 WORLD LEADERS IN STERILE SAMPLING™	DECLARATION OF COMPLIANCE	Page: 1 of 3
	<b>EPDM</b>	Effective date June 2017

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 a number of products containing either membrane(s) or O-ring(s), as identified in the table 2:

2	Product group	Item identification – items with membrane(s) (X designates any digit)	Item identification – items with O-rings (X designates any digit)
	M4 sampling valve	Head configurations: 40004XE	Body configurations: 400009, 400010, 400031
	Components for M4	774041EPDM, 774044EPDM, 400052	774031, 400208, 400308, 400820, 400830E, 900074, 900091, 900829
	W9 sampling Valve	Head configurations: 60004XE	Body configurations: 850008, 850009, 850013, 850031
	Components for W9	776041EPDM, 776044EPDM, 776048EPDM, 600052, 600252	778508, 778509, 778531
	W15 sampling valve	- none -	Body configurations: 860009, 400208, 850824, 900074
	W25	- none -	400208
	INGOLD	Head configurations: 3X004XE	- none -
	Components for INGOLD	773141EPDM, 773241EPDM, 773144E, 773244EPDM, 310052, 320052	300118
	REFLEX Sampling valve	8800XXE, 880052,	880008E, 880009E, 300118
	SESAME Sampling valve	Head configurations: 8900XXE, 880057, 890052,	890041E, 890043E, 890044E, 890055
	SIMPLEX Sampling Valve	83XX41EPDM, 83XX44EPDM, 830141.2EPDM, 831141.2EPDM	830941EPDM, 830944EPDM, 400208
	Components for SIMPLEX	600052, 778301EPDM, 778309EPDM, 778344EPDM, 778344-68EPDM	900074, 900091, 778344-68EPDM
	Multi Micro Port-49	- none -	840009

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

3	Material	
	Name	<b>EPDM</b> (Ethylene Propylene Diene Monomer)

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	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 <a href="http://www.keofitt.dk">www.keofitt.dk</a> . 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 <a href="http://www.keofitt.dk">www.keofitt.dk</a> .
	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 <sup>th</sup> October 2004 on materials and articles intended to come into contact with food.
	EU	Commission Regulations (EC) No 2023/2006 of 22 <sup>nd</sup> December 2006 amended, on good manufacturing practices for materials and articles intended to come into contact with food.
	Denmark	Bekendtgørelse nr. 822 af 26/06/2013 om fødevarekontaktmaterialer. Danish Ministerial Order No. 822 of 26 June 2013 on food contact materials.
	Denmark	Bekendtgørelse nr. 1647 af 15/12/2016 om autorisation og registrering af fødevarevirksomheder m.v.. Dette inkluderer bekræftelse på registrering hos Fødevarestyrelsen. Danish Ministerial Order No. 1647 of 15 December 2016 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 ( <b>where specified in the data sheet</b> ) The European/International counterpart to USP <88> is to be found in ISO 10993 "Biological Evaluation of Medical Devices".

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 Online Service Centre on our website [www.keofitt.dk](http://www.keofitt.dk), where you find the following material:

5	Supporting documents	
	Supplier certificates	<ul style="list-style-type: none"> <li>• Certificates from AVK Gummi A/S (membranes):</li> <li>• Certificates from Gunnar Haagensen A/S (O-rings)</li> <li>• Certificates from M-seals A/S (O-rings)</li> <li>• Certificate from ITE (gasket)</li> </ul>
	Data sheets and User Manuals	<ul style="list-style-type: none"> <li>• Data sheet for the given item no.</li> <li>• User Manual for the given product/valve</li> </ul>

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Svendborg, 7 of Decemberr 2017

**Rasmus Markvardsen**  
Technical Manager



f. Henrik L. Salomon  
Managing Director