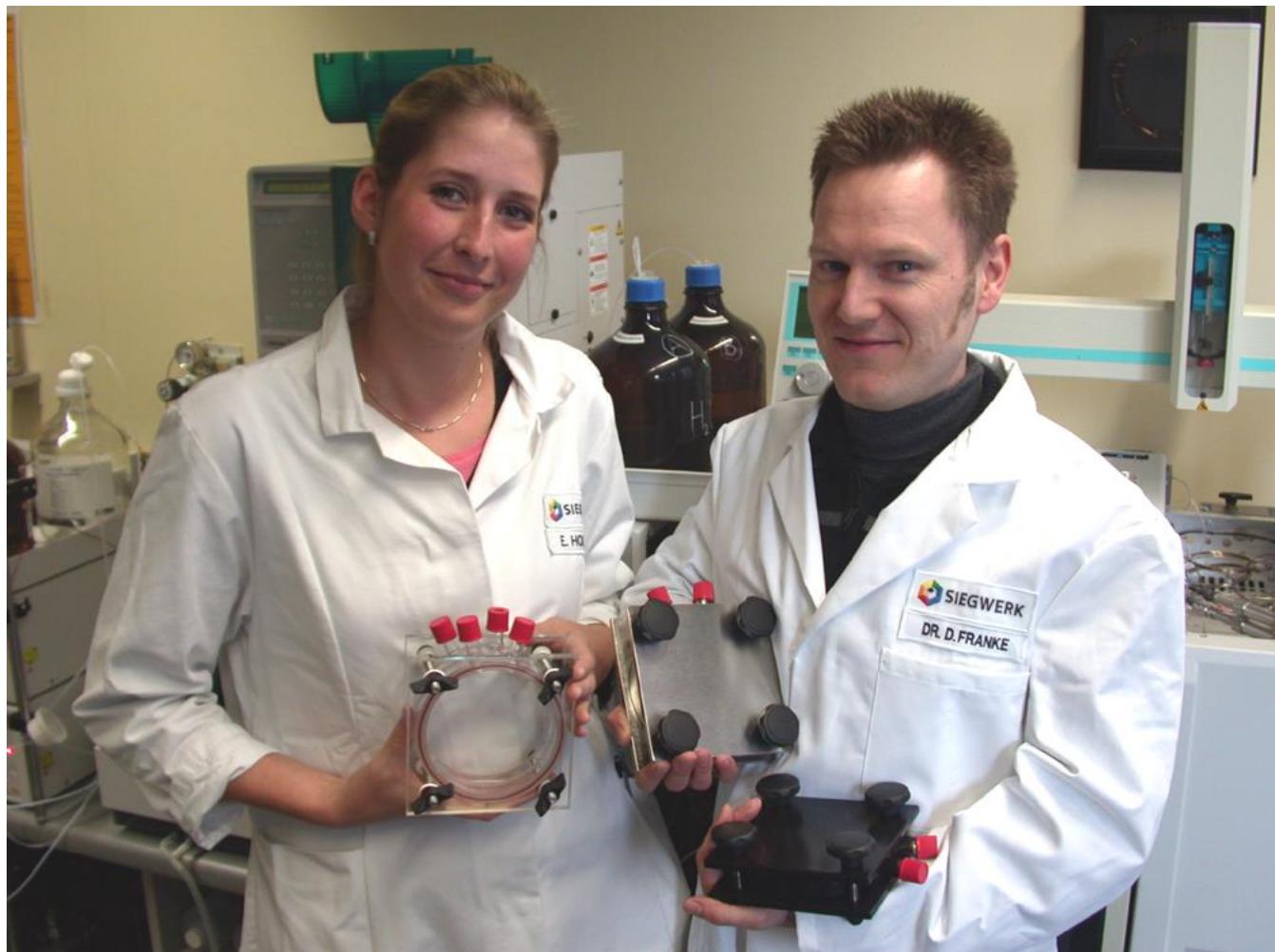


The migration cell System Siegwerk (Sieg-Mi-Flex)

Migrationszelle System Siegwerk (Sieg-Mi-Flex)

La cécula migratoria Sistema Siegwerk (Sieg-Mi-Flex)



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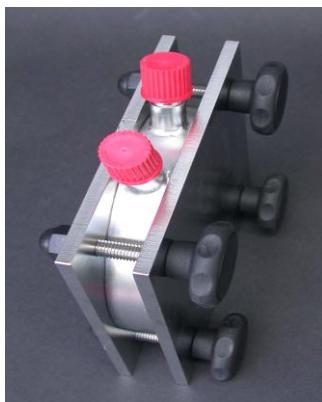
Measurement of the migration of low-molecular substances from packaging's by sample preparation with the migration cell System Siegwerk (Sieg-Mi-Flex) and following analytical quantification.

