

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, as identified in the table 2:

2	Product group	Item identification	Comments
	M4 Sampling Valve	Body configurations: 400001, 400009, 400010, 400011, 400014, 400021, 400022, 400031	Applies only to the steel part, which has permanent process media contact. All configurations are made from 1.4404 steel.
	W9 Sampling Valve	Body configurations: 850001, 850003, 850004, 850005, 850006, 850007, 850008, 850009, 850010, 850011, 850013, 850014, 850015, 850016, 850017, 850018, 850019, 850020, 850021, 850022, 850024, 850025, 850026, 850031, 850036, 850037, 850039, 850040	Applies only to the steel part, which has permanent process media contact. 1.4404 for "Hose piece" and "Thread" configurations. 1.4435 for "Clamp" and "Welding Liner" configurations.
	W15 Sampling Valve	Body configurations: 860001, 860002, 860003, 860004, 860007, 860009, 860011	Applies only to the steel part, which has permanent process media contact. All configurations are made from 1.4404 steel.
	W25 Sampling Valve	Body configurations: 870001, 870003, 870009	
	INGOLD Sampling Valve	Body configurations: 310002, 310005, 320002, 320005, 320007	Applies only to the steel part, which has permanent process media contact. All configurations are made from 1.4435 steel.
	SESAME Sampling Valve	Body configurations: 890001, 890003, 890005, 890006, 890007, 890008, 890009, 890010, 890011, 890013, 890019, 890021, 890022, 890036, 890039	
	SIMPLEX Sampling Valve	Body configurations: 830141, 830141.2, 830144, 830541, 830544, 830941, 830944, 831141, 831141.2, 831144, 832141, 832144, 832241, 832244, 830141EPDM, 830141.2EPDM, 830144EPDM, 830541EPDM, 830544EPDM, 830941EPDM, 830944EPDM, 831141EPDM, 831141.2EPDM, 831144EPDM, 832141EPDM, 832144EPDM, 832241EPDM, 832244EPDM, 830141PTFE, 830141.2PTFE,	Applies only to the steel part, which has permanent process media contact. All configurations are made from 1.4404 steel.

2	Product group	Item identification	Comments
		830144PTFE, 830541PTFE, 830544PTFE, 830941PTFE, 830944PTFE, 831141PTFE, 831141.2PTFE, 831144PTFE, 832141PTFE, 832144PTFE, 832241PTFE, 832244PTFE	Applies only to the steel part, which has permanent process media contact. All configurations are made from 1.4404 steel.
	Micro Port	900014, 900056, 900057, 900058, 900059	
	Multi Micro Port 49	840001, 840009, 840020	
	Carlsberg Flask	200001	

where the listed products are made from the below mentioned stainless steel alloys:

