

Date of issue: 4 December 2018

Valid until end: December 2020

# **EL Class I**

EHEDG hereby declares that the product

Lobe Positive Displacement Pump, type C series with EPDM gaskets

from

OMAC S.r.l., Via G. Falcone, 8, I-42048 Rubiera (RE), Italy

has/have been evaluated for compliance and meets/meet the current criteria for Hygienic Equipment Design of the EHEDG

# Certificate No. EHEDG-C1800034

Signed \_

President EHEDG

\_\_\_\_\_ EHEDG Certification Officer

Signed Mirjam Steenaard

Ludvig Joesefsberg

EHEDG Secretariat Lyoner Straße 18 60528 Frankfurt am Main Germany



©EHEDG

## Appendix 3

# **EHEDG Certification – Equipment Evaluation Form**

Date: 04.12.2018 EHEDG File Number: EHEDG-C1800034 Certification Type: EL CLASS I

Applicant: OMAC SRL, RUBIERA ITALY

Equipment: Lobe positive displacement pump

Type or model No/s.: Type C sizes C100, C110, C115, C220, C270, C330

Other essential identification: with EPDM gaskets and silicon carbide mechanical seals

## Evaluated by:

Name: Giampaolo BETTA [AEO]

## Approved by:

Name: Nicolas ROSSI Title: [AEO]

Date, Signature: 10

	At	7
10112/11	14	
.01 1411 7	V	

1.	Results of inspection for compliance with the EHEDG Hygienic Design Criteria. Conclusion:		Г
	The equipment complies with the criteria. The use of the EHEDG Certification logo is justified:	MAYBE	R
2.	Evidence for compliance provided and convincing for Certification. Conclusion:		
	The equipment complies with the criteria where possible. The use of the EHEDG Certification logo is justified:	YES	V

Signature: June Ale

Date: 04/12/2018

The original of this form will be kept by EHEDG together with the application, the inspection report, the evidence provided and any other relevant documentation, as listed on the back.

# Appendix 3

No.	Description
1	EHEDG Certificate of Compliance
2	Contract to use the EHEDG Certification Logo for equipment
3	Appendix 1: Equipment intended for cleaning in place with liquids without dismantling
4	Appendix 2: Conditions for use of the EHEDG Certification Logo
5	Appendix 3: Equipment evaluation form
6	EHEDG hygienic design criteria evaluation report 2018DRGB002
7	Drawings of the Lobe pump type C sizes C100, C110, C115, C220, C270, C330 with EPDM gaskets and silicon carbide mechanical seals – Drawings numbers SC-323, SC-324, SC-325, SC-326, SC-327, SC-328 - Original stamped
8	Test report no. 155/25.01.2008 – EHEDG 01 Cleanability Test lobe positive displacement pump, series C220
9	Example Logo EL class I

The original of this form will be kept by EHEDG together with the application, the inspection report, the evidence provided and any other relevant documentation, as listed on the back.

## EHEDG Hygienic Design Evaluation Report no. 2018DRGB002

**Items evaluated**: OMAC SRL (RUBIERA, ITALY) lobe positive displacement pump type C sizes C100, C110, C115, C220, C270 and C330 with EPDM gaskets and silicon carbide mechanical seals

The evaluation is based on the applicable EHEDG hygienic design criteria (HDC) in EHEDG Guidelines and particularly in documents 8 (2018), 9 (1993), 10 (2007), 16 (1997), 17 (2013), 25 (2002), 32 (2005), 35 (2006) and the test report "EHEDG 01 Clenability Test lobe positive displacement pump, series C220 test no. 155/25.01.2008" performed by the Authorised Testing Laboratory (ATL) Research Centre Weihenstephan for Brewing and Food Quality, University of Technology of Munich in Weihenstephan, Germany.

## Materials, Surface Roughness, Fabrication and Surface Geometry

- Product contact surfaces are constructed from stainless steel alloy 1.4404 (AISI 316L). This material is
  considered non-toxic and corrosion resistant under the intended conditions of use. All food contact
  surfaces are electropolished.
- The gaskets are made of EPDM (Angst+Pfister 70.10-02) and comply with relevant regulations on materials in contact with food. The surfaces of the gaskets are essentially smooth and without significant flash lines.
- The mechanical seals are from Roten (IT) and are made of SiC-SiC material.
- Product contact surfaces are free of imperfections and finished to 0.8 µm Ra or better. Measured Ra values on stainless steel surfaces < 0,6µm.</li>
- The seal design is according the specific requirements, with controlled compression and a flush sealing at the product contact side.
- Internal geometry of the pump complies with the design criteria of Documents 8 and 10 without crevices and dead areas. Sharp internal angles are justified by functional reasons. The evidence for compensation of the loss of cleanability is demonstrated by the cleanability test.
- Welding, when used to weld the fittings, is done with automatic TIG according Documents 9 and 35.