In the EU, for packaging with direct food contact, the standards of the EU regulation 1935/2004, Article 3, apply. The most important requirement basically states that all materials and objects shall be manufactured as to assure that their material components will only migrate in such small quantities that any possible health risks can be excluded.

The migration cell System Siegwerk (Sieg-Mi-Flex) simplifies sample preparation while dealing with migration analytics. With these migration cells, it is possible to achieve a migration estimation of low-molecular substances, for example of food packaging, that takes place even right at the ready-made rolls. Owing to the flexibility of cell system, all sorts of samples can be analyzed with the correct choice of the liquid food simulant. After the preparation and storage of the cells, according to the EU regulations, the simulant solutions can be quantified via the respective analytic methods (GC/MS, HPLC-MS, HPLC-DAD oder DC), or after a prior concentration of samples via SPE, SPME or rotary evaporation.

The migration cell System Siegwerk (Sieg-Mi-Flex) includes a ring shaped volume element (center ring) that has sealing elements that are arranged at it's frontal area (O-rings made of silicone, surrounded by FEP). The circular area is interrupted by two openings, that are filled with one filler pipe each. The filler pipe is either sealed with a common laboratory screw with a cap and a GL thread or with a septum. The volume element is being braced between the front and the bottom plate by four screws, with the bolts having ergonomically formed handwheels. The circular volume element (center ring) is offered in different sizes, making it possible that the migration cell can be adjusted rapidly to the current trial area.

Because of the modular construction of the migration cell (Sieg-Mi-Flex), an adaption of the cell for fixed adsorbents can be expected in the future.



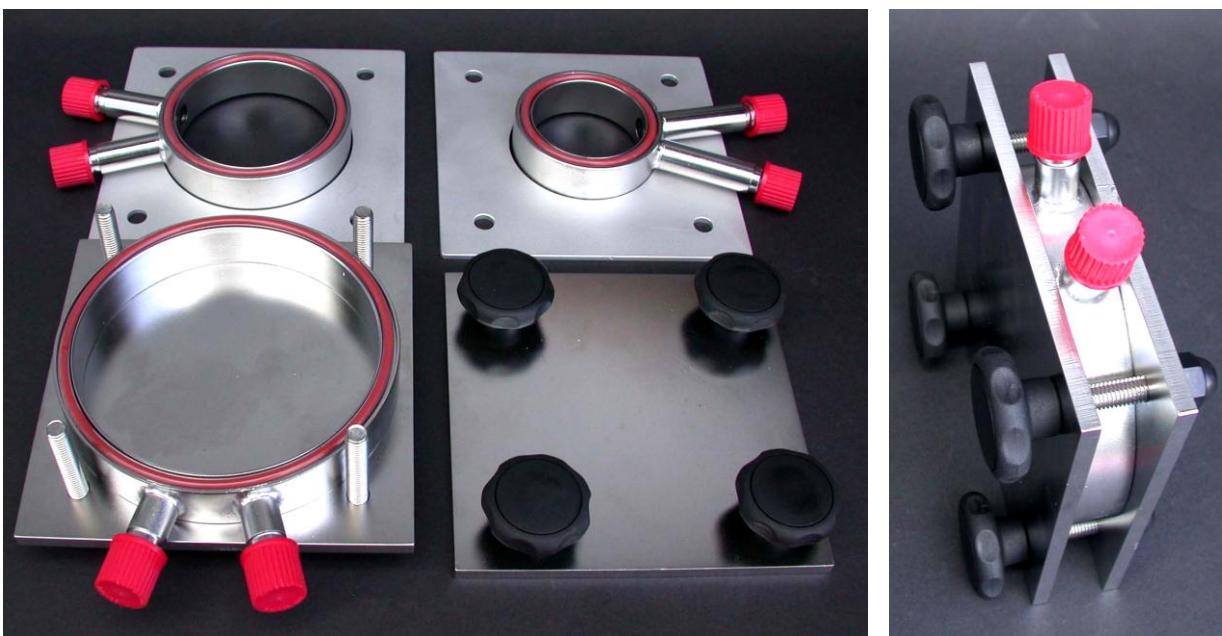
Stainless steel migration cell System Siegwerk (Sieg-Mi-Flex)

A transition of low-molecular substances from packaging to the filling material can take place in two different ways:

1. In the batch or in the roll by set off.
2. The migration of substances from the printed ink side through the foil material into the filling goods.

