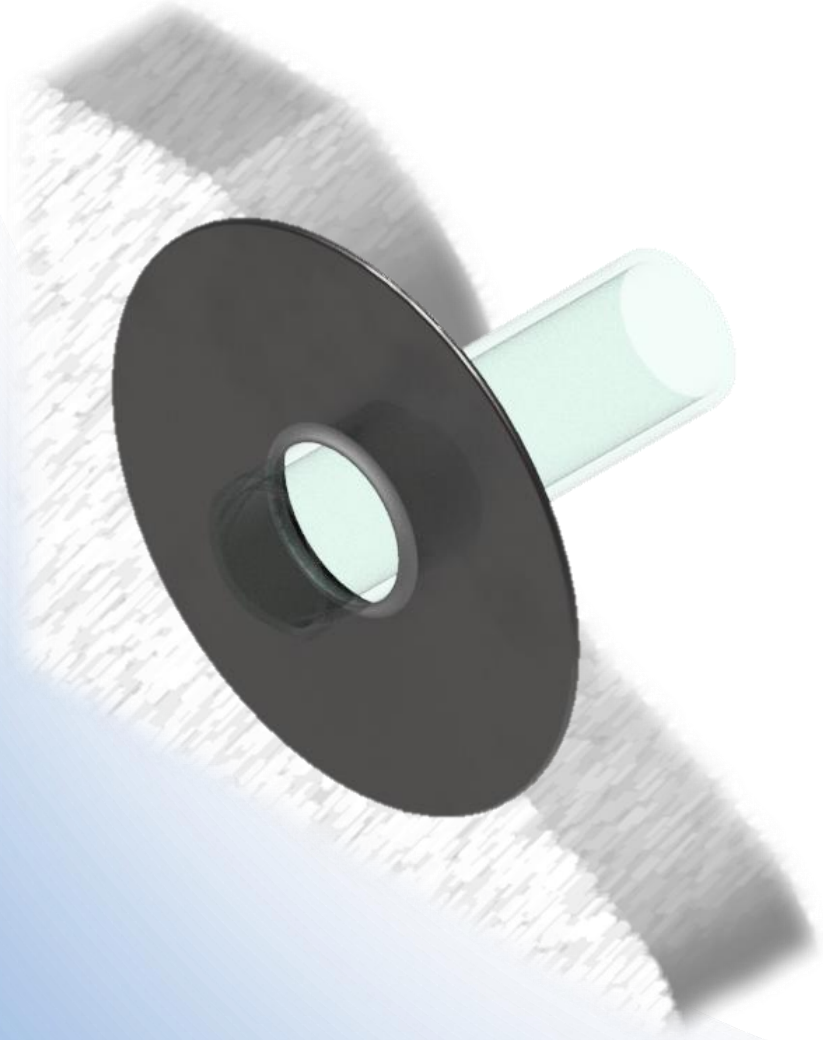
Pipe mono seal penetration system

PCR® Mono sealing system

PCR pipe sealing systems for penetrations through walls, ceilings, or floors



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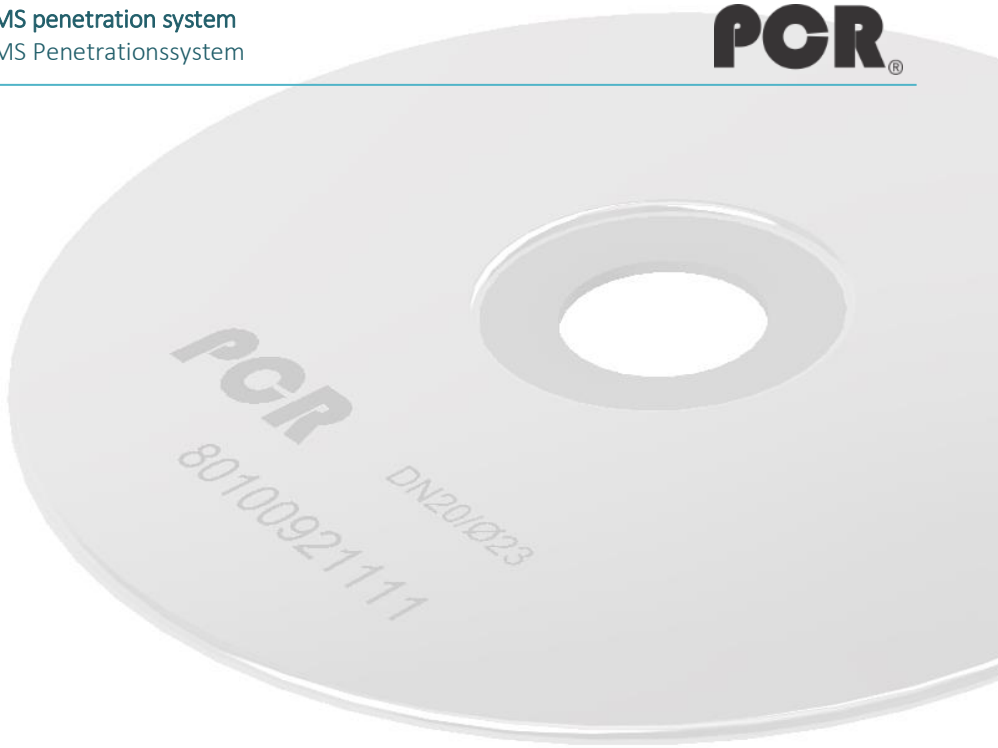

