

Product Information Process Connection EPA **PHARMA**

Build-In System PHARMadapt EPA



Application / Specified Usage

- Aseptic process connection for applications in pharma and biotechnology
- Process connection of sensors, especially in pipes with very small diameter
- Suitable for media with and without electrical conductivity

Application Examples

- System for mounting of sensors for production monitoring e. g. limit- and temperature monitoring with WIFI water
- Water and waste water treatment

Hygienic Design / Process Connection

- By using Negele build-in system EPA-... will result a measurement point which is aseptic and easy to sterilize
- Easy demounting for cleaning and calibration with clamp system
- Dead spot and gap free build-in system
- Sealing system with easy replaceable elastomer sealing ring (EPDM)
- CIP-/ SIP-cleaning up to 150 °C possible (depends on sensor)
- All wetted materials compliant to FDA
- 3-A compliant with diameter \geq DN25, ISO20, ASME1"

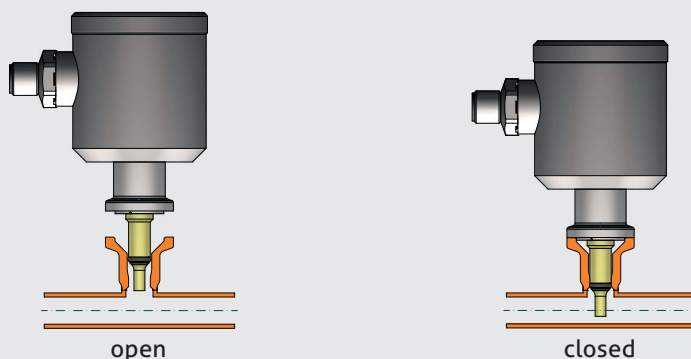
Features

- Quick and easy to install with an orbital welding machine
- From pipe diameter DN10
- Independent of pipe diameter - only two sizes of sensor connection necessary
- Measurement point with integrated leakage hole
- Negele sensors and build-in system with predefined and aligned build-in length
- Material certificate 3.1 in scope of delivery

Options / Accessories

- Various pipe standards available (DIN 11866, ISO 1127, ASME BPE)
- Surface quality $R_a \leq 0.6 \mu\text{m}$ and $0.4 \mu\text{m}$, including 3.1 certificate
- Delta ferrite content $< 0.5 \%$ and "Baseler Norm II"
- Custom specific labelling, TAG number plate made of stainless steel

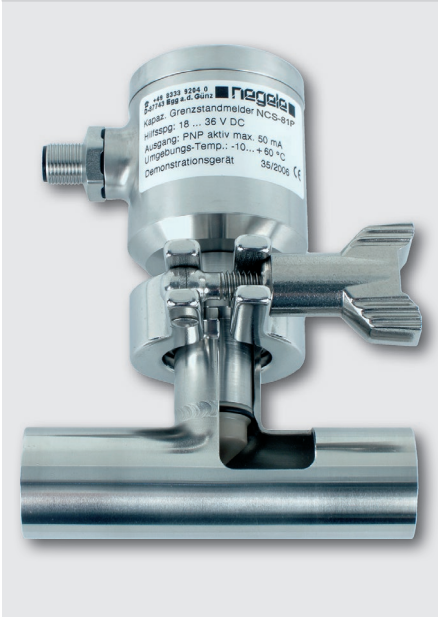
Schematic diagram of PHARMadapt sealing principle



