

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
	Micro Port	900014, 900056, 900057, 900058, 900059,	- none -
	Micro Port Components	900049, 779056	- none -
	Multi Micro Port 49	840001, 840009, 840020	- none -
	Multi Micro Port 49 Components	900049, 778401, 778409	- none -
	Micro Port varivent	900026, 900027, 900028	- none -

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

3	Material	
	Name	BUTYL (Isobutylene Isoprene Rubber)
	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. Simultaneously it is designed to be pierced several times with a needle to extract a liquid sample from the process side. 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 butyl are free of animal derived components.
	BSE/TSE	All products made of butyl 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 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.
	Denmark	Bekendtgørelse nr. 681 af 25/05/2020 om fødevarekontaktmaterialer. Danish Ministerial Order No. 681 of 25 th of 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 authorization and registration of Food Companies, etc.. This includes confirmation of registration at Danish and Food Administration.
	USA	Code of Federal Regulation, Title 21 §177.2600 "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
	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, 21st of February 2024

KEOFITT
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