

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: 440041E, 440044E	- none -
	4KAI Components	400052, 774441EPDM, 774444EPDM	- none -
	M4 Sampling Valve	Head configurations: 400041E, 400042E, 400043E, 400044E, 400045E, 400047E	Body configurations: 400009, 400010, 400031
	M4 Components	400052, 774041EPDM, 774044EPDM	400208, 400308, 774009, 774010, 774031, 900829
	W9 Sampling Valve	Head configurations: 600041E, 600042E, 600043E, 600044E, 600045E, 600047E, 600048E, 600049E	Body configurations: 850008, 850008-1, 850009, 850009-1, 850013, 850020, 850031, 850037
	W9 Components	600052, 600252, 776041EPDM, 776044EPDM, 776048EPDM	400208, 400308, 778508, 778509, 778531, 900829
	W15 Sampling Valve	- none -	Body configurations: 860009
	W15 Components	- none -	400208
	W25 Sampling Valve	- none -	870009
	W25 Components	- none -	400208
	INGOLD Sampling Valve	Head configurations: 310041E, 310043E, 310044E, 320041E, 320043E, 320044E	- none -
	INGOLD Components	310052, 320052, 773141EPDM, 773144EPDM 773241EPDM, 773244EPDM,	300118
	SESAME Sampling Valve	Head configurations: 890041E, 890043E, 890044E	Body configurations: 890008, 890009, 890013, 893105, 893205
	SESAME Components	890052	400208, 300118
	BASIX Sampling Valve	450141E, 450144E, 451141E, 451144E, 452141E, 452144E, 452241E, 452244E	- none -
	BASIX Components	400052, 774441EPDM, 774444EPDM	- none -

DECLARATION OF COMPLIANCE - EPDM

2	Product group	Item identification – items with membrane(s)	Item identification – items with O-rings
	SIMPLEX Sampling Valve	830141EPDM, 830141.2EPDM, 830144EPDM, 830541EPDM, 830544EPDM, 830941EPDM, 830944EPDM, 831141EPDM, 831141.2EPDM, 831144EPDM, 832141EPDM, 832144EPDM, 832241EPDM, 832244EPDM	830941EPDM, 830944EPDM
	SIMPLEX Components	600052, 778301EPDM, 778309EPDM, 778344EPDM, 778344-68EPDM	400208, 778344-68EPDM
	Multi Micro Port 49	- none -	Body configurations: 840009
	Multi Micro Port 49 Components	- none -	400208
	Carlsberg Flask Components	- none -	200830, 772002, 900074

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

3	Material	
	Name	EPDM (Ethylene Propylene Diene Monomer)
	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 rubber material is intended to seal against liquids in the liquid processing industries such as breweries, dairies, fruit juices, other liquid foodstuff, biotech and pharmaceuticals. For more information, please consult the relevant data sheets and user manuals available at our website www.keofitt.dk .
	Additional information	The materials contact area per volume or weight of the end-user's liquid product media will in most cases be negligible.
	ADI free	All products made of EPDM are free of animal derived components.
	TSE/BSE free	All products made of EPDM are free from BSE (Bovine Spongiform Encephalopathies) and TSE (Transmissible Spongiform 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.

4	Area of validity	Regulation / Standard
	China	Membranes: Chinese standard GB4806.11-2016, specifying the migration limits in simulated foodstuff solutions. Extraction conditions: 4% acetic acid, 10% ethanol and 50% ethanol, 4 hours at reflux temperature. Membranes do NOT comply with the additives list as stated in GB9685:2016.
	Denmark	Bekendtgørelse nr. 681 af 25/05/2020 om fødevarekontaktmaterialer. Danish Ministerial Order No. 681 of 25 May 2020 on food contact materials.
	Denmark	Bekendtgørelse nr. 1352 af 10/12/2019 om autorisation og registrering af fødevarevirksomheder m.v.. Dette inkluderer bekræftelse på registrering hos Fødevarestyrelsen. Danish Ministerial Order No. 1352 of 10 December 2019 on autorisation and registration of Food Companies, etc.. This includes confirmation of registration at Danish and Food Administration.
	Germany	Membranes: German Federal Institute for Risk Assessment (BfR, Bundesinstitut für Risikobewertung): Membranes meet the requirements stated in BfR XXI, cat. 2 (Extractions only) for EPDM. Food simulant and extraction conditions: 10% ethanol, 24 hours at 40°C; 3% acetic acid, 24 hours at 40°C; water 24 hours at 40°C. Specific Migration Limit (SML) is met for <i>Formaldehyde</i> (Cas.no. 50-00-0), <i>PAH</i> and <i>Primary Aromatic Amines</i> . Limits for <i>Migratable N-nitrosamines</i> are met. Limits for content of <i>Lead (Pb)</i> and <i>Zinc (Zn)</i> are met.
	USA	Code of Federal Regulation, Title 21 §177.2600 "Rubber articles intended for repeated use with food for human consumption"
	USA	U.S. Pharmacopeia, General Chapter 88 "Biological Reactivity Test, in Vivo". USP <88> Class VI. The European/International counterpart to USP <88> is to be found in ISO 10993 "Biological Evaluation of Medical Devices".

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	<ul style="list-style-type: none">• 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, 25th of October 2022

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