Authorisations



EPA-18 with limit switch



Build-in system EPA-18



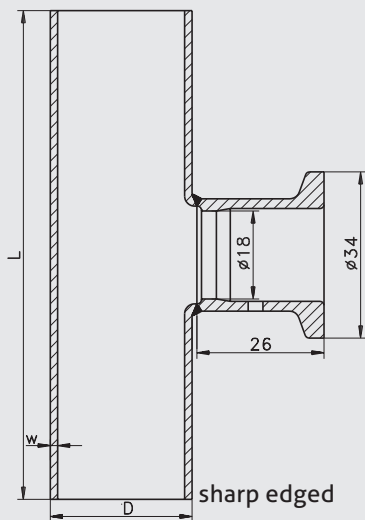
Specification of Measure Point and Adapter		
Pipe style		DIN 11866 series A DIN 11866 series B, ISO 1127 DIN 11866 series C, OD-Tube
Material	thermowell pipe pipe	stainless steel 1.4435 (316L) mit 3.1 certificate stainless steel 1.4435 (316L) mit 3.1 certificate stainless steel 1.4404 (316L) with sulphur content acc. to ASME BPE 2009, table DT-3 (only for order option "S")
Surface	wetted parts optional	$R_a \leq 0.8 \mu\text{m}$ (not in welded areas) electro polished $R_a \leq 0.6 \mu\text{m}$, $R_a \leq 0.4 \mu\text{m}$
Delta ferrite DF	standard optional Baseler Norm II	< 1.0 % (weld-seam < 3 %) < 0.5 % (weld-seam < 3 %) BN II
Sulfur content at pipe edges	standard acc. to ASME	max. 0.030 % min. 0.005 %, max. 0.017 %
Diameter	Diameter	
Tolerances	pipes with DN10...DN40 pipes with DN50...	$\pm 0.3 \text{ mm}$, length: $\pm 1.0 \text{ mm}$ $\pm 0.5 \text{ mm}$, length: $\pm 1.0 \text{ mm}$
Sensor connection	EPA-8 EPA-18	SRC-05 clamp ring DN10...20 SRC-10 clamp ring DN25...40
Sealing principle	sealing ring	EPDM, FDA compliant, USP Class VI
Operating pressure		10 bar max.

Advice

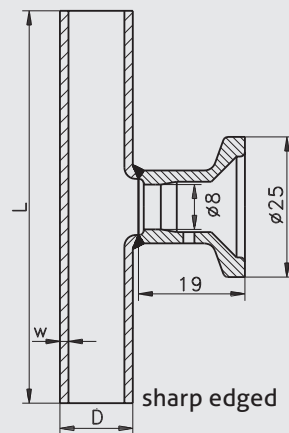


The technical specification of pipes is according to DIN 11866 if no other is defined.
Delta ferrite values are valid for delivery condition.
Mechanical treatment after delivery can increment the Delta ferrite value.

Build-in system EPA-18



Build-in system EPA-8



DIN 11866 series A

Type	DN	L [mm]	Rohr D x w	suitable for
EPA-8 / A / 10	10	70	13 x 1.5	NCS-6xP, TFP-6... / 010
EPA-8 / A / 15	15	70	19 x 1.5	NCS-6xP, TFP-6... / 010
EPA-8 / A / 25	25	100	29 x 1.5	NCS-6xP, TFP-6... / 025
EPA-8 / A / 32	32	110	35 x 1.5	NCS-6xP, TFP-6... / 025
EPA-8 / A / 40	40	120	41 x 1.5	NCS-6xP, TFP-6... / 025
EPA-8 / A / 50	50	160	53 x 1.5	NCS-6xP, TFP-6... / 025
EPA-8 / A / 65	65	210	70 x 2.0	NCS-6xP, TFP-6... / 050
EPA-8 / A / 80	80	260	85 x 2.0	NCS-6xP, TFP-6... / 050
EPA-8 / A / 100	100	310	104 x 2.0	NCS-6xP, TFP-6... / 050

