

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
	4KAI Sampling Valve	Body configurations: 440001, 440011, 440021, 440022	Applies only to the steel part, which has permanent process media contact. All configurations are made from 1.4404 steel.
	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.
	SESAME Sampling Valve	Body configurations: 890001, 890003, 890005, 890006, 890007, 890008, 890009, 890010, 890011, 890013, 890019, 890021, 890022, 890036, 890039	All configurations are made from 1.4435 steel.
	BASIX Sampling Valve	Body configurations: 450141, 450144, 451141, 451144, 452141, 452144, 452241, 452244, 450141E, 450144E, 451141E, 451144E, 452141E, 452144E, 452241E, 452244E, 450141PTFE, 450144PTFE, 451144PTFE, 452141PTFE, 452144PTFE, 452241PTFE, 452244PTFE	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
	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, 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	<b>Stainless Steel 316L</b>
	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>

3	Material																																																																					
	Chemical composition	<div>Steel 1.4404</div> <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> <div>Steel 1.4435</div> <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>																																																																				
	Additional information	<p>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>.</p>																																																																				

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, 29<sup>th</sup> of July 2020

**KEOFITT**  
WORLD LEADERS IN STERILE SAMPLING™  
*Sanne Dahl*  
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**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 48 14 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: 440041E, 440044E	- none -
	4KAI Components	400052, 774441EPDM, 774444EPDM	- none -
	M4 Sampling Valve	Head configurations: 400041E, 400042E, 400043E, 400044E, 400045E, 400047E	Body configurations: 400009, 400010, 400031
	M4 Components	400052, 774041EPDM, 774044EPDM	400208, 400308, 774009, 774010, 774031, 900829
	W9 Sampling Valve	Head configurations: 600041E, 600042E, 600043E, 600044E, 600045E, 600047E, 600048E, 600049E	Body configurations: 850008, 850009, 850013, 850020, 850031, 850037
	W9 Components	600052, 600252, 776041EPDM, 776044EPDM, 776048EPDM	400208, 400308, 778508, 778509, 778531, 900829
	W15 Sampling Valve	- none -	Body configurations: 860009
	W15 Components	- none -	400208
	W25 Sampling Valve	- none -	870009
	W25 Components	- none -	400208
	INGOLD Sampling Valve	Head configurations: 310041E, 310043E, 310044E, 320041E, 320043E, 320044E	- none -
	INGOLD Components	310052, 320052, 773141EPDM, 773144EPDM 773241EPDM, 773244EPDM,	300118
	SESAME Sampling Valve	Head configurations: 890041E, 890043E, 890044E	Body configurations: 890008, 890009, 890013, 893105, 893205
	SESAME Components	890052	400208, 300118
	BASIX Sampling Valve	450141E, 450144E, 451141E, 451144E, 452141E, 452144E, 452241E, 452244E	- none -
	BASIX Components	400052, 774441EPDM, 774444EPDM	- none -

## DECLARATION OF COMPLIANCE - EPDM

2	Product group	Item identification – items with membrane(s)	Item identification – items with O-rings
	SIMPLEX Sampling Valve	830141EPDM, 830141.2EPDM, 830144EPDM, 830541EPDM, 830544EPDM, 830941EPDM, 830944EPDM, 831141EPDM, 831141.2EPDM, 831144EPDM, 832141EPDM, 832144EPDM, 832241EPDM, 832244EPDM	830941EPDM, 830944EPDM
	SIMPLEX Components	600052, 778301EPDM, 778309EPDM, 778344EPDM, 778344-68EPDM	400208, 778344-68EPDM
	Multi Micro Port 49	- none -	Body configurations: 840009
	Multi Micro Port 49 Components	- none -	400208
	Carlsberg Flask Components	- none -	200830, 772002, 900074

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)
	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:

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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> <li>• ITE Intertechnik Elze GmbH &amp; Co. KG (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>

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



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

f. Henrik L. Salomon  
Managing Director



# AVK GUMMI A/S

Mosegaardsvej 1

DK-8670 Laasby



## Datasheet

## EPL-60

### Physical properties

Rubber type				EPDM
Colour				Black
Hardness	DIN 53 505	ShA		62 ± 3
Tensile strength	ISO 37	MPa		20 ± 3
Elongation at break	ISO 37	%		400 ± 60
M100	ISO 37	MPa		3,1 ± 0,5
Tear strength	ISO 34-1	N/mm		36 ± 5
Density	ISO 2781	g/ml		1,08 ± 0,01

### Compression set

70 °C / 24 h, 25 %, 30 m	ISO 815			13 ± 2
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### Field of application

Wear resistance				Good
Temperature (dry atmospheric air)		°C		-40–140
Weather and ozone				Excellent
Hydrolysis				Excellent
Chemicals (acid/base)				Good
Oil				Poor
Gas impermeability				Poor

The given results are based on laboratory tests and must be evaluated for the specific articles and applications.

# AVK GUMMI A/S

Mosegaardsvej 1

DK-8670 Laasby



## Datasheet

**EPL-60**

### Approvals

3A Sanitary Standard

Low fat

EC 1935/2004

BfR XXI cat. 2, Extraction only.

FDA 21 CFR 177.2600

GB 4806.11

Extraction only, 130 °C / 15 min

USP <87>

37 °C / 24 h

USP <88>

Class VI (70 °C / 24 h)

## Regulatory compliance

ADI free	Do not contain any substances originating from humans or animals.
Bisphenols	Do not contain Bisphenols as described in 1895/2005/EEC. BPA, BADGE, BFDGE, NOGE
Conflict materials	In accordance with US Law: "Dodd Frank Wall Street Reform & Consumer Protection Act", sec 1502, of 21.07.2010.
GMP	Good Manufacturing Process in accordance with 2023/2006 EC
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
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.
Pthalates	Do not contain pthalates
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, Annex XVII
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.