

The undersigned, representing the following company

1	Company	
	Name	Keofitt A/S
	Address	Kullinggade 31 DK-5700 Svendborg DENMARK
	VAT No	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
	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	- 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 -
	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)
	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. 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 the vast majority of cases be negligible.

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 to come into 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 to come into contact with food.
	EU	Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food is an implementing measure under the Framework Regulation (so-called "PIM" or Plastics Implementation Measure) addressing Plastics specifically.
	Denmark	Bekendtgørelse nr. 1248 af 30/10/2018 om fødevarekontaktmaterialer. Danish Ministerial Order No. 1248 of 30 October 2018 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 authorization and registration of Food Companies, etc.. This includes confirmation of registration at Danish and Food Administration.
	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. 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	Certificates from <ul style="list-style-type: none">Gunnar Haagenzen A/S (membranes)
	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, 27th of January 2020

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