DIN 11866 series B / ISO 1127

Type	DN	L [mm]	Rohr D x w	suitable for
EPA-8 / B / 8	ISO8	64	13.5 x 1.6	NCS-6xP, TFP-6... / 010
EPA-8 / B / 10	ISO10	68	17.2 x 1.6	NCS-6xP, TFP-6... / 010
EPA-8 / B / 15	ISO15	72	21.3 x 1.6	NCS-6xP, TFP-6... / 010
EPA-8 / B / 20	ISO20	110	26.9 x 1.6	NCS-6xP, TFP-6... / 010
EPA-8 / B / 25	ISO25	120	33.7 x 2.0	NCS-6xP, TFP-6... / 025
EPA-8 / B / 32	ISO32	130	42.4 x 2.0	NCS-6xP, TFP-6... / 025
EPA-8 / B / 40	ISO40	130	48.3 x 2.0	NCS-6xP, TFP-6... / 025
EPA-8 / B / 50	ISO50	180	60.3 x 2.0	NCS-6xP, TFP-6... / 025
EPA-8 / B / 65	ISO65	220	76.1 x 2.0	NCS-6xP, TFP-6... / 050
EPA-8 / B / 80	ISO80	260	88.9 x 2.3	NCS-6xP, TFP-6... / 050

DIN 11866 series C / OD-Tube / Dimensions acc. to ASME BPE

Type	DN	L [mm]	Rohr D x w	suitable for
EPA-8 / C / 3/4"	3/4"	102	19.05 x 1.65	NCS-6xP, TFP-6... / 010
EPA-8 / C / 1"	1"	108	25.4 x 1.65	NCS-6xP, TFP-6... / 010
EPA-8 / C / 1½"	1½"	120.5	38.1 x 1.65	NCS-6xP, TFP-6... / 025
EPA-8 / C / 2"	2"	146	50.8 x 1.65	NCS-6xP, TFP-6... / 025
EPA-8 / C / 2½"	2½"	160	63.5 x 1.65	NCS-6xP, TFP-6... / 050
EPA-8 / C / 3"	3"	170	76.2 x 1.65	NCS-6xP, TFP-6... / 050
EPA-8 / C / 4"	4"	210	101.6 x 2.11	NCS-6xP, TFP-6... / 050

DIN 11866 series A

Type	DN	L [mm]	Rohr D x w	suitable for
EPA-18 / A / 25	25	100	29 x 1.5	NCS-8xP, TFP-8... / 020
EPA-18 / A / 32	32	110	35 x 1.5	NCS-8xP, TFP-8... / 020
EPA-18 / A / 40	40	120	41 x 1.5	NCS-8xP, TFP-8... / 020
EPA-18 / A / 50	50	160	53 x 1.5	NCS-8xP, TFP-8... / 020
EPA-18 / A / 65	65	210	70 x 2.0	NCS-8xP, TFP-8... / 050
EPA-18 / A / 80	80	260	85 x 2.0	NCS-8xP, TFP-8... / 050
EPA-18 / A / 100	100	310	104 x 2.0	NCS-8xP, TFP-8... / 050

DIN 11866 series B / ISO 1127

Type	DN	L [mm]	Rohr D x w	suitable for
EPA-18 / B / 20	ISO20	110	26.9 x 1.6	NCS-8xP, TFP-8... / 020
EPA-18 / B / 25	ISO25	120	33.7 x 2.0	NCS-8xP, TFP-8... / 020
EPA-18 / B / 32	ISO32	130	42.4 x 2.0	NCS-8xP, TFP-8... / 020
EPA-18 / B / 40	ISO40	130	48.3 x 2.0	NCS-8xP, TFP-8... / 020
EPA-18 / B / 50	ISO50	180	60.3 x 2.0	NCS-8xP, TFP-8... / 020
EPA-18 / B / 65	ISO65	220	76.1 x 2.0	NCS-8xP, TFP-8... / 050
EPA-18 / B / 80	ISO80	260	88.9 x 2.3	NCS-8xP, TFP-8... / 050