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Subject to technical modification without prior notice.

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Safety instruction

The element may only be installed by authorised and qualified persons. Maintenance and processing may only be done by authorised personnel who are trained for the work.

Intended use

The system provides sealing for pipe penetrations between spaces of various classifications to provide quality sealing within the acceptable pressure and temperature limits while taking into account the chemical and corrosive effects on the sealing element. In certain conditions of use it is necessary to check the stability of the element in the environment. Suitable for buildings with cleanliness classified according to the ISO 14644-1 and GMP standard.

Danger

There is no direct danger. Danger can be caused by improper installation, which can consequently affect functioning, causing improper sealing which may lead to cross contamination. Contamination resulting from improper assembly may affect the product and the health of the user.

The assembly and maintenance may only be done by authorized persons in room temperatures and with zero difference in pressure! During removal sharp pieces may cause cuts, therefore extra care is required during dismantling. The use of protective measures is necessary during assembly and dismantling.

ATEX (Atmosphères Explosibles)

The sealing element does not indicate a potential for accidental ignition and is therefore not subject to the anti-explosion directive 94/9/ES.

Can be used in explosion hazard zones 2, 22 (1999/92/ES).

Preparations do not receive an explosive hazard label.

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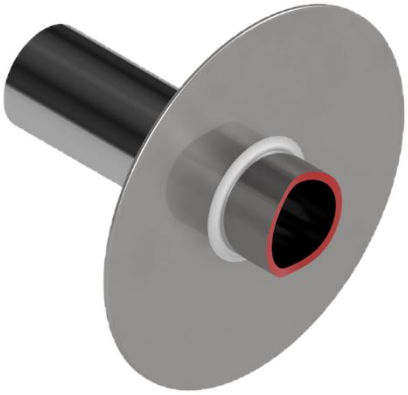
Product description

The **PCR-MS** sealing system for penetrations is a fast and easy provision of in situ airtightness, waterproofing, and sound reducing for pipe penetration points. It is recommended and useful for sealing pipe systems penetrating concrete walls, so-called sandwich panels, sheet metal, laboratory devices, and machines. Installation is simple and fast without additional elements or specificities and without the use of special tools.

- The **PCR-MS** material for penetrations with a mono seal is composed of two metal elements and a sealing part. The **PCR-MS** sealing element is made from a controlled material and is suitable for use in clean and sterile environment classified under the ISO 14644-1 and GMP standard.

- The metal part of the **PCR-MS** system is made of quality acid-resistant stainless steel, suitable for use in the chemical, pharmaceutical, and food industries in the most demanding systems, and is resistant to all external influences.

- The second part of the assembled **PCR-MS** sealing element is the mono seal, the specification of which is jointly decided on by the user and manufacturer according to the product's purpose, function, and the position of the installed sealing element. The shape of the sealing part of the element is designed to provide the best sealing and the best fit to the pipe system. The design of the seal also allows for vibrations and deviations without any impact on the basic sealing function of the **PCR-MS** sealing element. The proper assembly of the **PCR-MS** sealing element on the pipe section and in the place of penetration provides high-quality sealing, damping of sounds and vibrations from the pipe system to the surface or the other way around. The seal's tight fit ensures the quality of the sealing in all positions.