## **Drainability and Layout**

• Instruction manual specifies correct installation orientation for self-draining.

## Installation and Cleaning

- Process connections provided are in compliance with the EHEDG position paper "Easy cleanable Pipe couplings and Process connections", last version.
- The cleaning instructions include information specifying the minimum running rpm to achieve a 1.5 m/s velocity in relation to the process connections pipe diameter.

## Adhesives, Lubricants and Signal transfer liquids

- No adhesives or lubricants are used in the pump where they can come into contact with the product.
- Gear box oil is food grade mineral oil.
- No signal transfer liquids are used in the pump construction.

## Result of the cleanability test according EHEDG Doc 2

 The in-place cleanability test method has proven that this positive displacement lobe pump C220 with inlet and outlet of DN40 is easy to clean. The results of the test are documented in the test report 155/25.01.2008

#### Types of the pump

• The pump is available in several sizes. The tested pipe size is the worst case in cleanability among the pump sizes C100, C110, C115, C220, C270 and C330 due to the lowest rpm to achieve 1,5 m/s in the process connections. Therefore, it is assumed that the cleanability is better in the other sizes.

#### Conclusion

The Hygienic Design Criteria Evaluation Report concludes that these positive displacement lobe pumps C100, C110, C115, C220, C270 and C330 with EPDM gaskets and silicon carbide mechanical seals comply with the applicable EHEDG Hygienic Design Criteria for Hygienic Equipment Class I. The in-place cleanability test method has proven that this positive displacement lobe pump C220 with inlet and outlet of DN40 is easy to clean

Dr.-Ing. Giampaolo Betta 04.12.2018

groupe Dec

















Forschungszentrum Weihenstephan für Brau- und Lebensmittelqualität

# REPORT

# **EHEDG 01 Cleanability Test**

# lobe positive displacement pump, series C 220

test no. 155/25.01.2008

# Omac Pompe S.r.I. I-42048 Rubiera, Italy

The report covers 11 pages with 1 appendix, 4 figures and 1 table.

The test results apply only to the subject equipment. The tests have been carried out according to the test requirements by trained personnel.

Dr.-Ing. Fritz Jacob Technische Leitung

Dr.-Ing. Vladimir Ilberg Abteilungsleitung Hygienic Design



Weihenstephan, 06. June 2008





Akkreditierung nach DIN EN ISO/IEC 17025:2005 für: "mikrobiologisch-hygienische Untersuchungen an Maschinen und Apparaten der Lebensmittelverarbeitung"

The present report is done in cooperation with Dr.-Ing. Jürgen Hofmann.

Weihenstepahn, 06. June 2008

uam

Dr-Ing. Jürgen Hofmann Hygienic Design Experte

All rights reserved.

No part of this publication may be reproduced and/or published without the previous written consent of the Research Centre Weihenstephan for Brewing and Food Quality (Forschungszentrum Weihenstephan BLQ).

# Content

1.	Pu	rpose	3
2.	De	scription of the lobe positive displacement pump	4
3.	De	scription of the EHEDG cleanability test	5
4.	Te	st Execution	7
5.	Re	sults	8
6.	Dra	awings	9
7.	Re	ferences	10
8.	Ар	pendix to the report	11
8	3.1	Discussion of the cleanability test and evaluation	11
8	3.2	Conclusion	11

# 1. Purpose

Omac Pompe S.r.I., Via G. Valcone 8, I-42048 Rubiera, Italy, commissioned the Research Centre Weihenstephan for Brewing and Food Quality, University of Technology of Munich in Weihenstephan, Germany, to perform the EHEDG Cleanability Test Method [1] to test the cleanability of the product-contact surfaces of a lobe positive displacement pump. For this, a lobe positive displacement pump with an in- and outlet of DN 40, type C220, was provided as an example for this pump series.

The tests run from February 20, 2008 until March 13, 2008.

# 2. Description of the lobe positive displacement pump

The lobe positive displacement pump series C is used in food, beverage and pharmaceutical industry. The design allows CIP cleaning without dismantling.

The wetted parts are made out of stainless steel, alloy AISI 316L, the bearing housing of C series is made out of nickel-plating cast iron, while the bearing housing of Cph series is made out of stainless steel, AISI 304. It is a mild housing (case and front cover) and mild lobe. Both are electro polished on the product contact surfaces. All inner surfaces are smooth and without any defects, like pockets and pores. The two lobe are electro polished. The mean roughness value Ra is less than 0.8  $\mu$ m.