DIN 11866 series C / OD-Tube / Dimensions acc. to ASME BPE

Type	DN	L [mm]	Rohr D x w	suitable for
EPA-18 / C / 1"	1"	108	25.4 x 1.65	NCS-8xP, TFP-8... / 020
EPA-18 / C / 1½"	1½"	120.5	38.1 x 1.65	NCS-8xP, TFP-8... / 020
EPA-18 / C / 2"	2"	146	50.8 x 1.65	NCS-8xP, TFP-8... / 020
EPA-18 / C / 2½"	2½"	160	63.5 x 1.65	NCS-8xP, TFP-8... / 050
EPA-18 / C / 3"	3"	170	76.2 x 1.65	NCS-8xP, TFP-8... / 050
EPA-18 / C / 4"	4"	210	101.6 x 2.11	NCS-8xP, TFP-8... / 050

Labelling of measurement point

The pipes are labelled with following informations:

- Material, electro polished
- Pipe dimensions
- Charge number of pipe, serial number
- Charge number of weld-on bushing

The weld-on bushings are labeled with following informations:

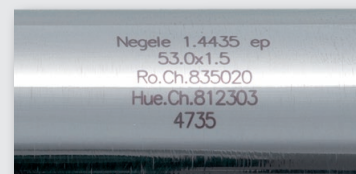
- Material
- Charge number

All labelling is made with wire printing on the metal pieces.

Customized labelling of package

The package can be labeled with customized informations on request.

Pipe labelling



Example of package labelling

TYP.: ESP-G-ASME-G 1,5"
 Teilekennzeichen: 2EW 611
 Modernisierung H84,
 Warenann. Baufeld, G74, Halle 1
 Inhalt: 10 Stück

Surface Quality

In order to provide favourable conditions for sterile production, the surface must be smooth and non-porous down into the microscale range. Overlapping areas, or material laminations, must be avoided as far as possible on account of the dead spaces that result, since these areas are difficult or impossible to clean and therefore represent ideal breeding grounds for germs and bacteria.

Moreover, the dimensions (including height!) must be kept as small as possible to minimise the influences of the surfaces in contact with the product. Such surfaces can be obtained by means of electropolishing. In the pharmaceutical sector, but not only there, the quality of the surface is generally defined in terms of the "R_a"-roughness. A surface with R_a ≤ 0.8 µm is normal, in special cases also R_a ≤ 0.6 µm and even R_a ≤ 0.4 µm. All these qualities can be achieved by machining appropriately good quality steels and electropolishing them for a sufficiently long period of time. Ra is the arithmetic average of all protuberances on the surface y over a certain measurement distance L in the x-direction.

Delta Ferrite

The higher the delta ferrite content (DF), the more magnetic phases are present in the austenitic structure. These arise as a result of thermal effects, e.g. during welding and turning. The strain-induced martensite that is formed here leads to increased susceptibility to corrosion for the workpiece and is therefore undesirable.

According to DIN 11866 Table B.1 differentiation can be made between three DF classes:

- Class 1: < 3.0 % delta ferrite in the as-supplied state
- Class 2: < 1.0 % delta ferrite in the as-supplied state
- Class 3: < 0.5 % delta ferrite in the as-supplied state

In order to achieve DF Classes 2 and 3, the tubes must in general be "solution annealed" before delivery. The solution annealing takes place at temperatures between 1020 °C and 1150 °C, depending on the material.

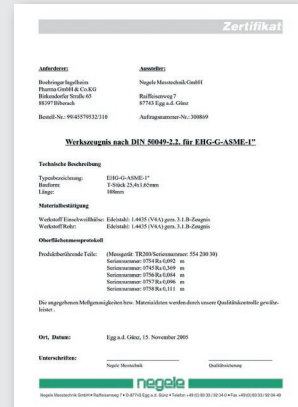
1.4435 stainless steel has a reduced delta ferrite content much lower than 1 % compared with 1.4404. The increase caused by welding processes can be minimised by the use of suitable welding materials, shielding gas, and the correct current, so that the delta ferrite content at least remains below 3 %. If the whole work piece is required to have a delta ferrite content less than 0.5 %, it must be ordered in accordance with "Baseler II Norm".

The reduction of the delta ferrite must not be too excessive, however, because with too low a content there is a tendency for the stainless steel to form cracks during machining or welding.