3	Material																																																																					
	Name		Stainless Steel 316L																																																																			
	Specifications:		<p>316L is the SAE grade; the equivalent EN-standard designation is 1.4404 or 1.4435 for the high-alloyed end of the 316L alloy interval (see Chemical composition below).</p> <p>316L is an 18/8 austenitic stainless steel enhanced with an addition of at least 2.0% Molybdenum, to provide superior corrosion resistance to type 304 stainless steel.</p> <p>316L is the low-carbon version of 316 having a guaranteed maximum content of carbon of 0.03%.</p> <p>316L has improved pitting corrosion resistance and has excellent resistance to sulphates, phosphates and other salts.</p> <p>316L has better resistance than standard 18/8 types to seawater, reducing acids and solution of chlorides, bromides and iodides.</p> <p>Specific or relative limits are given in datasheets for a valve body. The data sheets with the most recent information are available at our website <a href="http://www.keofitt.dk">www.keofitt.dk</a>.</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>																																																																			
	Chemical composition		<p>Steel 1.4404</p> <table><tr><td></td><td>C %</td><td>Si %</td><td>Mn %</td><td>P %</td><td>S %</td><td>Cr %</td><td>Ni %</td><td>Mo %</td><td>N %</td></tr><tr><td>Min.</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td><td>16.5</td><td>10.0</td><td>2.00</td><td>-</td></tr><tr><td>Max.</td><td>0.030</td><td>1.00</td><td>2.00</td><td>0.045</td><td>0.015</td><td>18.5</td><td>13.0</td><td>2.50</td><td>0.11</td></tr></table> <p>Steel 1.4435</p> <table><tr><td></td><td>C %</td><td>Si %</td><td>Mn %</td><td>P %</td><td>S %</td><td>Cr %</td><td>Ni %</td><td>Mo %</td><td>N %</td></tr><tr><td>Min.</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td><td>17.0</td><td>12.5</td><td>2.50</td><td>-</td></tr><tr><td>Max.</td><td>0.030</td><td>1.00</td><td>2.00</td><td>0.045</td><td>0.015</td><td>19.0</td><td>15.0</td><td>3.00</td><td>0.11</td></tr></table>									C %	Si %	Mn %	P %	S %	Cr %	Ni %	Mo %	N %	Min.	-	-	-	-	-	16.5	10.0	2.00	-	Max.	0.030	1.00	2.00	0.045	0.015	18.5	13.0	2.50	0.11		C %	Si %	Mn %	P %	S %	Cr %	Ni %	Mo %	N %	Min.	-	-	-	-	-	17.0	12.5	2.50	-	Max.	0.030	1.00	2.00	0.045	0.015	19.0	15.0	3.00	0.11
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	Intended use		<p>The stainless-steel parts are intended to become an integral part of the process equipment and to be in permanent contact with the 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 <a href="http://www.keofitt.dk">www.keofitt.dk</a>.</p>																																																																			

3	Material	
	Additional information	For information on the composition on steel part with <u>no</u> permanent process media contact, please see the corresponding data sheet on our website <a href="http://www.keofitt.dk">www.keofitt.dk</a> .

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. 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	NSF/ANSI-51:2014 Food Equipment Materials.

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](http://www.keofitt.dk), where you find the following material:

5	Supporting documents	
	Supplier certificates	Each valve body has an engraved number. Entering this number on the front page of <a href="http://www.keofitt.dk">www.keofitt.dk</a> will lead you to the steel batch certificate corresponding to the steel bar this particular article has been machined from, revealing among other things the actual alloy composition.
	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>

Svendborg, 3<sup>rd</sup> of February 2020



**KEOFITT**  
WORLD LEADERS IN STERILE SAMPLING™  
KEOFITT A/S • Koldinggade 31B + E • DK-5700 Svendborg  
Phone +45 63 16 70 80 • Fax +45 63 16 70 81

**Sanne Dahl** E-mail: [info@keofitt.dk](mailto:info@keofitt.dk)  
Quality Management Assistant

f. Henrik L. Salomon  
Managing Director

## Søby CNC A/S

Sneppevang 1  
3450 Allerød  
Phone: +45 48140656  
Fax: +45 48142132  
CVR no.: 21830941  
[info@sobycnc.dk](mailto:info@sobycnc.dk)

20 November 2018

### Declaration of Conformity

Søby CNC A/S hereby declares that steel parts that have food contact comply with applicable legislation:

Applicability	
EU	No. 1935/2004 of 27 October 2004 About materials and articles intended for food contact.
EU	No. 2023/2006 of 22 December 2006 On good manufacturing practices for materials and articles intended for food contact.
EU	No. 1907/2006 of December 2006 (REACH Regulation) incl. The candidate list of particularly problematic substances.
France	Notice of 13 January 1976 concerning stainless steel materials and articles in contact with foodstuffs.
France	NF A 36-711 of April 2002 Non-packing steel - Stainless steel intended for use in food, human and animal consumption.

#### Material certificate:

All stainless steel is certified according to EN 10204 - 3.1. All goods are supplied with a material certificate, partly to ensure traceability and partly to ensure the actual content of alloying elements.

