for direct contact with consumer goods, food and pharmaceutical applications

Revoseal Europe GmbH
Industriestraße 1

50259 Pulheim

EU-/FDA- Declaration of Conformity „Food- and Pharmaceutical- Safety“

We hereby confirm the suitability of our products (gaskets)
„revoseal Revolution and revoseal Eco+“; materials: stainless steel 1.4571 (optional 1.4404) and virginal PTFE
„revoseal JP – JG“; materials: stainless steel 1.4571 (optional 1.4404) and virginal PTFE
for use as consumer items for direct contact with food and thus applicable in pharmaceutical plant construction.

The products are in accordance with
- **EG-framework Regulation 1935/ 2004/EG and §§ 30 and 31 LFGB**
- **EG-framework Regulation 2023/2006/EG (GMP)**
- **EG-framework Regulation 2002/72/EG and the**
- **US Regulation 21CFR177.1550 (from 01.04.2015) as well as 21CFR175.105 (from 01.04.2015)**

Used Materials

Our products - as well as the additives used in the production process - consist only of materials from the above mentioned EU-Positive-List and the FDA white list. The maximum permitted quantities of substances are also observed.

Specific Migration Limit (SML) and maximum residual content (QM) resp. (QMA)

The prescribed SML regulations and / or QM resp. QMA values are applied under the test conditions. This includes the following substance:

Material	PM / Ref.-no.	SML / QM / QMA (mg/kg)
TFE	R / NUE 1	0,05 mg/kg

Ingredients with a restricted utilization ("dual use additives")

Substances as mentioned above are not included.

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