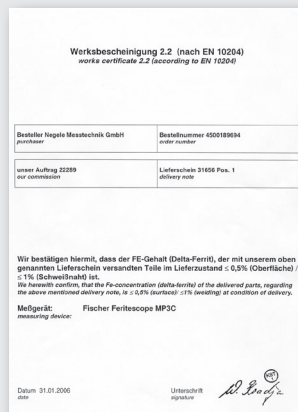
USP Class VI

Relative new and initialized from US market is a new qualification of product contacting plastics. Primary a requirement from the medical sector this will get a standard of the pharmaceutical industries in the future for a lot of applications. Plastics and elastomers according to the so called USP Class VI standard is suitable for implantation into the human body without any complications. Presently this is the highest requirement to material harmlessness.

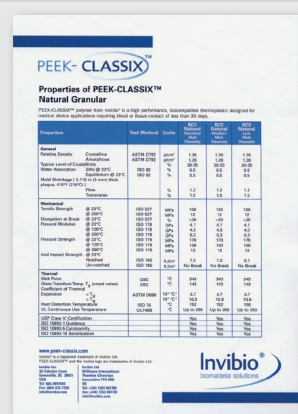
Inspection Certificate



Inspection Certificate



USP Class VI



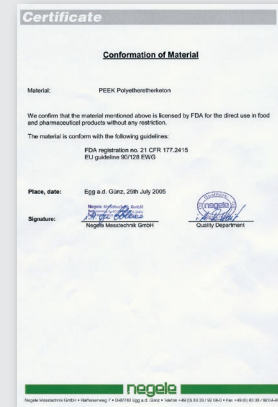
FDA

The „Food and Drug Administration“ (FDA) is a US authority that issues approvals for agents, foodstuffs, cosmetics and pharmaceutical products. In addition, it generates recommendations for the use of materials in facilities in the foodstuffs and pharmaceutical industries. This supplementary task is administered because the individual components, materials and design details have significant influence on the quality of the end product.

An “FDA Approval” can only be issued for a product generated in the particular facility in question. For components and materials there is no FDA approval; these parts are “FDA listed” in terms of their innocuousness if in direct contact with the product.

The FDA directives are published as so-called „Codes of Federal Regulations“ (CFR...). The 21 CFR 170 – 199 directives have a special significance, in particular with regard to material selection for sensor manufacturers. They contain a listing of specifications for plastics. Thus, 21 CFR 177.2415, for example, contains the plastic PEEK that is often used in the food and pharmaceutical market sectors.

FDA Certificate



ASME

In the pharmaceutical sector one often comes across the requirement to deliver tubes to meet ASME. In most cases what is meant here is simply the tube dimensions with regard to diameter and wall thickness. In this event ASME is identical with the ODT dimensions.

However, ASME BPE also defines a minimum and maximum content for elemental sulphur, which in fact must lie between 0.005 % and 0.017 %. According to ASME regulations this requirement applies, however, just to tube ends that are still to be automatically welded, and not to those that are already welded. The definition of a certain range for the sulphur content makes total sense, since parts with strongly differing sulphur content would deflect the arc during welding and as a result would lower the quality of the weld seam.

Otherwise, the value prescribed in the German Key to Steel or the value defined in AISI for 316L of 0.030 % sulphur content applies.

Comment: ASME BPE specifies not only the sulphur content of the work piece, but also the contents of other materials contained in the steel such as nickel, molybdenum, etc. These, however, essentially correspond to the values in the German Key to Steel, which applies in Europe.

3-A Sanitary Standards

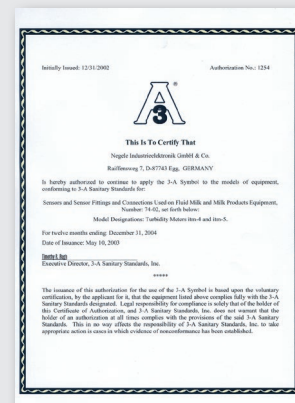
In 1920 three US associations published directives for milk pipe connections. Hence the name 3-A, for 3 Associations.

