DECLARATION OF CONFORMITY **DC069**

For the following product **2025-06**

Type 3241/3244

Valves with special execution for the food and pharmaceutical industries

European regulation
Food contact

Valves Type 3241/3244 with special execution for the food and pharmaceutical industries meet the requirements of the food and pharmaceutical industry.

Manufacturing processes of Samson Regulation and those of its suppliers comply with the good manufacturing practices established by regulation (EC) No. 2023/2006[1].

The valve components in contact with foodstuffs meet the following requirements:

- the metal parts (valve body and plug) are made of cast stainless steel 1.4404 in accordance with:
    - the regulations (EC) No. 1935/2004[2]
    - the Council of Europe Resolution CM/Res(2020)9 on metals and alloys used in food contact materials and articles;
    - the French decree of 13 January 1976 on stainless steel materials and objects in contact with foodstuffs;
    - the sheet published by the French authority DGCCRF: MCDA n°1 (V2 - 2017), Aptitude for food contact of metals and metal alloys intended to come into contact with foodstuffs.
- The body seals are made of PTFE TFM™ 1700 in accordance with :
    - the regulations (EC) No. 1935/2004[5] and (EU) No. 10/2011[3] as amended

    The conditions and results of the overall and specific migration tests are detailed in the Annex 1.

According to the migration tests carried out on the plastic components in accordance with Regulation (EU) No 10/2011[3] as amended, the overall and specific migrations remain within the limits set by the above-mentioned Regulation when the complete apparatus is used under the conditions indicated below:

- repeated short-term and long-term contact with all kinds of foodstuffs in applications at room temperature up to 175 °C.

[1] Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food

[2] Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food

[3] Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, as last amended by Regulation (EU) No 2020/1245

Environmental regulation and others

The valves 3241/3244 are compliant with

- Directive RoHS 2011/65/EU, 2015/863/EU
- Regulation REACH 1907/2006/EC

USA regulation

Food contact and pharmaceutical regulation

The valves 3241/3244 meet the requirements of food and pharmaceutical industries according to the following parameters.

- The PTFE used in the manufacture of the seals, complies with :
  - the regulation FDA CFR 21 §177.1550,
  - USP Class VI Chapter 88, 121°C (in vivo) and Chapter 87 (in vitro)
- The grease used for the assembly of parts in contact with the fluid, complies with :
  - the regulation FDA CFR 21 §178.3570,
  - NSF-H1 requirements

Other regulations

The composition of the plastic materials in contact with the fluid is:

- free of animal-derived ingredients (ADI free) and thus free of TSE/BFE
- free of human-derived ingredients,
- purely of synthetic origin.

SAMSON REGULATION S.A.S.

Bruno Soulas

General Director
Head of Strategy and Development

SAMSON REGULATION S.A.S.

Jean-Louis Bard

Head of Quality, Environment Safety & Health

Annex 1/Annexe 1

elringklinger
Engineered Plastics

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22. August 2022

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Declaration of compliance to Regulation (EU) 10/2011 (1,2) and (EC) 1935/2004 for materials made from plastic intended to come into contact with food

We hereby confirm that our product:
Flat sealing Ring - Order No. 4700005274
Material number: *TFM 1700*

complies with the legal regulations laid down in the European Plastic Regulation (EU) 10/2011[1,2] as well as in Regulation (EC) 1935/2004, both as amended.

When used as specified, the overall migration[3] as well as the specific migration does not exceed the legal limits.
The testing was performed according to Regulation (EU) 10/2011[1,2] (Annex V).
See IVV -Test-Reports No PA/4777/15 part 1 + 2 from 18. March 2016 and the IVV Certificates of Conformity No PA/4777/15 for "Flat sealing rings" and for "V-rings" dated 13. May 2016

The materials and raw materials used comply with Plastic Regulation (EU) 10/2011[1,2]

The following substances, subject to limitations and/or specification, are used in the above mentioned product:

Name of substance	Restriction
Tetrafluoroethylene TFE CAS 116-14-3	SML = 0,05 mg/kg
Perfluoropropylvinyl Ether PPVE (TFE:PPVE-Copolymer) CAS 26655-00-5 100,0	SML = 0,05 mg/kg

Note on dual use substances:
In the above mentioned product, no dual-use substances are included.

