Declaration of conformity
Adapter

acc. to VO (EG) 1935/2004 and VO (EU) 10/2011
as well as acc. to FDA

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CFR
FDA stands for Food and Drug Administration, a U.S. authority. Among other things, this authority issues a regulation on the use of product-contacting materials in the pharmaceutical, food and beverage and cosmetics industries (Code of Federal Regulations CFR).

EG 1935/2004
Regulation (EC) No. 1935/2004 of 27.10.2004 is aimed at ensuring a high level of protection of human health as well as the safety of consumers, respecting articles and materials intended to come into contact with food.

Along with this regulation, individual measures can be implemented. For plastics, this is for example regulation (EU) no. 10/2011.

The special focus of the regulation is on compliance with good manufacturing practice. We understand the principal aspect of good manufacturing practice to be making sure that parts with potential food contact are designed so that, at least under foreseeable conditions, the migration of constituent substances is largely avoided or does not occur in quantities that would endanger human health or bring about unacceptable changes in composition or organoleptic properties.

FDA
For materials for which 21 CFR's 177 are not applicable, we refer to the current state of knowledge of independent experts from the pharmaceutical and food sectors or to statements of the Public Health Service of the Food and Drug Administration.

GMP EG 2023/2006
Under the second aspect of good manufacturing practice (GMP) acc. to EG 2023/2006 of 22.12.2006, we understand ensuring the traceability of components and products potentially coming into contact with foodstuffs throughout all stages of manufacturing and sales. This is guaranteed by our quality management system according to ISO 9001 and ISO 14001.

The manufacturer declaration contains no information on additional hygienic aspects or cleanability, e.g. absence of gaps and undercuts, surface quality.

Some process fitting versions of our sensors also have the EHEDG or 3A certification in order to meet hygiene-specific requirements.

To ensure that there is no unintentional contamination through transport, installation or mounting, a rinsing with aqueous medium is recommended before the first contact with the foodstuff.

Always use a suitable process seal that meets the product-specific requirements.

In the process, a leaky seal represents a hygienic risk. To avoid this, the seals should be replaced with new ones at regular intervals and the sensor checked for damage.

USP
The USP (US Pharmacopial Convention) is a non-commercial organisation for development and formulation of requirements and standards for the identity, quality and purity of drugs as well as food components and supplements.

With elastomers and plastics there is the requirement of USP Class VI for the assessment of the physiological concern.

For sensor versions for which an USP Class VI proof of the material supply is available, this is confirmed in addition.

We herewith declare that the wetted parts of the following versions are made of materials meeting in the composition with regulation VO (EC) No. 1935/2004 and VO (EU) 10/2011 or stainless steel alloys (such as e.g. 316L) proven over years in the pharmaceutical and food processing industry.

The requirement acc. to VO (EC) 10/2011 is not applicable because no plastic parts are used in the below listed adapter versions which are in contact with the foodstuff.

Above and beyond this, the seal supplier confirms conformance with USP Class VI in connection with the seal versions "3, P and X".

FDA, EG1935/2004, USP Class VI

G¾: for VEGAFLEX series 80 and VEGAPULS 64

GEWADA-A.	CC / CD / CE / CI / G1 / LE / RG / RA / RC / RD / RE / RF SA / SD / SB / AA / QB / AB / TA / SC / IG / IH / KA	3

G1½: for VEGAFLEX series 80 and VEGAPULS 64

GEWADA-C.	CA / CD / CE / RB / RF / RC / CJ / CZ / GZ	3

for VEGABAR

GEWADA-D.	GV / GD / GG / GW / GF / GX / GA / GB / GC / GH / GP / GL GM / GN / GO / BF / BJ / BH / BI / BL / BB / BK / BM / BV BD / BE / AE / CH / LB / LC / LD / SE / VP / DA / BS / BA DJ / DO / DI / DF / DH / DL / DE / DG / D2 / DK	P / X

for VEGAPULS 64

GEWADA-F.	TA / TE / TD	3	TJ / AJ / AA / AB / AC / AD / AE / AI / AF / AG / AH

In connection with the versions with the seal characteristics "3, P and X" listed below, the seal supplier confirms conformance with USP Class VI.

G¾: for VEGAFLEX series 80 and VEGAPULS 64

GEWADA-A.	NE / CG / CA / CI / CD / CE / CC / AC / AD / RA / RB / RC RD / RE / RF / SA / SD / SB / AA / QB / AB / TA / SC / IG IC / IH / KA	1

for VEGACAL and VEGACAP

GEWADA-E.	CA / GK / CF / GE / GQ / CB / GI / GK / LA / LP / GY / TC	3

for VEGABAR

GEWADA-D.	GV / GD / GG / GW / GF / GX / GA / GB / GC / GH / GP / GL GM / GN / GO / BF / BJ / BH / BI / BL / BB / BK / BM / BV BD / BE / AE / CH / LB / LC / LD / SE / VP / DA / BS / BA DJ / DO / DI / DF / DH / DL / DE / DG / D2 / DK	3

This declaration is based on the following certificates:

- Official statements of the seal suppliers for the following measuring cells and process fittings: EPDM (E70Q), FKM 75.16-04 (FKM 75.5/VA75F), EPDM (A+P 75.5/KW 75 F), FEPM (Fluoraz SD890) and FFKM (Perlast G74S) for conformity with the FDA requirements as well as their conformity with EG regulation 1935/2004 as well as USP Class VI
- Statement of the seal supplier for the following seals: FKMFDA73 green

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Entwicklung

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