For migration analysis of various samples, Eva Holster, Dr. Dieter Franke (Siegwerk Druckfarben AG & Co. KGaA) and Werner Zillger (LABC Labortechnik, Hennef) developed the System Siegwerk(Sieg-Mi-Flex). It guarantees the highest possible flexibility regarding different surface sizes and structures of the samples.

1. Central rings with smaller diameters than nom. width DN120 achieve flexibility in analysis of sample sizes. A fixing plate clamps the central ring into the housing made of stainless steel.



2. Ergonomically formed plastic hand-wheels ensure an easy handling in locking and opening of the stainless steel migration cells. Additionally, the compact and space saving design of these cells allows horizontal or vertical storage e.g. for tempering in an oven.



3. Flexible, chemical resistant FEP/Silicon O-rings are used for sealing elements. The diameter of the filler necks is big enough for a practicable handling in filling the volume of the central ring. The volume ring can be closed/locked by temperature stable laboratory standard GL14 cylindrical cup.

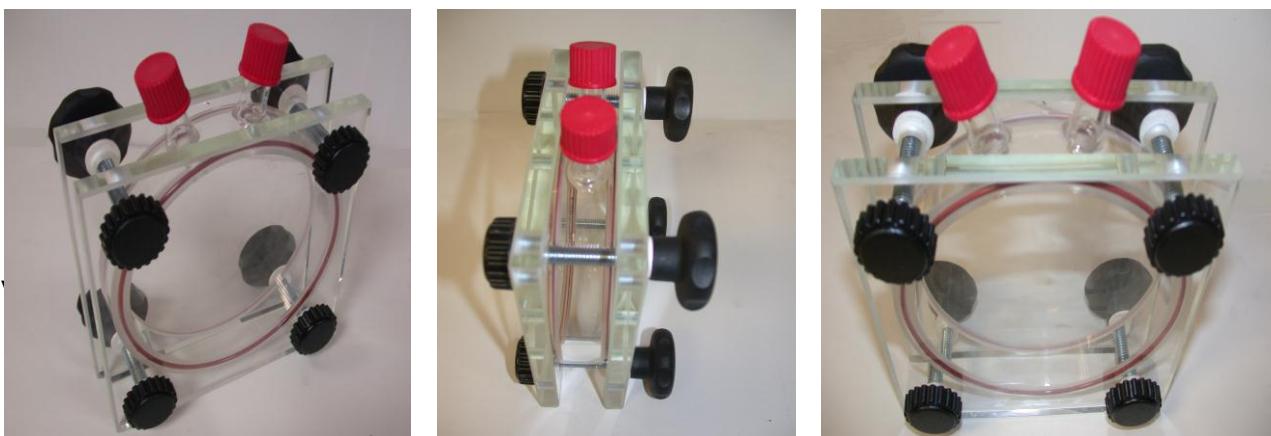
Glass-Migration-Cell System-Siegwerk (Sieg-Mi-Flex)

used for sample preparation in the measurement of migration of low molecular weight substances from packaging materials and subsequent analytical quantification.

A transition of low-molecular substances from packaging to the filling material can take place in two different ways:

1. In the batch or in the roll by set off.
2. The migration of substances from the printed ink side through the foil material into the filling goods.

For migration analysis of various samples, Eva Holster, Dr. Dieter Franke (Siegwerk Druckfarben AG & Co. KGaA) and Werner Zillger (LABC Labortechnik, Hennef) developed the glass-migration-cell "System Siegwerk".