An O-ring is used for sealing the housing. This one and the O-rings at the mechanical seals and on the locking nuts are made of EPDM. The designs are open and the O-rings are in contact with the product, so that gaps and crevices are minimized.

All materials used on the food contact area meet the FDA requirements for food application and are recommended by the hygienic design criteria of EHEDG.

The required self-drainability can be achieved if the outlet port is turned to the bottom. Then the pump can drain into the outlet pipe line (see Fig. 1).

The shaft seal is a single mechanical seal without open springs on the product side. The ring material is on both sides silicon carbide.

The hygienic design requirements of EHEDG [2] are fulfilled.



The following figure shows the tested lobe pump.

Fig. 1: lobe positive displacement pump type C220

# 3. Description of the EHEDG cleanability test

The test method is based on a comparison of the cleanability of a reference pipe (straight piece of pipe of known hygienically good internal surface roughness, Ra = 0.5 - 0.7 micrometers or 20 – 28 microinches) and the test object. The test begins with the soiling of the reference pipe and the test object with a suspension of sour milk and spores of the bacterium *Geobacillus stearothermophilus* var. *calidolactis* at a concentration of  $10^5$  spores/ml. The test strain used is a thermophilic, fast-growing bacterium, which, when cultivated on a special, purple growth medium (modified Shapton & Hinds Agar) produces a well-defined yellow colour reaction (due to the metabolic formation of acid).

The reference pipe and the test object are filled with the soil suspension, drained and then dried with sterile air and afterwards cleaned with a mild, alkaline detergent solution.

The cleaning process consists of rinsing with cold water (1 minute), circulating the 1.0% (weight/volume) cleaning solution at approx. 63 °C for 10 minutes, and final rinsing with cold water (1 minute). The average flow velocity of the cleaning solution in the reference pipe is 1.5 m/s (5 ft./s) for all pipe sizes. Samples are taken from the rinse water before and after cleaning and are tested for the presence of the test bacterium.

For the cleaning test, the reference pipe and the test object are mounted in a test rig, consisting additionally of 2 supply tanks, the necessary piping (recirculation loop), a controllable centrifugal pump, and a throttle valve (Fig. 2). After the cleaning procedure, the reference pipe and the test object are removed from the rig, filled with agar, and incubated. Following this, the agar is carefully removed from the reference pipe and the test object, and a comparison is made.

For a valid test result, approximately 5 - 30 % of the inner surface area of the reference pipe must show yellow discoloration, due to spores remaining on this surface after cleaning. Only when this requirement is fulfilled, it is possible to make a statement about the cleanability of the test object. If polymeric materials and gaskets are present, there is a potential that they may contain components, which have a bactericidal effect, which would greatly influence the test results. Before starting the test, it is therefore necessary to analyse these types of materials with a spore suspension, to prove their suitability for the test.



Fig. 2: test rig for cleanability tests

With regard to the test results, the following cases are differentiated:

## Milk Residue

If milk residues are found to be present in the test object, these result are coming either from test handling errors or poor equipment design not corresponding to hygienic requirements. The test must be repeated. If, in spite of repeated and careful testing, milk residues continue to be found, serious problems in the hygienic design of the test object are evident.

## **Colonies/Yellow Discoloration**

If microbial colonies of the test strain or yellow discoloured areas are present in the test object, the test protocol dictates that the test has to be repeated five times. If results from at least three repetitions exhibit microbial germination in the same location, problems in the hygienic design of the test object are evident. If discolorations are distributed randomly across the entire test object, test protocol dictates that a comparison is made between the yellowed surface areas of the reference pipe and the test object. A qualitative judgment is made, as to whether the cleanability of the test object is better than, equal to, or worse than the reference pipe.

## Absence of Germination

If no germination is apparent in the test object, the test object is judged to be very well cleanable (better than the reference pipe). The reference pipe must show, as already mentioned, a degree of 5 - 30 % yellow discoloration.

# 4. Test Execution

The lobe positive displacement pump type Cph 220 with DN 40 ports was tested. The reference pipe was 2 inch in diameter.

Gaskets: white EPDM, with FDA food contact conformity Mechanical seal: Rotating seal ring SiC, stationary seal ring AISI 316L

All test parameters were set according to the EHEDG-Cleanability method [1]. The previous sterilisation of the reference pipe and the centrifugal pump was carried out with vapour for 30 minutes in the autoclave at a temperature of 121°C. As reference pipe a straight piece of stainless steel pipe of known internal surface roughness (Ra = 0.6 micrometers or 24 micro inches) and an ID of 50 mm (2 inch) was used. During soiling the pump was pressurised 3 times with 5 bar while running the pump temporary in both directions. After the soiling matrix has dried, the pump was installed in the test rig. The reference pipe was installed into the pipeline with adapters upstream of the lobe pump. During cleaning, the lobe pump supplied a pressure of p = 1.5 bar. The flow velocity was set to 1.5 m/s (5 ft/s) referring to the reference pipe (DN 50).