Pressure sealing ensures up to Δp 0.3 bar of pressure difference between environments of penetration.

The **PCR-MS** sealing element is standard according to the pipe system diameter and is therefore manufactured according to the size of the pipe system in penetration. The sealing element is fitted exactly to the diameter of the pipe system. The seal is specially designed for any pipe system size. The exact fit of the **PCR-MS** sealing element to the pipe system ensures high-quality sealing. The position and assembly of the penetration is not restricted by orientation; therefore the element can be used to seal penetrations through walls, ceilings, or floors. The **PCR-MS** sealing element is designed to optimally fit the pipe system in the given conditions and therefore ensure the best possible sealing in the given conditions.

For affixing the **PCR-MS** sealing element we recommend the use of silicone sealant or equivalent adhesive sealant suitable for use in controlled spaces, which enables the attachment of the **PCR-MS** sealing element to the surface of the point of penetration. We recommend adhesion to the wall of the penetration with an adhesive sealant of the quality which is the standard in the given space and with the prescribed requirements of quality and adhesion. By using an appropriate adhesive we can achieve the optimal installation of the element, as well as impermeability to water, dust, insects, and bugs.

The cleaning and maintenance of **PCR-MS** elements is simple and does not require special products or tools. Because the element does not have large surfaces that could potentially collect dust or dirt and that cannot be reached for cleaning, maintaining cleanliness is the same as for other parts in the space without any particularities. The visible surface of the element can be cleaned with the use of cleaning products and disinfectants.

Application

PCR-MS stainless steel sealing element with a mono seal for pipe penetration between controlled environments is used in systems requiring special conditions.

A Wide Area of Application

- clean room in manufacturing pharmaceutical products
- environmental protection from chemical processes
- maintains ambiance for food processing
- protects the semiconductor fabrication

The Suitability for Use

- in areas with multiple temperature fluctuations
- machines, mechanical parts that cause vibration
- retention of atmospheric conditions in the area
- provides clean environment for laboratories and production

Function

- insensitive to liquid, moisture or solid particles
- vibration resistance / redundant
- electro-conductive
- biologically and chemically resistant

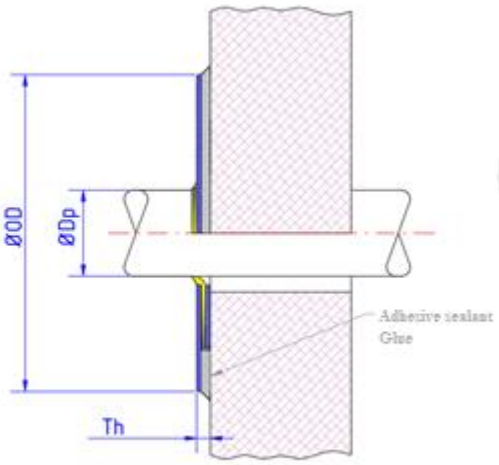
Properties

- simple cleaning
- ensures cleanliness - sterile space
- does not contain animal products
- limited use in explosive hazard zones

Documentation

- checklist
- certificate FDA
- certificate EN 10204/3.1
- instructions for use

Dimensions



Sealing element **PCR - MS**

ØOD	PCR element dimension (diameter)
ØDp	External pipe diameter
Th	PCR element dimension total thickness

Standard penetration element dimension / pipe dimension:

No.	Pipe	Standard	ØDp	ØOD	Th
1	DN04 , 1/4"	DIN 11866 Series A,C (DIN11850,ASTM.BPE)	Ø6 – Ø6,35	Ø 60	3 mm
2	DN06	DIN 11866 Series A (DIN11850)	Ø 8	Ø 60	3 mm
3	DN08 , 3/8"	DIN 11866 Series A,B,C (DIN11850,ISO1127,ASTM.BPE)	Ø9,53 – Ø10,3	Ø 70	3 mm
4	DN8-10 , 1/2"	DIN 11866 Series A,B,C (DIN11850,ISO1127,ASTM.BPE)	Ø12 – Ø13,7	Ø 70	3 mm
5	5/8''	METRIC / ISO / BS	Ø14 – Ø16	Ø 70	3 mm
6	DN10 -15	DIN 11866 Series B (ISO1127), DIN11850-R1	Ø17,2 – Ø18	Ø 70	3 mm
7	DN15-20 , 3/4"	DIN 11866 Series A,C (DIN11850,ASTM.BPE)	Ø19 – Ø20	Ø 70	3 mm
8	DN15 -10	DIN 11866 Series B (ISO1127), DIN11850-R1	Ø21,3 – Ø22	Ø 80	3 mm
9	DN20	DIN 11866 Series A (DIN11850-R2)	Ø 23	Ø 80	3 mm
10	DN25, 1''	DIN 11866 Series C (ASTM.BPE), SMS(3008)	Ø25 – Ø25,4	Ø 80	3 mm
11	DN20	DIN 11866 Series B (ISO1127)	Ø 26,9	Ø 80	3 mm
12	DN25	DIN 11866 Series A (DIN11850-R2)	Ø28– Ø30	Ø 80	3 mm
13	DN25-32	DIN 11866 Series B (ISO1127), SMS(3008)	Ø32– Ø34	Ø 100	3 mm
14	DN32	DIN 11866 Series A (DIN11850-R2)	Ø 35	Ø 100	3 mm
15	1''1/2, DN40	DIN 11866 Series C (ASTM.BPE), SMS(3008)	Ø38 – Ø38,1	Ø 100	3 mm
16	DN32-40	DIN 11866 Series A,B (DIN11850,ISO1127), DIN11850-R1	Ø40 – Ø42,4	Ø 100	3 mm
17		METRIC / ISO	Ø43 – Ø44,5	Ø 100	3 mm
18	DN40-50 , 2"	DIN 11866 Series B,C (DIN11850,ISO1127,ASTM.BPE), SMS(3008)	Ø48,2 – Ø51	Ø 120	3 mm
19	DN50	DIN 11866 Series A (DIN11850-R2)	Ø52 – Ø53	Ø 120	3 mm
20	DN50	DIN 11866 Series B (ISO1127)	Ø 60,3	Ø 120	3 mm
21	2''1/2	DIN 11866 Series C (ASTM.BPE)	Ø 63,5	Ø 120	3 mm
22	DN65	DIN 11866 Series A (DIN11850-R2)	Ø70 – Ø73	Ø 140	3 mm
23	DN65 , 3''	DIN 11866 Series B,C (ISO1127,ASTM.A270)	Ø76 – Ø76,2	Ø 140	3 mm
24	DN80	DIN 11866 Series A (DIN11850-R2)	Ø84 – Ø85	Ø 150	3 mm
25	DN80	DIN 11866 Series B (ISO1127)	Ø 88,9	Ø 150	3 mm
26	DN100, 4''	DIN 11866 Series A,C (DIN11850,ASTM.BPE)	Ø101,6 – Ø104	Ø 160	3 mm
27	DN100	DIN 11866 Series B (ISO1127)	Ø 114,3	Ø 170	3 mm
28	DN125	DIN 11866 Series A (DIN11850-R2)	Ø 129,0	Ø 180	3 mm
29	DN125	DIN 11866 Series B (ISO1127)	Ø139,7– Ø141,3	Ø 200	3 mm
30	DN150, 6''	DIN 11866 Series A,C (DIN11850,ASTM.BPE)	Ø152,4– Ø154	Ø 220	4 mm
31	DN150	DIN 11866 Series B (ISO1127)	Ø 168,3	Ø 240	4 mm
32	DN200, 8''	DIN 11866 Series A,C (DIN11850,ASTM.BPE)	Ø203,2– Ø204	Ø 280	4 mm

Table 1 (standard dimension sealing element PCR-MS)

© PCR-MS/Jun-2018 / M2418 – R03

Identity code

Penetration element configuration:

PCR - MS

40	2	07	3

	PCR-MS
40	PCR-MS

	DIN
1	DIN 11866 Series A(DIN11850)
2	DIN 11866 Series B (ISO1127)
3	DIN 11866 Series C (ASTM BPE)
4	DIN11850-R1
5	SMS(3008)
6	Other pipe diameter

	1 (DN)	2 (DN)	3 inch	4 (DN)	5 inch	6
01	×	×	×	04	×	×
02	×	6	1/8"	06	×	×
03	×	8	1/4"	08	×	×
04	10	10	3/8"	10	×	×
05	15	15	1/2"	15	×	∅14
06	20	20	3/4"	20	×	∅24
07	25	25	1"	25	1"	×
08	32	32	×	32	1"1/4	∅30
09	40	40	1"1/2	40	1"1/2	∅42
10	50	50	2"	50	2"	×
11	65	65	2"1/2	×	2"1/2	×
12	80	80	3"	×	3"	×
13	100	100	4"	×	4"	×
14	125	125	×	×	×	×
15	150	150	6"	×	×	×
16	200	×	8"	×	×	×