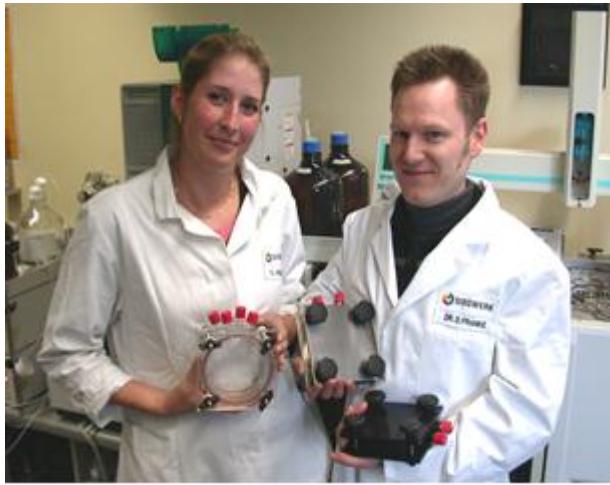
1. Middle rings from the same high made from borosilicate glass 3.3, with the nominal diameter of DN120 with the help of two plan glass-fixing-plates clamped.
2. Ergonomically formed plastic hand-wheels ensure an easy handling in locking and opening of the glass steel migration cell. Additionally, the compact and space saving design of these cells allow horizontal or vertical storage e.g. for tempering in an oven.
3. Flexible, chemical resistant FEP/Silicon O-rings are used for sealing elements. The diameter of the filler necks is big enough for a practicable handling in filling the volume of the central ring. The volume ring can be closed/locked by temperature stable laboratory standard GL14 cylindrical cup.

Technical data from the *glass-migration-cell System-Siegwerk* :

Two fixing plates and one central ring with Nom. width (DN120), One-sided approx. contact area = 1,00 dm², Two-sided approx. contact area = 2,0 dm², Capacity 200ml.

- 2 borofloat plates with holes, protective inserts for screws, bolts and nuts
- 1 borosilicate glass ring with O-ring DN120-slots, 2 x GL14, ID max. 8.5 to 9 mm,

Part No.: 715350: Price on request!



Eva Holster and Dr. Dieter Franke, member of analytical department Siegwerk Druckfarben AG & Co. KGaA, located in Siegburg remarked: „The migration cell “System Siegwerk” offers an optimum of sealing between sample and cells, a maximum conviniens in daily handling and guarantees the highest possible accuracy in migration analysis“.

Technical data:

The migration cell “**System Siegwerk**” consists of: One Fixing plate (A) and different central rings (B) of your choice.

A) Fixing plate (fits all following central rings!):

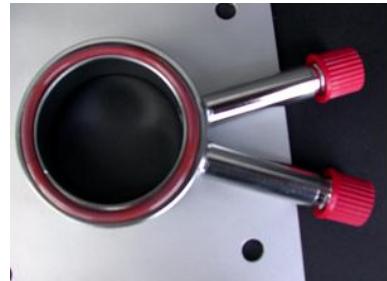
- Stainless steel (VA 1.4571) plates with threaded holes, inside polishes,
- 4 x stainless steel bolt, plastic star nut and thread (DIN 125B A2)

Part No.: 715318: Price on request!



B) Central rings:

- Stainless steel (VA 1.4571) in and filling connecting pieces with GL14 thread inclusive. Cover screw-cap GL14 (PBT housing + PTFE/Sil. - Seal)
- 2 x O-ring FEP/Silicon suitable for groove in central ring (top and bottom)
- Aluminium-positioning-plate (except for the nom. width DN120!)

