



DECLARATION OF COMPLIANCE
Food Contact Regulations

Apparatus model/Product: **Stainless Steel Clean Steam Filters:**
CSF16 Filter Housings (CSF16, CSF16T, CSF16L, CSF16 LT, CSF16H, CSF16HT)
CSF16 Filter Elements (CSF16-SE, CSF16-SF)

Name and address of the manufacturer or his authorised representative: **Spirax Sarco Ltd,**
 Runnings Road
 Cheltenham
 GL51 9NQ
 United Kingdom

The object of the declaration described above is in conformity with the relevant requirements of:

- (EC)1935/2004 Materials and Articles Intended to come into Contact with Food**
- (EC)2023/2006 Good Manufacturing Practice for materials and articles intended to come into contact with food**
- (EU)10/2011 Plastic Materials and Articles Intended to come into Contact with Food**
- FDA Code of Federal Regulations - Title 21 - Food and Drugs**

Additional information:

Conditions of use (Steam and Condensate, temperature): For use on steam at a maximum allowable temperature as specified in the product Technical Information document (Products with EPM O-ring = 178°C, Fluoraz O-ring or Stainless Steel/PTFE Spiral wound gasket = 220°C)

If used, materials in contact with food will conform to:

<i>Material</i>	<i>will conform to</i>	
	<i>(EC)1935/2004</i>	<i>FDA</i>
Metal	Council of Europe Resolution CM/Res(2013)9	CFR title 21: 211.65 (or GRAS)
Rubber	BfR Recommendation XXI	CFR title 21: 177.2600
Plastic	(EU)10/2011	CFR title 21: <i>NOTE 1</i>
Silicone	BfR Recommendation XV	CFR title 21: 177.2600

NOTE 1
 177.1550 Perfluorocarbon resins (PTFE)
 177.2415 Poly(aryletherketone) resins (PEEK)
 177.2480 Polyoxymethylene homopolymer (POM)
 177.2500 Polyphenylene sulfone resins (PS)
 177.2510 Polyvinylidene fluoride resins (PVDS)

Assessment of parts in contact with food:

<i>Component</i>	<i>Material</i>	<i>Material Specification</i>
Filter Housing Parts	Metal	Stainless steel: 1.4301 (304) / 1.4307 (304L) / 1.4404 (316L) / 1.4432 (316L) / 1.4435 (316L) / 1.4541 (321) / 1.4571 (316TI)
Weld Filler Material	Metal	1.4430 (AWS 316L) / 1.4576 (ER318SI)
Filter Element Parts	Metal	Sintered Stainless steel: 1.4404 (316L) Stainless Steel: 1.4301 (304)
Filter Housing /Element seal	Rubber	EPM380 / Fluoraz 890
Filter Housing seal	Plastic/Metal	Stainless steel: 1.4541 spiral wound gasket with PTFE filler



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Additional Information


Information for wetted parts made of plastic materials:

The determined overall migration from the sample to the simulant is given in the table below.

<i>Material</i>	<i>Test Stimulant</i>	<i>Test Conditions</i>	<i>Results (mg/dm²)</i>	<i>Overall Migrations limits (OML)</i>
PTFE	3% Acetic Acid	4 hours, 100°C (± 2°C)	<1	10mg/dm ²

The determined specific migration to the simulant is given in the table below:

<i>Material</i>	<i>Parameter</i>	<i>Test Conditions</i>	<i>Results (mg/kg)</i>	<i>Specific Migrations limits (SML)</i>
PTFE	Formaldehyde Ref. No:17260/54880 CAS-Nr 50-00-0	Ethanol 10% 4 hours, 100°C	<1	15mg/kg
PTFE	Tetrafluoroethylene Ref. No: 25120 CAS No: 116-14-3	Ethanol 10% 4 hours, 100°C	<0.05	0.05mg/kg

Signed for and on behalf of: 
Spirax Sarco Ltd,

(signature): N Morris
(name, function): Compliance Manager
Steam Business Development Engineering

(place and date of issue): Cheltenham

21 June 2023

GNP237-FCR-C issue 2