1	EPDM	blue
2	EPDM	white
3	EPDM	gray
4	EPDM	black EC
5	Silicon	red HT
6	Silicon	purple

Seal

No.	Material	Colour	Working temperature area	Remarks
1	EPDM	blue	-15 ^{0}C – 85 ^{0}C	
2	EPDM	white	-15 ^{0}C – 85 ^{0}C	
3	EPDM	gray	-15 ^{0}C – 85 ^{0}C	
4	EPDM	black EC	-15 ^{0}C - 85 ^{0}C	Electro-conductive
5	Silicon	red HT	-30 ^{0}C – 150 ^{0}C	High temperatures resistance
6	Silicon	purple	-30 ^{0}C – 200 ^{0}C	High temperatures resistance

Properties

PCR-MS sealing element ensures a primary property of sealing pipe penetrations between environments of various classifications. The excellent properties of the PCR-MS system come from the simple execution with the mono seal that tightly fits the pipe system in any position and given environment. The composition and function of the PCR-MS system requires manufacturing according to special procedures and from metal materials that are acid-resistant and suitable for use in food, pharmaceutical, and chemical industry with a metal parts certificate EN 10204/3.1 and sealing elements from materials of equal resistance with an FDA certificate. Specific properties of PCR-MS elements for the penetration of pipes, such as electro-conductivity, antistatic properties, or resistance to certain chemicals or high temperatures, are achieved with the appropriate choice of the material for the seal part, which is also checked and documented. In addition to the physical properties of PCR-MS, the documentation complementing and verifying these properties with the documentation of measurements and additional certificates of quality and suitability for use is also specific. The quality of the embedded material affects the quality of the product. The materials for composition and function are carefully selected according to the application of the PCR-MS sealing element.

The correct choice of PCR-MS sealing element enables resistance to changes in temperature without affecting the element's properties and function. The correct choice of the sealing element's material enables good performance in both low and high temperatures. The special selection of the sealing part of the element enables the sealing of pipe systems with very high temperatures of the medium in the pipe system. Durable resistance to high temperatures of up to 220°C is an additional option in PCR-MS mono seal elements.

The selection of the special material of the PCR-MS sealing element enables electrical conductivity between 103 and 106 ohm. Elements with special electro conductive properties are marked with the label .
The PCR-MS pipe penetration sealing element marked with an electrical conductivity label can be conditionally used in explosion hazard zones 2, 22 (1999/92/ES). The element does not receive an explosion hazard label. If the element is intended for areas and zones of conditional explosion hazard this needs to be disclosed at the time of ordering and defined together with the user. Such PCR-MS sealing elements are equipped with a special document MEASUREMENT REPORT EN 10204-2.2 with additionally performed conductivity measurements on the seal.

The PCR-MS pipe penetration sealing system is designed to perfectly damp vibrations and also works as a noise reducer while ensuring optimal sealing. The sealing and proper functioning of the PCR-MS sealing element is dependent on the proper installation of the pipe system. The sealing function is limited by vibration amplitude, which must not exceed 0.3 mm at a frequency of no greater than 30 Hz.

The PCR-MS waste element can be 100% recycled following correct procedure.

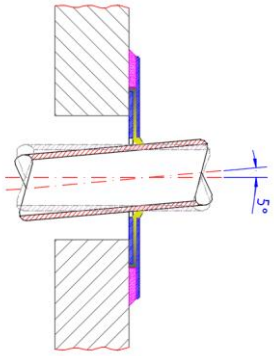
The element's properties are chosen from a spectrum of materials and colours of the sealant that are the most appropriate for installation in the given environment. The choice should be discussed with the manufacturer, who can advise on the choice of the appropriate sealing material.

The wide range of sealing materials provides resistance to chemical elements, solvents and cleaners, and the sealing element enables equally good resistance to high temperatures, certain vibrations and deviations in the pipe penetration, and ensures the safe functioning of the system with electro-conductive and electrostatic properties.

