

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: 440041, 440043, 440044	- none -
	4KAI Components	400051, 774441, 774444	- none -
	M4 Sampling Valve	Head configurations: 400041, 400042, 400043, 400044, 400045, 400047	- none -
	M4 Components	400051, 774041, 774044	- none -
	W9 Sampling Valve	Head configurations: 600041, 600042, 600043, 600044, 600045, 600047, 600048, 600049	- none -
	W9 Components	600051, 600251, 776041, 776044, 776048	- none -
	INGOLD Sampling Valve	Head configurations: 310041, 310043, 310044, 320041, 320043, 320044	Body configurations: 310002, 310005, 320002, 320005, 320007
	INGOLD Components	310051, 320051, 773141, 773144, 773241, 773244	300119
	SESAME Sampling Valve	Head configurations: 890041, 890043, 890044	Body configurations: 893105, 893205, 893205.8
	SESAME Components	890051	300119
	BASIX Sampling Valve	450141, 450144, 451141, 451144, 452141, 452144, 452241, 452244	- none -
	BASIX Components	400051, 774441, 774444	- none -
	SIMPLEX Sampling Valve	830141, 830141.2, 830144, 830941, 831141, 831144, 832141,	830144, 831144 Body configurations: 830144.2EPDM, 830144EPDM, 830144PTFE, 830944PTFE, 831144PTFE
	SIMPLEX Components	600051, 778301, 778309, 778344, 778344-68	- none -
			800830B, 400830

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

3	Material	
	Name	SILICONE
	Specifications:	<p>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.</p> <p>If an actual useful range of a given specification is incompatible with the anticipated use, alternative materials with better specifications are often available.</p>
	Intended use	<p>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.</p> <p>For more information, please consult the relevant data sheets and User Manuals available at our website www.keofitt.dk.</p>
	Additional information	<p>The materials contact area per volume or weight of the end-user's liquid product media will in most cases be negligible.</p>
	ADI free	<p>All products made of silicone are free of animal derived components.</p>
	BSE/TSE free	<p>All products made of silicone are free from BSE (Bovine Spongiforme Encephalopathies) and TSE (Transmissible Spongiforme Encephalopathies).</p>

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.
	China	Membranes: Chinese standard GB4806.1-2016, general safety requirements. Chinese standard GB4806.11-2016, specifying the migration limits in simulated foodstuff solutions. Extraction conditions: 4% acetic acid, 10% ethanol and 50% ethanol, 2 hours at 70 °C.
	Denmark	Bekendtgørelse nr. 681 af 25/05/2020 om fødevarekontaktmaterialer. Danish Ministerial Order No. 681 of 25 th of August 2020 on food contact materials.
	Denmark	Bekendtgørelse nr. 1520 af 15/12/2022 om autorisation og registrering af fødevarevirksomheder m.v.. Dette inkluderer bekræftelse på registrering hos Fødevarestyrelsen. Danish Ministerial Order No. 1520 of 15 of December 2022 on authorization 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 XV for silicones.
	USA	Code of Federal Regulation, Title 21 §177.2600 "Rubber articles intended for repeated use with food for human consumption"
	USA	Membranes: U.S. Pharmacopeia, General Chapter 88 "Biological Reactivity Test, in Vivo". USP <88> Class VI (70°C/24h). The European/International counterpart to USP <88> is to be found in ISO 10993 "Biological Evaluation of Medical Devices". U.S. Pharmacopeia, General Chapter 87 "Biological Reactivity Test, in vitro". USP<87> Elution Test in MEM (37°C/24h).

The listed item No. can occasionally be added with an “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, April 15th 2024

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