These organisations are:

- International Association of Milk, Food and Environmental Sanitarians (IAMFES)
- United Public Health (UPH)
- Dairy Industry Committee (DIC)

In 1944 the body of regulations, which in the intervening period had become more comprehensive, was accredited by the US Government. Over 50 standards have been published, primarily for the milk industry. Other sectors, in particular the pharmaceutical industry, are oriented towards these standards or prescribe them as mandatory.

3-A Certificate



Advice

Certificates can be ordered as an additional option with the product order code.

Example: EPA-8 / ... / RAC / DFC

Conditions for a measuring point according to 3-A Sanitary Standard 74-06

- The sensors TFP-641, -661, -681, -841, -861, -881 and NCS-61P, -62P, -81P, -82P are approved according to the 3-A Sanitary Standard.
- Only with the build-in system EPA with pipe diameter \geq DN25, ISO 20 and 1" allowed.'
- The weld must comply to the requirements of the current 3-A Sanitary Standard.
- Mounting position, self draining and the position of the leakage hole must be in accordance to current 3-A Sanitary Standard.

Transport / Storage

- No outdoor storage
- Dry and dust free
- Not exposed to corrosive media
- Protected against solar radiation
- Avoiding mechanical shock and vibration
- Storage temperature -55...+90 °C
- Relative humidity maximum 98 %

Reshipment

- Sensors and process connection shall be clean and free of media or heat-conductive paste and must not be contaminated with dangerous media!
- Use suitable transport packaging only to avoid damage of the equipment!

Cleaning / Maintenance

- In case of using pressure washers, don't point nozzle directly to electrical connections of mounted sensors!

Standards and Guidelines

- You have to comply with applicable regulations and directives.

Order code build-in system PHARMadapt EPA

EPA-8 (Pharma conform build-in system, for sensor connection 8 mm)
EPA-18 (Pharma conform build-in system, for sensor connection 18 mm)

Pipe style

- A** (DIN 11866 series A)
- B** (DIN 11866 series B
ISO 1127)
- C** (DIN 11866 series C
OD-Tube)

Diameter: see dimension tables page 3 and 4

Surface

- 0.8** ($R_a \leq 0.8 \mu\text{m}$, standard)
- 0.6** ($R_a \leq 0.6 \mu\text{m}$)
- 0.4** ($R_a \leq 0.4 \mu\text{m}$)

Certificate surface

- X** (without)
- RAC** (Certificate surface quality)

Delta ferrite- / sulphur content

- X** (standard: DF < 1 % - class 2)
- DF** (DF < 0.5 % - class 3)
- BN** (DF < 0.5 % - Baseler Norm II)
- S** (material pipe 1.4404/316L, sulphur content acc. to ASME BPE 2009, table DT-3, only weld ends)

Certificate delta ferrite content

- X** (without)
- DFC** (Certificate delta ferrite content incl. measurement protocol with 3 measurement points)

EPA-8 / A / 40 / 0.8 / RAC / DF / DFC

Accessories

- SRC-05** Clamp-tension ring for EPA-8, material 1.4301
- SRC-10** Clamp-tension ring for EPA-18, material 1.4301
- BSP-8** Dummy flange for EPA-8, material 1.4435
incl. 3.1 certificate acc. to EN10204
- BSP-18** Dummy flange for EPA-18, material 1.4435
incl. 3.1 certificate acc. to EN10204
- DRE-5** Sealing ring for EPA-8, Ø 5 x 1.5 mm, material EPDM (FDA compliant)
- DRE-15** Sealing ring for EPA-18, Ø 15 x 1.5 mm, material EPDM (FDA compliant)

Clamp-tension ring SRC



Note for clamp-tension ring

The tension ring is not in scope of delivery of sensors or process connection and must be ordered separately.



Dummy flange BSP