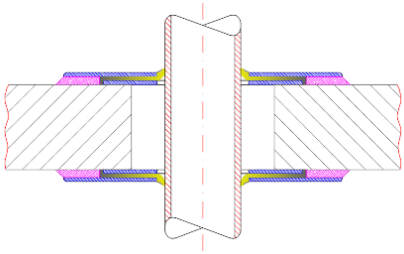
The technical properties of the PCR-MS sealing element are listed in the technical sheet as an appendix to the documentation.

Installation and placement

The installation of the **PCR-MS** pipe penetrations sealing element and the orientation of the penetration is practically unrestricted. The position of the penetration's sealing element can be installed for pipe system penetrating from the ceiling, the walls, or it can be used for floor penetration. The sealant ensures sealing and impermeability in any position. The sealing element cannot support or bear the pipe system at the penetration point. In the preliminary final installation of the **PCR-MS** sealing element it is necessary to position the pipe segment in the middle of the opening and to ensure a good fit of the sealing element on the surface of the opening. Before the final installation of the **PCR-MS** sealing element, the pipe segment must be statically fixed on both sides of the penetration point. The functioning of the **PCR-MS** element and the sealing of the penetration depend on the correct installation of the pipe system.



The placing of the **PCR-MS** sealing system on a pipe segment where it is necessary to provide a slope in the pipeline is carried out with a permitted deviation of the slope of the pipe segment and **PCR-MS** sealing element of up to 5°. A gradient of up to 5° is permitted and does not affect the functioning of the **PCR-MS** sealing element.



The manner of using the **PCR-MS** sealing element in more demanding circumstances. To ensure additional protection, the element must be placed on both sides of the pipe at the point of penetration into and out of the space. By using two **PCR-MS** sealing elements we maximize the protection of the seal of the pipe penetration.

Optimal installation and placement of the **PCR-MS** sealing element through the opening, which is of the prescribed size and must be smaller than the element's diameter **ØOD** by approximately 40 mm. The size of the opening of the pipe's penetration **ØOD-40 mm** is the optimal size of the hole for the correct installation of the **PCR-MS** penetration sealing element. The surface around the pipe penetration point which is covered by the sealing element must be smooth and must provide a good grip for the adhesive sealant with which the **PCR-MS** sealing element will be fixed to the surface to finish the installation.

The **PCR-MS** sealing element for pipe penetrations is suitable for installation into environments requiring cleanliness classification under the ISO 14644-1 and GMP standard.

Direct exposure of the **PCR-MS** sealing element to potential mechanical damage, sharp objects, and UV light can cause deformations in the sealing part of the element. As a result, the **PCR-MS** sealing element may lose the sealing function over time.

An important step in the installation of the **PCR-MS** sealing element is the preparation of the penetration. The hole needs to be planned according to the size of the penetration and the installed sealing element. The bore for the penetration must be within the prescribed limits; if that is not possible, the manufacturer needs to be consulted. If there is a need for larger or higher-quality sealing, the manufacturer of the **PCR-MS** sealing element needs to be consulted regarding the possibility of installing two sealing elements on each side of the penetration point.

Assembly

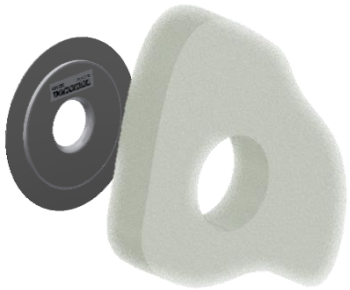
The assembly process of the **PCR-MS** sealing element for pipe penetrations to seal pipes penetrating through walls is simple and fast. The correct assembly does not require any additional tools or special additional elements. In preparing for the assembly it is important to correctly choose the size and specification of the **PCR-MS** sealing element for the penetration of a pipe system through the wall. The choice of options for the **PCR-MS** sealing element are listed in Table 1 and depend on the size of the pipe system. The function, conditions of placement, and the correct choice of the sealing element's material need to be coordinated with the **PCR-MS** sealing element manufacturer.

The penetration through the wall needs to be done at the size (dia. ∅) of the bore which is prescribed according to the size of the pipe and cannot be bigger than the prescribed size for the assembly of **PCR-MS** the pipe penetration sealing element:

Drilling ∅ hole (mm) = ∅ OD (mm) – 40 (mm) (Table 1)

Depending on the size of the passing pipe system penetrating through the opening it is crucial to choose the correct size of the **PCR-MS** pipe penetration sealing element. The assembly process begins with the correct choice of element size depending on the size of the passing pipe system and the correct choice of the material for the sealing part of the element depending on the conditions and impact in the functioning and the orientation of the **PCR-MS** pipe penetration element.

