

The undersigned, representing the following company

1	Company	
	Name	Keofitt A/S
	Address	Kullinggade 31 DK-5700 Svendborg DENMARK
	VAT No	DK 42 88 82 14

selling several products containing either membrane(s) or O-ring(s), as identified in the table 2:

2	Product group	Item identification – items with membrane(s)	Item identification – items with O-rings
	4KAI Sampling Valve	Head configurations: 445541, 445543, 445544	- none -
	4KAI Components	400055, 774441PTFE, 774444PTFE	- none -
	M4 Sampling Valve	Head configurations: 405541, 405542, 405543, 405544, 405545, 405547	- none -
	M4 Components	400055, 774041PTFE, 774044PTFE	- none -
	W9 Sampling Valve	Head configurations: 855541, 855542, 855543, 855544, 855545, 855547	- none -
	W9 Components	778541, 778544, 850055	- none -
	W15 Sampling Valve	Head configurations: 865541, 865544, 865547	- none -
	W15 Components	778641, 778644, 860055, 860055.2	- none -
	W25 Sampling Valve	Head configurations: 875544, 875547	- none -
	W25 Components	778747, 870055	- none -
	INGOLD Sampling Valve	Head configurations: 315541, 315543, 315544, 325541, 325543, 325544	- none -
	INGOLD Components	310055, 320055, 773141PTFE, 773144PTFE, 773241PTFE, 773244PTFE	- none -
	SESAME Sampling Valve	Head configurations: 893141PTFE, 893143PTFE, 893144PTFE, 893241PTFE, 893243PTFE, 893244PTFE, 895541, 895543, 895544	- none -
	SESAME Components	890055, 895531, 895532	- none -
	BASIX Sampling Valve	450141PTFE, 450144PTFE, 451141PTFE, 451144PTFE, 452141PTFE, 452144PTFE, 452241PTFE, 452244PTFE	- none -
	BASIX Components	400055, 774441PTFE, 774444PTFE	- none -

DECLARATION OF COMPLIANCE - PTFE

2	Product group	Item identification – items with membrane(s)	Item identification – items with O-rings
	SIMPLEX Sampling Valve	830141PTFE, 830141.2PTFE, 830144PTFE, 830541PTFE, 830544PTFE, 830941PTFE, 830944PTFE, 831141PTFE, 831141.2PTFE, 831144PTFE, 832141PTFE, 832144PTFE, 832241PTFE, 832244PTFE	- none -
	SIMPLEX Components	850055, 778301PTFE, 778309PTFE, 778344PTFE, 778344-68PTFE	- none -

where the listed membranes and O-rings are made from the below mentioned material:

3	Material	
	Name	PTFE (Polytetrafluoroethylene)
	Raw material	PTFE TFM 1705 = PTFE PEW10659. Modified granular PTFE for compression moulding from Dyneon.
	Specifications	The components made from the material have specific properties against temperature, moisture, acidity, fat content etc. Specific or relative limits are given in datasheets for the individual item (i.e. a membrane) or the component (i.e. a valve head). The data sheets with the most recent information are available at our website www.keofitt.dk . If an actual useful range of a given specification is incompatible with the anticipated use, alternative materials with better specifications are often available.
	Intended use	The plastic material is intended to seal against liquids in the liquid processing industries such as breweries, dairies, fruit juices, other liquid foodstuff, biotech and pharmaceuticals. This material is suitable for contact with all types of food at any food contact conditions at a temperature exceeding 40°C for aqueous food, and high temperature applications for fatty food. For more information, please consult the relevant data sheets and User Manuals available at our website www.keofitt.dk .
	Additional information	When evaluating the risk associated with the material's contact with the product media, it is important to notice how small the material's permanent contact area is per volume or weight of the end-user's liquid product media. The permanent contact surface area is typically 1-2 cm ² with a maximum of 5 cm ² for the largest valves. In relation to the size of an average production line, this will in most cases be negligible.
	ADI free	All products made of PTFE are free of animal derived components.
	TSE/BSE free	All products made of PTFE are free from BSE (Bovine Spongiforme Encephalopathies) and TSE (Transmissible Spongiforme Encephalopathies).

hereby declares that all the above-mentioned items having liquid product contact and made from the above-mentioned material comply with the terms laid down in the regulations below as amended at the time of the underlying declarations from our suppliers:

4	Area of validity	Regulation / Standard
	EU	Framework Regulation (EC) No 1935/2004 of 27 th October 2004 on materials and articles intended for contact with food.
	EU	Commission Regulations (EC) No 2023/2006 of 22 nd December 2006 amended, on good manufacturing practices for materials and articles intended for contact with food.
	EU	<p>Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended for contact with food is an implementing measure under the Framework Regulation (so-called "PIM" or Plastics Implementation Measure) addressing Plastics specifically.</p> <p>Only authorized monomers, other starting substances and additives as listed in Annex I of (EU) 10/2011 have been used in the manufacture of plastic intermediates. Final material is compliant with the limits set out in Annex II.</p> <p>Overall Migration Limit (OML) is found to be below 10 mg/dm² at the following standard testing conditions laid down under (EU) 10/2011: 3% acetic acid and 10% ethanol at OM6 (4 hours at 100°C or at reflux) and olive oil at OM7 (2 hours at 175°C).</p> <p>No Specific Migration Limit set out in Annex I is exceeded for the final product.</p> <p>The material contains substances that are subject to a restriction by a specific migration limit (SML).</p> <p>Those substances and their SML are: Heptafluoropropyl trifluorovinyl ether (CAS 1623-05-8) 0.05 mg/kg and Tetrafluoroethylene (CAS 116-14-3) 0.05 mg/kg.</p> <p>There are no dual-use additives present in the material.</p>
	EU	Regulation (EC) No 1895/2005 on the restriction of use of certain epoxy derivatives.
	EU	All products are compliant with EC 1907/2006 - REACH.
	EU	All products are compliant with DIR 2011/65/EU – RoHS.
	China	<p>GB 4806.1-2016 General safety requirements for food contact materials and articles.</p> <p>GB 4806.6-2016 Food contact plastic resins.</p> <p>The following substance is subject to restriction under GB 4806.6-2016: Tetrafluoroethylene (CAS 116-14-3), SML = 0.05 mg/kg. Specific Migration Limit is not exceeded for final material at following test conditions: 95% ethanol for 2 hours at 60°C.</p> <p>GB 4806.7-2016 Food contact plastic materials and articles.</p> <p>The final material does not exceed the limits set out in GB 4806.7-2016 on sensory index, decoloring testing, potassium permanganate consumption, heavy metal fraction and overall migration. Overall migration limit is found below 10 mg/dm² at following test conditions: 4% acetic acid for 2 hours at 70°C, 20% ethanol for 2 hours at 70°C and olive oil for 2 hours at 70°C.</p> <p>GB 9685-2016 Standard for use of additives in food contact materials and articles.</p> <p>Raw material is compositional compliant with GB 9685-2016.</p>
	Japan	Japanese Food Sanitation Act
	Denmark	Bekendtgørelse nr. 681 af 25/05/2020 om fødevarekontaktmaterialer. Danish Ministerial Order No. 681 of 25 May 2020 on food contact materials.
	Denmark	<p>Bekendtgørelse nr. 1520 af 15/12/2022 om autorisation og registrering af fødevarevirksomheder m.v.. Dette inkluderer bekræftelse på registrering hos Fødevarestyrelsen.</p> <p>Danish Ministerial Order No. 1520 of 15 December 2022 on authorization and registration of Food Companies, etc.. This includes confirmation of registration at Danish and Food Administration.</p>

4	Area of validity	Regulation / Standard
	USA	Code of Federal Regulation, Title 21 §177.1550 "Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces - Perfluorocarbon resins"
	USA	U.S. Pharmacopeia, General Chapter 88 "Biological Reactivity Test, in Vivo". USP <88> Class VI (extraction conditions 121°C for 1 hour). The European/International counterpart to USP <88> is to be found in ISO 10993 "Biological Evaluation of Medical Devices".
	USA	U.S. Pharmacopeia, "Biological Reactivity Test, in Vitro". USP <87>.

The listed item No. can occasionally be added with a "X" and still be included in this Declaration of Compliance.

This Declaration of Compliance is not complete without the relevant data sheets, user manuals and supplier certificates.

As supporting material, we kindly refer to our "Service Center" on our website www.keofitt.dk, where you find the following material:

5	Supporting documents	
	Supplier certificates	Can be supplied on request by contacting Keofitt quality manager directly.
	Data sheets and User Manuals	<ul style="list-style-type: none"> Data sheet for the given item no. User Manual for the given product/valve

Svendborg, 13th of March 2024



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