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REGISTERED OFFICE

Bietigheim-Bissingen
Amtsgericht Stuttgart
HRB 301607
USt-IdNr. DE147325746

BANKING DETAILS

Commerzbank AG, Stuttgart
IBAN DE96600800000901027000
BIC DRESDEFF600

Deutsche Bank AG, Stuttgart
IBAN DE61600700700110275500
BIC DEUTDESSXXX

Specification of the intended use or restrictions:

Type(s) of food or processes for which the material is suitable:
Repeated contact for all kinds of food with contact conditions ranging from short term to long term contact at room temperature as well as hot temperature applications at a maximum temperature of 175 °C

Type(s) of food or processes for which the material is not suitable:
none

Test conditions overall migration:
Simulant aqueous simulants, 3% acetic acid, 4 h/100°C, EN 1186-3
Simulant isooctane, 6h/60°C, EN 1186-15
Simulant 95% ethanol (worst case simulant), 6h/60°C, EN 1186-15
Simulant Tenax (modified polyphenylene oxide MPPO), 2h/175°C, EN 1186-13B

Differing from the standard EU 10/2011 [1,2] worst case study isooctane was used instead of oil simulant "olive oil".

Ratio of food contact surface area to volume used to determine the compliance of the material or article:
Based on the obtained screening results, the investigated samples are in compliance with the safety requirements of Article 3 of Regulation (EC) No 1935/2004 and 21 CFR § 170.39 "Threshold of Regulation" at proper use provided that the surface to volume ratio is 0,5 dm^2 to at least 1 kg food (flat sealing rings Tl-No: 8414-2596 / 573.240) and 0,8 dm^2 to at least 1 kg of food (V-rings Tl-No: 0430-3311 // 573.190), respectively.

Under the given conditions, for the other parts, the correlating volume of food and the real food-contact area are listed in the chart below.

V-Rings			**Flat sealing rings**		
Part-No	Real food contact surface area	**Minimum volume of food**	Part-No	Real food contact surface area	**Minimum volume of food**
100009670 (0430-3310)	512,07 mm^2	0,064 kg	100009196 (8414-2592)	62,83 mm^2	0,013 kg
100009673 (0430-3311)	712,7 mm^2	0,089 kg	100009197 (8414-2593)	115,1 mm^2	0,023 kg
100009674 (0430-3312)	3929,1 mm^2	0.491 kg	100009201 (8414-2594)	160,8 mm^2	0,032 kg
			100009202 (8414-2595)	189,1 mm^2	0,037 kg
			100009210 (8414-2596)	204,8 mm^2	0,041 kg
			100009213 (8414-2597)	236,2 mm^2	0,047 kg
			100009218 (8414-2598)	275,7 mm^2	0,055 kg
			100009221 (8414-2599)	409,5 mm^2	0,082 kg
			100009222 (8414-2600)	504,7 mm^2	0,101 kg
			100009227 (8414-2601)	630,4 mm^2	0,126 kg

A functional barrier made from plastic is not used in the above mentioned product.

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Traceability:
The product is produced according to our quality management system, on good manufacturing practice GMP (EC 2023/2006 [2]) for materials and articles intended to come into contact with food.

This declaration is valid for the product as described and delivered by us. The verification of compliance was performed based on the rules set out in Regulation (EU) 10/2011 [1,2]; according to which the product complies with the legal requirements subject to adherence to the stated conditions for the contact with food.

Due to the specified production process and to the quality assurance measures for the manufacture of our parts there is an equivalence between the test specimen and the mentioned parts in the chart above (other dimensions).
The relevant migration values will not be exceeded if the relation „Real Food contact surface areas" and „Minimum volumes of food" (in the chart above) is respected.

This declaration of conformity includes therefore all mentioned parts in the chart above.

In case of deviating from the intended use, the user is responsible for verifying compliance and suitability.

Yours sincerely
ElringKlinger Kunststofftechnik GmbH

i. A. Lena Ried
Material Development

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[1] = with amendments EU N° 321/2011, 1282/2011, 1183/2012, 202/2014, 865/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/37, 2019/988, 2019/1338 and 2020/1245
[2] = in its valid version
[3] = global migration limit: 10 mg/dm^2 or 60 mg/kg food or LM-simulant

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