Allerød, November 2018

  
SPÅNTAGENDE BEARBEJDNING  
Sneppevang 1 3450 Allerød  
Manager John Søby 4814 06 56

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
	4KAI Sampling Valve	Head configurations: 440041, 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
	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, 830541, 830544, 830941, 830944, 831141, 831141.2, 831144, 832141, 832144, 832241, 832244	- none -
	SIMPLEX Components	600051, 778301, 778309, 778344, 778344-68	- none -

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

3	Material	
	Name	<b>SILICONE</b>
	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 most 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.
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	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](http://www.keofitt.dk), where you find the following material:

5	Supporting documents	
	Supplier certificates	Certificates from <ul style="list-style-type: none"> <li>• AVK Gummi A/S (membranes)</li> <li>• Gunnar Haagensen A/S (O-rings)</li> <li>• M Seals A/S (O-rings)</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>

Svendborg, 1<sup>st</sup> of April 2020

  
 WORLD LEADERS IN STERILE SAMPLING™  
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**Sanne Dahl** E-mail: [info@keofitt.dk](mailto:info@keofitt.dk)  
 Quality Management Assistant

f. Henrik L. Salomon  
 Managing Director



Keofitt a/s  
Industrivænget 6-8  
5700 Svendborg

Deres reference:  
Your reference:  
Ihre Zeichen:  
**Susanne Bakman Borup**

Vor reference:  
Our reference:  
Unsere Zeichen:  
**AGC/aki**

Dato:  
Date:  
Datum:  
**02.04.2020**

## **CERTIFICATE**

**AVK GUMMI A/S**, hereby certify that our silicone rubber compound

### **QBF-65**

meets the following regulations:

<b>FDA 21 CFR 177.2600</b>	Rubber articles intended for repeated use in contact with foods. <u>Aqueous and fatty foods:</u> QBF-65 meets the specifications (extraction in distilled water and n-hexane) regarding repeated use in contact with aqueous and fatty foods.
<b>3A Sanitary Standards</b>	For Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment for low-fat applications, Number 18-03: Class I
<b>EC No 1935/2004</b>	AVK GUMMI A/S confirms the harmlessness for human health as required in EC No 1935/2004 and in addition, AVK GUMMI A/S confirms that the requirements for traceability have been fulfilled.
<b>USP Class VI Chapter 87</b>	The material complies with USP chapter 87 requirements, in vitro testing. The extracts were prepared at 37°C for 24 hours.
<b>USP Class VI Chapter 88</b>	The Rubber Article extracts meets the requirement of a USP Class VI. The extracts were prepared at 70°C for 24 hours.



<b>BfR XV Silicone</b>	QBF-65 meets the requirement stated in BfR XV for silicones.
<b>GB4806.11</b>	The rubber article meets the migration requirements of GB4806.11:2016 for all foods with a contact time of 100°C and 15 minutes. It does however not comply with the positive list as stated in GB9685:2016.

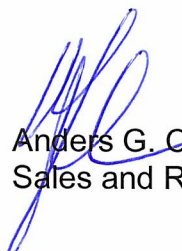
The above applies to the following Keofitt article Nos.:

310051      320051      400051      600251      600051      880056

Yours sincerely,  
**AVK GUMMI A/S**



Esben Øster  
R&D Manager




Anders G. Christensen  
Sales and R&D Director

## CERTIFICATE

**AVK GUMMI A/S**, hereby certifies that our rubber compounds  
are in compliance with the following regulations:

<b>GMP</b>	Good Manufacturing Process in accordance with 2023/2006 EC
<b>REACH</b>	In accordance with regulation EC 1907/2006.  Do not contain any substances above 0.1% (w/w) from: The Candidate List of Substances of Very High Concern (16.01.2020), Annex XVII (19-11-2019)
<b>RoHS</b>	In accordance with the Directives 2011/65/EC, RoHS 2, and 2015/863/EC, RoHS 3, of The European Parliament and of the Council.
<b>Bisphenols</b>	Do not contain Bisphenols as described in 1895/2005/EEC. BPA, BADGE, BFDGE, NOGE
<b>Phthalates</b>	Do not contain phthalates
<b>ODS</b>	Do not contain Ozone Depleting Substances. In accordance with the Regulation EC 1005/2009 OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 16 SEPTEMBER 2009 and Regulation EC 2037/2000 OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 29 JUNE 2000.
<b>ADI free</b>	Do not contain any substances originating from humans or animals.
<b>Hazardous Materials</b>	Do not contain any hazardous substances as described in the Hong Kong International Convention for the Safe and Environmentally Sound Recycling of Ships, 2009
<b>Conflict Materials</b>	In accordance with US Law: "Dodd Frank Wall Street Reform & Consumer Protection Act", sec 1502, of 21.07.2010.

