

# Declaration of conformity

## Adapter

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



Document ID: 34466



**VEGA**



## **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**

We meet these general requirements by purchasing parts and materials that potentially come into contact with food with proof of compliance with FDA requirements or, in cases where there are no explicit FDA requirements, with a "No Objection Letter" from the Public Health Service of the Food and Drug Administration, or by obtaining the expert opinion of independent (accredited) laboratories and organizations in cases where uncertainties still exist.

## **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.

Issued by: Issue date: 19.05.2017

VEGA Grieshaber KG

Am Hohenstein 113

77761 Schiltach

We herewith declare that the wetted parts of the adapter versions listed in the following table are suitable for contact with foodstuffs and comply with the requirements of regulation VO (EC) No. 1935/2004 as well as the FDA requirements.

Furthermore we confirm for the sensor versions listed in the following table that either for the wetted antenna material as well as the listed sealing materials, a USP Class VI certificate from the supplier exists.

**FDA, EG1935/2004, USP Class VI**

**G1½: for VEGAFLEX series 80 and VEGAPULS 64**

GEWADA-B.	CA / CJ / CE / RB / RC / RF	1 / 3
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**G1½: for VEGAFLEX series 80 and VEGAPULS 64**

GEWADA-C.	CA / CD / CE / RB / RF	1 / 3
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**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 / O / X
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**for VEGAPULS 64**

GEWADA-F.	TA / TE / TD	3	TJ / AJ / AA / AB / AC / AD / AE / AI / AF / AG / AH
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For the wetted parts of the adapter versions listed in the following we confirm that the FDA requirements are fulfilled:

**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
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**for VEGACAL and VEGACAP**

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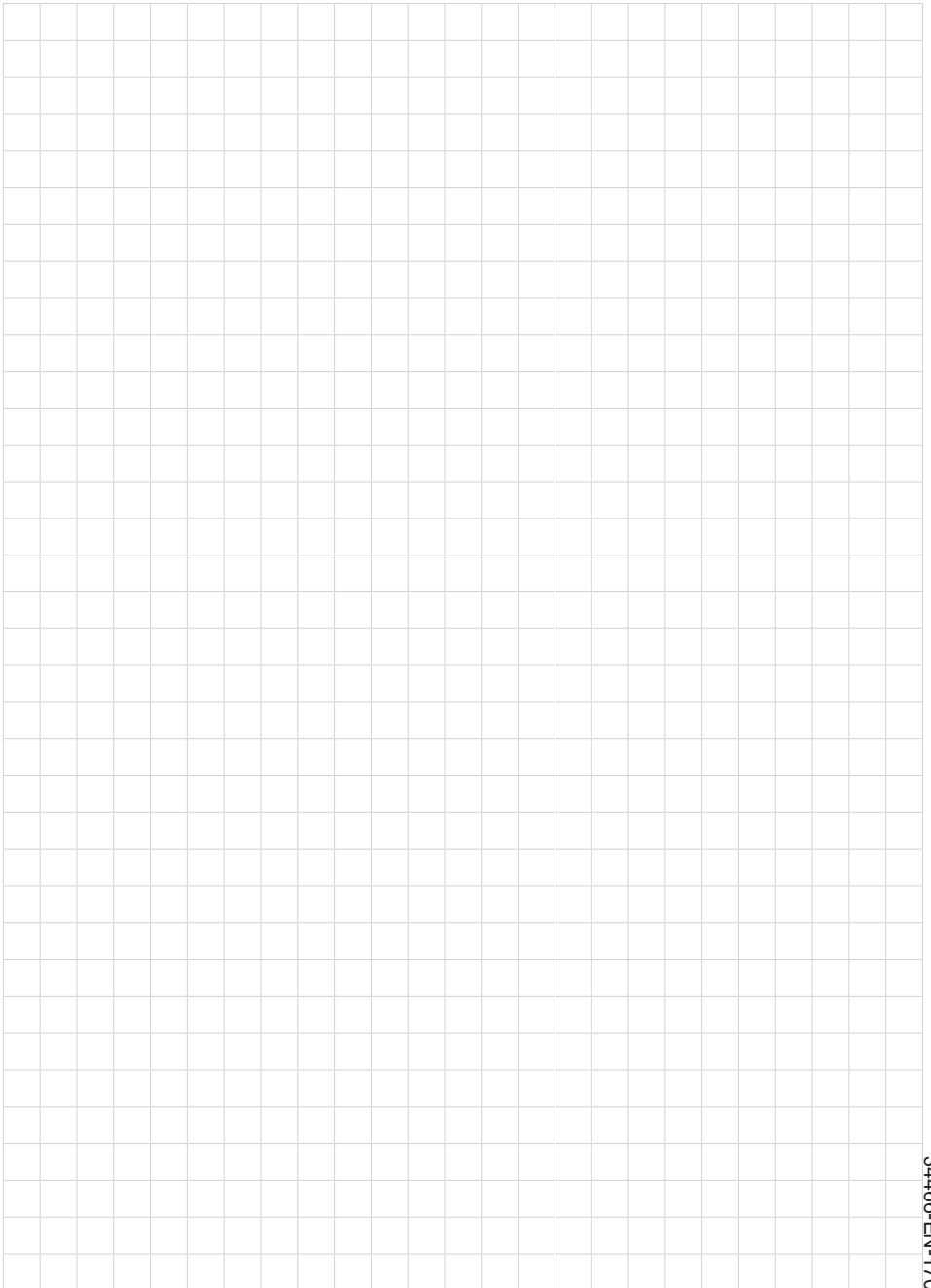
**for VEGABAR**

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
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This declaration is based on the following certificates:

- The official statement of the Public Health Service of the Food and Drug Administration on the implemented stainless steels (College Park, MD 20740 of 22.11.2004)

- 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 G75S) 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





Printing date:

# VEGA

All statements concerning scope of delivery, application, practical use and operating conditions of the sensors and processing systems correspond to the information available at the time of printing.

Subject to change without prior notice

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