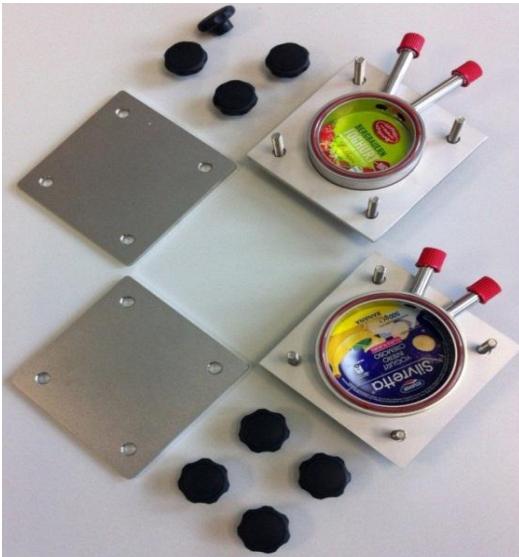


Central rings article No.	Nom. width	One-sided approx. contact area	Two-sided approx. contact area	Capacity (ml)
715319	DN120	1.00 dcm ²	2.0 dcm ²	ca. 200
715328	DN110	0,95 dcm ²	1,9 dcm ²	ca. 170
715320	DN100	0.75 dcm ²	1.5 dcm ²	ca. 150
715329	DN90	0,60 dcm ²	1,2 dcm ²	ca. 120
715321	DN80	0.50 dcm ²	1.0 dcm ²	ca. 100
715322	DN70	0.35 dcm ²	0.7 dcm ²	ca. 70
715323	DN60	0.25 dcm ²	0.5 dcm ²	ca. 50
715324	DN30	0.05 dcm ²	0.1 dcm ²	ca. 10

Prices on request!

Sample preparation when analysing the migration of yogurt lids using the migration cell system Siegwerk (Sieg-Mi-Flex)

To specify the migration measurement in mg/dm² it is practical to be able to work with a defined area as large as possible when preparing the sample. The migration cell system Siegwerk (Sieg-Mi-Flex) offers appropriate sizes to test the largest possible area of the most common yogurt lid (peel-off lid) diameters. LABC-Labortechnik produces customer-specific migration cells on request.



The top figure shows the system Siegwerk (Sieg-Mi-Flex) migration cells with the central rings DN90 and DN70. These are the optimum fit for the conventional yogurt lid diameters of 95.5 mm and 75.5 mm.



The bottom figure shows the system Siegwerk (Sieg-Mi-Flex) migration cells with the central rings DN120 and DN110. These are the optimum fit for aluminium yogurt lids with a diameter of 125 mm and clip-on yogurt lids with a diameter of 115 mm.

When analysing the migration of food packaging, the food simulants in the migration cell only come into contact with the materials stainless steel (VA 1.4571) and PTFE and therefore meet analytical requirements. The migration cell is resistant against all the food simulants listed in Commission Regulation (EU) No 10/2011 as well as against 3% acetic acid.

Further information on food packaging:

Overall migration limit (global migration) OML

The maximum permitted amount of non-volatile substances released from a material or article into food simulants; expressed in mg/dm².

Specific migration limit (SML)

The maximum permitted amount of a given substance released from a material or article into food or food simulants (SML = ADI x 60)

Acceptable daily intake (ADI)

Expressed in mg/kg. The amount of a toxicologically evaluated substance that can be consumed in foodstuffs on a daily basis without any risk to health ((toxicological concentration limit x safety factor 100). The migration of substances for which no toxicological data is available must fall below 10 µg/kg (ppb) in accordance with the Note of Guidance from the European Food Safety Authority (EFSA).

(QM)

The maximum concentration of a toxicologically evaluated substance in the packaging in mg/kg

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food

Commission Regulation (EU) No 10/2011 is a specific measure as defined by Article 5 (1) of Commission Regulation (EU) No 1935/2004. This Regulation should establish the specific rules for plastic materials and articles to be applied for their safe use. Furthermore, the Regulation should repeal Commission Directive 2002/72/EC of 6 August 2002 on plastic materials and articles intended to come into contact with foodstuffs. In the past, Directive 2002/72/EC and its amendments have had to be transposed into national legislation – a process for which a time period of 12 months was normally required. This led to a retardation of the authorisation for new substances and thus slowed down innovation. It therefore seemed appropriate to adopt rules on plastic materials and articles in the form of a Regulation directly applicable in all Member States, which no longer has to be transposed into national legislation.

What are the key changes and features of this Regulation?

Expansion of the scope: compared to Directive 2002/72/EC, the scope has been extended to plastic layers in materials and articles with multi-material multi-layers.

Union list of authorised substances (Annex I): Directive 2002/72/EC contains different lists for monomers or other starting substances as well as for additives authorised for the manufacture of plastic materials and articles. For monomers, other starting substances and additives, the Union list in Annex I is now complete. This means that only the 885 substances authorised at EU level and included in this list may be used to manufacture plastic materials and articles under consideration of their specific migration limits (SML).

Restrictions on materials and articles (Annex II): Annex II specifies the specific migration limits for several metals (e.g. barium, iron and zinc) as well as for primary aromatic amines.

Selection of the food simulants for specific migration (Annex III): new food simulants such as ethanol (10% v/v, 20% v/v and 50% v/v), vegetable oil and Poly(2,6-diphenyl-p-phenylene oxide) are to be used for migration testing.