Yours sincerely,  
**AVK GUMMI A/S**



Esben Øster  
R&D Manager

27.02.2020



Anders G. Christensen  
Sales and R&D Director

**KVALITET:** Quality, Werkstoff

**QBF-65**

<b>Gummitype:</b> Type; Typ		<b>Q</b>
<b>Farve:</b> Colour; Farbe		<b>Grå</b> Grey; Grau
<b>Hårdhed:</b> Hardness; Härte	ShA DIN 53 505	<b>70 ± 3</b>
<b>Trækstyrke:</b> Tensile strength; Zugfestigkeit	MPa ISO 37	<b>Min 8,5</b>
<b>Brudforlængelse:</b> Elongation at break; Bruchdehnung	% ISO 37	<b>550 ± 80</b>
<b>Massefylde:</b> Density; Spezifisches Gewicht	g/cm <sup>3</sup> ISO 2781	<b>1,19 ± 0,01</b>
<b>Anvendelsestemperatur i tør atmosfærisk luft:</b> Range of temperature in dry atmospheric air; Temperaturbereich in trockener Atmosphäre	°C	<b>-60 - +200</b>
<b>Compression Set, 24 timer /175 °C</b> Compression set, 24 h / 175 °C; Druckverformungsrest, 24 St./175 °C	% DIN 53 517	<b>Max. 25</b>
<b>Slidstyrke:</b> Wear resistance; Verschleißfestigkeit		<b>1</b>
<b>Kærvstyrke:</b> Tear resistance; Kerbzähigkeit		<b>3</b>
<b>Vejr- og ozonbestandighed:</b> Resistance to weather and ozone; Wetter- und Ozonwiderstandsfähigkeit		<b>4</b>
<b>Hydrolysebestandighed (vand og damp):</b> Resistance to hydrolysis (water and steam); Hydrolysewiderstandsfähigkeit (Wasser und Dampf)		<b>2</b>
<b>Kemikaliebestandighed (syre/baser):</b> Resistance to chemicals (acids/bases); Chemikalienwiderstandsfähigkeit (Säuren/Basen)		<b>2</b>
<b>Olie- og gasbestandighed:</b> Resistance to mineral oil and gas; Erdöl- und Gaswiderstandsfähigkeit		<b>1</b>
<b>Luft- og gastæthed:</b> Permeability; Luft- und Gasdichte		<b>0</b>

**Bemærkninger:**

Remarks: FDA 21 CFR 177.2600, BfR XV Silicone, 3A Sanitary Standard Class I,  
Bemerkungen: USP Class VI, RAL 7035

Ovenstående resultater er fremkommet ved laboratorietest og skal vurderes i forhold til aktuelle emner og applikationer.  
The above mentioned results are based on laboratory tests and must be evaluated for the specific articles and applications.  
The obigen Ergebnisse rühren von Laborprüfungen her und müssen gemäß aktuellen Werkstücken und Applikationen beurteilt werden.

Ved brand kan der dannes små mængder af hydrogensulfid og carbondioxid. Kan bortskaffes ved forbrænding i overensstemmelse med lokale bestemmelser.  
Fire may create small amounts of hydrogen sulphide, and carbon dioxide. Disposal by incineration in compliance with local regulations.  
Bei Feuer können kleine Mengen von Hydrogensulfid und Kohlendioxid gebildet werden. Entsorgung durch Verbrennung unter Beachtung der örtlichen behördlichen Vorschriften.

**Egenskaber**

**4** Uvæsentlig påvirkning  
**3** Mindre påvirkning  
**2** Medium påvirkning  
**1** Betydelig påvirkning  
**0** Uegnet

**Characteristics**

**4** Insignificant influence  
**3** Minor influence  
**2** Medium influence  
**1** Considerable influence  
**0** Unfit

**Eigenschaften**

**4** Unwesentlicher Einfluss  
**3** Weniger Einfluss  
**2** Mittel Einfluss  
**1** Erheblicher Einfluss  
**0** Ungeeignet

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