OPTISWITCH 4000C Declaration of conformity

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

Always use a suitable process seal that meets the product-specific requirements.
We herewith declare that the versions of OPTISWITCH 4000C listed in the following Table 1 are suitable for contact with foodstuffs and comply with the requirements of regulation VO (EC) No. 1935/2004 and VO (EU) 10/2011 as well as the requirements of the Food Drug Administration.

### Process fittings

#### Thread

| VF39. | * | * | GA / GB / GH | GL / GP / NA | NB / NH / NL | NP | * | * | *
|-------|---|---|---------------|---------------|--------------|---|---|---|---

#### Clamp

| VF39. | * | * | * | C | * | * | * | * | *
|-------|---|---|---|---|---|---|---|---|---

#### Slotted nut

| VF39. | * | * | * | RL / RM / RN | * | * | * | * | *
|-------|---|---|---|---------------|---|---|---|---|---

#### Hygienic fitting with compression nut

| VF39. | * | * | * | LA | * | * | * | * | *
|-------|---|---|---|---|---|---|---|---|---

#### Tuchenhagen Varivent

| VF39. | * | * | * | RR | * | * | * | * | *
|-------|---|---|---|---|---|---|---|---|---

EG 10/2011 is deleted because the versions do not have any wetted plastic materials. The material is taken from GMP conform production acc. to VO (EC) 2023/2005 and mounted.
KROHNE product overview

- Electromagnetic flowmeters
- Variable area flowmeters
- Ultrasonic flowmeters
- Mass flowmeters
- Vortex flowmeters
- Flow controllers
- Level meters
- Temperature assemblies
- Pressure transmitters
- Analysis products
- Products and systems for the oil and gas industry

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