Declaration of compliance: pursuant to Articles 15 and 16, at each stage of manufacture, supporting documentation substantiating the declaration of compliance should be kept available for the enforcement authorities.

Link to Commission Regulation (EU) No 10/2011 of 14 January 2011:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:DE:PDF>

Other interesting links in relation to food packaging:

Conformity of food packages, migration and invisible set-off (Technical information hubergruppe, 19/01/2003):
<http://www.hubergruppe.info/lang/deu/tipdf/19103D.PDF>

Online FAQ portal for migration (Dresden packaging conference):

<http://www.verpackungstagung.org/dvt-faq.html>

Migration of packaging contents in food, current legislation on printing on food packaging (CH, D, Europe) by Dr.Jörg Langhammer, Siegburg: <http://www.dfta.de/media//dfta/veranstaltungen/dr.-langhammer.pdf>

Packaging printing: Best Practice Guide - Low Migration (SUN Chemical):

http://www.druckfarben.net/Best_Practice_Guide_-_Low_Migration_D.pdf

Migration of mineral oil from cardboard packaging into dry foods (Koni Grob, Cantonal lab Zürich):

http://www.bfr.bund.de/cm/343/migration_von_mineraloel_aus_kartonverpackungen_in_trockene_lebensmittel.pdf

Specifications within the scope of the food packaging chain (Dr. Sieglinde Stähle, Alliance for food right and food customer inc.): <http://www.bll.de/themen/bedarfsgegenstaende/spezifikationen-lebensmittelverpackungskette.pdf>

Headspace analysis of the migration of substances from packaging materials by means of sample preparation using the migration cell system Siegwerk (Sieg-Mi-Flex) in 'sandwich format'

In the EU, packaging that comes into direct contact with food is subject to Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. In addition to the preparation of samples with liquid food simulants, the analysis of the headspace (steam chamber) is an interesting alternative for research & development. By using the 'sandwich format', the headspaces of the food contact side and the outer side can be measured simultaneously and free from the matrix of the food simulants. The sampling and analyte enrichment processes ideally occur using SPME (solid phase microextraction). An inert carrier gas can optionally be used to flush the steam chamber and the volatile substances can be concentrated on a test tube with an adsorbent.

The 'sandwich format' of the migration cell (Sieg-Mi-Flex) also makes it possible to test the barrier properties (H_2O , CO_2 ; O_2) of composite packaging. The film to be tested is placed between the two central rings and pulled taut. The GL14 threaded connections provide an inlet and an outlet for each steam chamber.

To create the 'sandwich format' you need not only another central ring but also a threaded extension connection set (product no.: 715325) to double the reaction area of the migration cell 'Sieg-Mi-Flex'.



The film to be tested is placed between the two central rings and pulled taut. The GL14 threaded connections provide an inlet and an outlet for each steam chamber.

Product no.	Nominal diameter (mm)	Area (dcm ²)	Total fill volume (ml)	Quantity
A: Fixing plate (suitable for use with all the central rings listed below!): VA 1.4571 Plates with threaded holes, polished inner, 4 x stainless steel bolts, plastic star nut and bolt DIN 125B A2				
715318	-	-	-	1
B: Central rings: VA 1.4571, cast-in and cast-out connecting pieces with GL14 thread incl. cover cap GL14 (PBT housing + PTFE/sil. seal), 2 x O-ring FEP/silicone that fit in the central ring's nut (top and bottom), aluminium positioning aid (except with DN120!)				
715319	DN120	2 x 1,00 dcm ²	approx. 2 x 200	2
715328	DN110	2 x 0,95 dcm ²	approx. 2 x 190	2
715320	DN100	2 x 0,75 dcm ²	approx. 2 x 150	2
715329	DN90	2 x 0,60 dcm ²	approx. 2 x 120	2
715321	DN80	2 x 0,50 dcm ²	approx. 2 x 100	2
715322	DN70	2 x 0,35 dcm ²	approx. 2 x 70	2
715323	DN60	2 x 0,25 dcm ²	approx. 2 x 50	2
715324	DN30	2 x 0,05 dcm ²	approx. 2 x 10	2
C: Threaded extension connection: threaded extension connection for doubling the reaction area in 'sandwich format', 1 set = 4 complete threaded connections				
715325	-	-	-	1

Prices on request!

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