- The dimension of the penetration's opening (dia. ∅) needs to be defined according to the size of the passing pipe system and according to the size of the **PCR-MS** sealing element of the pipe's penetration through the wall. At the desired penetration point the wall must be penetrated at the size (dia. ∅) of the hole ± 5 mm.



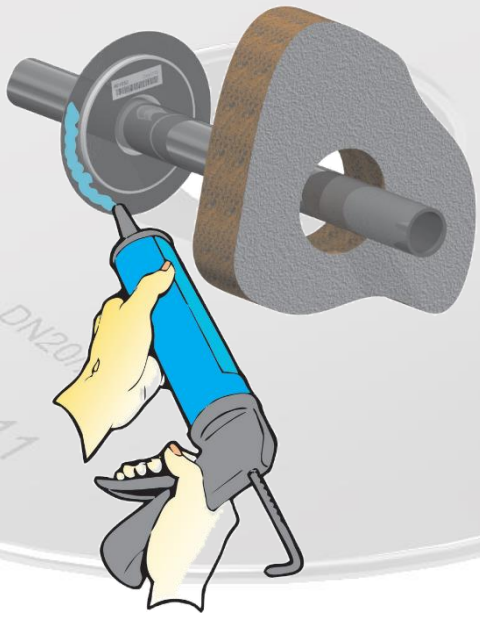
- The point of penetration and the hole must be clean of dust and foreign particles and must not be wet or greasy. The surface ready for the installation of the **PCR-MS** pipe penetration sealing element must be smooth and clean.

- The **PCR-MS** pipe penetration sealing element must be checked, cleaned, and placed on the prepared pipe segment. It is important to correctly place the **PCR-MS** sealing element; it is necessary to direct it according to the position of the penetration so that the face of the penetration element is oriented towards the interior in relation to the surface on which the sealing element will be fixed. The pipe segment with the correctly placed **PCR-MS** sealing element is positioned into place through the penetration point.

- The pipe segment with the installed **PCR-MS** sealing element needs to be fixed with a pipe support system. The pipe segment positioned through the penetration with the correctly placed **PCR-MS** sealing element needs to be statically affixed on both sides of the point of penetration so that the pipe segment is statically embedded. The affixing point of the pipe segment must be static before and after it passes through the penetration point. The correctly fitted pipe segment cannot deviate in any direction in relation to the penetration point. The distance between the pipe system's two static attachment points on either side of the penetration cannot exceed 0.5 m + the thickness of the penetrated wall.

- The fitting in place of the **PCR-MS** sealing element of the penetration and the final installation of the element is carried out in the final phase of the installation of the pipe system.

- The preparation for the finished assembly of the **PCR-MS** sealing element includes checking, cleaning, and degreasing of the surface of the sealing element as well as cleaning the surface of the penetration point. The surface of the penetration point must be clear of dust, degreased, and dry.



- Affixing is the process of even distribution of adhesive sealant to the clean and degreased back side of the **PCR-MS** sealing element on the thinner part, which is the prepared surface of the sealing element, as seen on the picture. The adhesive sealant must not be applied to the seal or the pipe segment itself. The visual completion of the sealant application is done after affixing into place and by removing and cleaning the excess application of adhesive sealant from the place of the seal and the pipe segment, as well as the penetration point. The sealing element placed into position should not be moved for the duration of the drying time prescribed by the manufacturer of the adhesive sealant.

- The installation of the **PCR-MS** sealing element is complete after a visual inspection of the fit of the sealing element to the pipe segment and the penetration surface.

The adhesive sealant for securing the **PCR-MS** sealing element must be environmentally friendly and must have a safety sheet upon the user's request. The sealant must be intended for use on painted and raw metals, zinc plated surfaces, aluminum, and most plastics without the use of primer. It must be able to bond surfaces such as metal, glass, most plastics, acrylic glass, rubber, ceramic, concrete, brick, and polystyrene.