Prior to the start of the test, all O-rings with product contact were evaluated with the test organism *Geobacillus stearothermophilus* var. *calidolactis* to determine whether a bactericidal effect is present. The result is that the EPDM material of the O-rings does not have any bactericidal effect and could be used for in the microbial test method.

# 5. Results

Table 1:	summary	of test	results
----------	---------	---------	---------

	test	test	test	
reference pipe (yellow discoloration)	11 %	19 %	14 %	
lobe positive displacement pump C 220				
inlet	purple	purple	purple	
surface of cover	purple	purple	purple	
gasket of cover	purple	purple	purple	
left lobe	purple	purple	purple	
right lobe	purple	purple	purple	
mechanical seal with O-ring on the left lobe	purple	purple	purple	
mechanical seal with O-ring on the right lobe	purple	purple	purple	
locking nut with O-ring	purple	purple	purple	
outlet	purple	purple	purple	

The test results shown in Table 1 use the yellow discoloration of the agar as the qualitative indicator, which determines the amount of residue after cleaning and incubation. The percentage of yellow discoloration in the reference pipe is relative to the total surface area of the pipe (reference pipe ID= 50 mm, length 200 mm).

The table describes the most important test results of the test series. The individual tests show different degrees of discoloration in the reference pipe. Purple is the original colour of the agar and indicates good cleaning. At these areas no residual soil was detected. "Yellow spots" result from spores remaining after cleaning. So residual soil was detected in these areas. The single yellow spots which were detected are randomly distributed over the inner surface of the reference pipe.

# 6. Drawings



Fig. 3: cross sectional view of the lobe positive displacement pump



Fig. 4: single mechanical seal

## 7. References

- [1] A method for the assessment of in-place cleanability of food processing equipment, EHEDG-Doc. 2, 3<sup>nd</sup> edition, 2004.
- [2] Hygienic equipment design criteria, EHEDG-Doc. 8, 2<sup>nd</sup> edition, 2004.
- [3] Hygienic design of closed equipment for the processing of liquid food, EHEDG-Doc.10, 1993.
- [4] Hygienic pipe couplings, EHEDG-Doc. 16, 1997.
- [5] Welding stainless steel to meet hygienic requirements, EHEDG-Doc. 9, 1993.
- [6] Welding of Stainless Steel tubing in the food industry, EHEDG-Doc. 35, 2006

## 8. Appendix to the report

# EHEDG 01 cleanability test lobe positive displacement pump, series C 220

test no. 155/25.01.2008

Omac Pompe S.r.I. I-42048 Rubiera

## 8.1 Discussion of the cleanability test and evaluation

The cleanability test according to EHEDG compares the cleanability of a stainless steel reference pipe with a known surface roughness and at a defined cleaning fluid velocity with that of the test object. Plainly obvious from the test set-up is the fact that only very few pieces of machinery can be as well cleanable as the reference pipe, because mechanical components in general diverge more or less from the ideal geometry of the reference pipe. Minute changes of the fluid flow profile result for example in different frictional tension relationships at the walls of the test object, and therefore a different degree of cleanability. From this we conclude, that the results of an EHEDG cleanability test mainly represent a judgment or an evaluation of the cleanability of a piece of machinery in comparison to the reference pipe. The test shall provide indicators where there are weak spots in the design, which may result in difficulty while cleaning. Such poor hygienically designed spots are found by means of a systematic and repetitive appearance of yellow discoloration at certain, identifiable points. The consequence of such findings must be design improvement. If this is no longer possible due to technical and/or functional reasons additional consideration can be given to the aggravating conditions for the cleaning method. Good cleanable design is present, when the statistically distributed yellow discoloration of the reference pipe surface is about the same as in the test object.

## 8.2 Conclusion

The test results of the EHEDG cleanability test show that the lobe positive displacement pump series C is deemed to be easily cleanable. All inner surfaces (product contact area) are better cleanable as the ones of the stainless steel reference pipe. All gaskets sealed joints are designed according the EHEDG requirements and have no crevices where soil can remain. The welding is smooth and flush to the wall. There are no areas in the pump where residual soil can remain after an appropriate CIP-cleaning. The lobe positive displacement pump type C 220 meets all requirements for hygienic design and is to be classified as easy to clean.

