

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	Applies only to the steel part, which has permanent process media contact. All configurations are made from 1.4404 steel.
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,	

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 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>																																																												
	Chemical composition	<p>Steel 1.4404</p> <table border="1"> <thead> <tr> <th></th> <th>C %</th> <th>Si %</th> <th>Mn %</th> <th>P %</th> <th>S %</th> <th>Cr %</th> <th>Ni %</th> <th>Mo %</th> <th>N %</th> </tr> </thead> <tbody> <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> </tbody> </table> <p>Steel 1.4435</p> <table border="1"> <thead> <tr> <th></th> <th>C %</th> <th>Si %</th> <th>Mn %</th> <th>P %</th> <th>S %</th> <th>Cr %</th> <th>Ni %</th> <th>Mo %</th> <th>N %</th> </tr> </thead> <tbody> <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> </tbody> </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 www.keofitt.dk.</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 www.keofitt.dk .

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. 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 fødevarer virksomheder 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, 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 www.keofitt.dk 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"> Data sheet for the given item no. User Manual for the given product/valve

Svendborg, 3rd of February 2020



WORLD LEADERS IN STERILE SAMPLING™
KEOFITT A/S • Koldinggade 31B + E • DK-6700 Svendborg
Phone +45 63 16 70 80 • Fax +45 63 16 70 81

Sanne Dahl E-mail: 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

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


Snepevang 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	SILICONE
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. 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.

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.
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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, where you find the following material:

5 Supporting documents	
Supplier certificates	Certificates from <ul style="list-style-type: none"> • AVK Gummi A/S (membranes) • Gunnar Haagensen A/S (O-rings) • M Seals A/S (O-rings)
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, 1st of April 2020



WORLD LEADERS IN STERILE SAMPLING™

KEOFITT A/S • Kullinggade 31B + E • DK-5700 Svendborg
Phone +45 63 16 70 80 • Fax +45 63 16 70 81

Sanne Dahl E-mail: 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:

FDA 21 CFR 177.2600	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.
3A Sanitary Standards	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
EC No 1935/2004	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.
USP Class VI Chapter 87	The material complies with USP chapter 87 requirements, in vitro testing. The extracts were prepared at 37°C for 24 hours.
USP Class VI Chapter 88	The Rubber Article extracts meets the requirement of a USP Class VI. The extracts were prepared at 70°C for 24 hours.

BfR XV Silicone	QBF-65 meets the requirement stated in BfR XV for silicones.
GB4806.11	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.

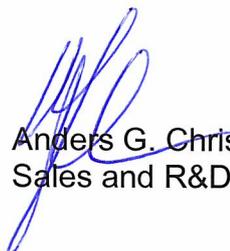
The above applies to the following Keofitt article Nos.:

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:

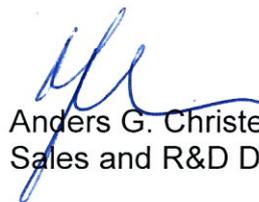
GMP	Good Manufacturing Process in accordance with 2023/2006 EC
REACH	In accordance with regulation EC 1907/2006. Do not contain any substances above 0.1% (w/w) from: The Candidate List of Substances of Very High Concern (16.01.2020), Annex XVII (19-11-2019)
RoHS	In accordance with the Directives 2011/65/EC, RoHS 2, and 2015/863/EC, RoHS 3, of The European Parliament and of the Council.
Bisphenols	Do not contain Bisphenols as described in 1895/2005/EEC. BPA, BADGE, BFDGE, NOGE
Phthalates	Do not contain phthalates
ODS	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.
ADI free	Do not contain any substances originating from humans or animals.
Hazardous Materials	Do not contain any hazardous substances as described in the Hong Kong International Convention for the Safe and Environmentally Sound Recycling of Ships, 2009
Conflict Materials	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

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

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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