The desired properties of the adhesive sealant mass for affixing the **PCR-MS** sealing element:

Drying time of 24 h:	3 mm (20 ^{0}C/50%RH)		
Shore A hardness:	55 (DIN 53505)	Tensile strength (100%):	1.7 MPa (DIN53504/ISO37)
Volume changes:	<3% (DIN 52451)	Tearing resistance:	16 N/mm(DIN53515/ISO34)
Application temp:	+5 ^{0}C to +35 ^{0}C	Temp. resistance:	-40 ^{0}C to +120 ^{0}C

It is important to choose the correct **PCR-MS** sealing element depending on the size of the pipe system, and it is necessary to consult with the manufacturer in the choice of the sealing material. Metal or sharp tools or sharp objects that could damage the element or the seal of the **PCR-MS** sealing element should not be used in assembly. The use of protective measures is necessary during assembly and dismantling.

The **PCR-MS** sealing element is improperly assembled if the element lies improperly with regard to the surface of the penetration point, if the element is touching the pipe segment in any place other than with the sealing part, and if the pipe segment is touching anything other than the **PCR-MS** sealing element on the seal itself. It is advisable to keep an equal free space in the installation of the penetration and everywhere around the penetration point.

The adhesive sealant or other means for securing the **PCR-MS** sealing element to the surface of the penetration must ensure a good grip on the surface, assured quality of the strength and durability of the adhesion, impermeability, and suitability for the environment. The choice of the material for the installation of the element to the surface of penetration needs to take into account the suitability for use and the possible effect on the area in which the element is being installed.

Maintenance

The PCR-MS sealing system is simple to maintain and clean as it is not composed of elements that would be difficult to maintain, nor does it have any areas or hidden edges that could collect dirt. Due to its simple shape and high-quality, resistant materials, it is very easy to clean and does not require special measures or additional maintenance work.

Water and regular cleaners, as well as cleaning supplies used in the space, suffice for daily cleaning of the PCR-MS sealing elements. Solvents and degreasers may also be used.

- Care must be taken during cleaning and maintaining of the PCR-MS sealing element that sharp parts do not damage the sealing part or the surface of the PCR-MS sealing element.
- Cleaning the PCR-MS sealing element is done with cleaning cloths or sponges and with the use of cleaning supplies.

An important part of the maintenance of PCR-MS elements for sealing penetrations is to not allow them to be exposed to mechanical damage, short-term or permanent loads, or UV light, which could damage the exposed part of the seal by prolonged exposure.
If the PCR-MS sealing element will be installed later, it needs to be stored in a dry and dark place.

PCR MS® – penetration system

Puddle flange system for sealing pipe penetrations through ceilings, walls, and floors.

Authorised service and sale:
MABHOM d.o.o.,
Papirniška ulica 13, SI-8270 Krško - EU
E-mail: info@clean-system.eu

Associate with green line think positive think green

MABHOM d.o.o. Papirniška ulica 13, SI-8270 Krško -EU
Tel.: 00386 40 894 685
E-mail: info@clean-system.eu

EC Declaration of Conformity

M2406 R01 02/2018

Product/type:	PCR-MS Sealing System
Manufacturer:	MABHOM, d.o.o.
Address:	Papirniška ul.13, 8270 Krško SLOVENIA

The authorized representative declares with full responsibility that the PCM-MS system for sealing pipes between environments, which is subject to this declaration, meets the requirements of the following regulations:

- Directive (EU) 2017/1572 supplementing Directive 2001/83/EC the principles and guidelines of good manufacturing practice for medicinal products for human use
- Regulation (EU) 1935/2004 and EC2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food
- Directive 2007/19/EC amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food
- FDA (US Food and Drug Administration) Regulation 21 CFR 177.2600 .

and the requirements of the following harmonised standards::

EN 10204:2004	Metallic products: Types of inspection documents	01-dec-2004

The person responsible for drawing up the technical documentation is Borut Medvešek, Company Representative. The documentation is kept at the company's headquarters.

Date / place of issue:
Krško, 09.02.2018

Name / position:
Borut Medvešek, Director

Warning:
The Declaration of Conformity loses its validity in the event of interference with the product by an unauthorised person with the purpose of altering or servicing, if the instructions contained in the enclosed manual are not followed, and in the event of incorrect use or maintenance of the products, etc. This Declaration relates exclusively to the product in the condition in which it was put on the market and excludes components subsequently added or operations subsequently performed by the end user. The Declaration is valid for products with traceable manufacturing and an EN 10204 - 3.1 certificate of traceability, as well as an FDA certificate.