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Accreditation for Hygienic Tests by German Accreditation Service

EUROPEAN HYGIENIC ENGINEERING & DESIGN GROUP
EHEDG

REPORT

EHEDG 01 cleanability test of pipe coupling, type Connect S®

Test no. 76.1/23.12.2003

Neumo GmbH & Co.KG
75438 Knittlingen

The report comprised of 10 pages with 1 appendix, 3 figures and 1 table.
The test results pertains exclusively to the tested components mentioned in this report.
The appraisal was performed by trained personnel working in accordance with the EHEDG test procedure.

Freising-Weihenstephan, 29.10.2004

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1 STATEMENT OF PURPOSE

Neumo GmbH & Co. KG, Henry-Ehrenberg-Platz, 75438 Knittlingen, Germany, commissioned the Chair of Process Engineering of Disperse Systems, University of Technology of Munich, Weihenstephan, to perform the EHEDG Cleanability Test Method [1] to test the cleanability of the product-contact surfaces of the pipe coupling, type Connect S®. For this, a flanged version with a diameter of 50 mm (2 inch) was provided as an example. The tests run from January 19, 2004 until April 22, 2004.

2 DESCRIPTION OF THE PIPE COUPLING

With processes, during which conventional elastomers such as EPDM lose their durability, the use of elastomer-free pipe couplings is an alternative. The metal to metal pipe coupling Connect S® could be used in all ranges of food production, but above all also in equipment of the biotechnology and pharmaceutical industry. The flanged version is supplied in sizes of DN 10 (1/2") to DN 100 (4").

The pipe coupling Connect S® fulfils all other requirements for hygienic design of EHEDG except the presence of the metal to metal joint. Of the EHEDG not permissible conical or flat metal to metal joints do not exhibit no defined sealing flush with the product surface. Here, in this case a special sealing outline creates a line shape sealing of the two flanges directly at the product side. Further the two S-shape sealing edges are resiliently pressed together, so that dismantling and reconnecting is possible without any problems. The defined grouting of the connection, which is for this necessary, is reached by means of a metallic stop of the two connecting flanges. A centring of the connection is likewise present. The main intended purpose is therefore CIP-able piping systems.

The product contact surface of the pipe coupling is made of stainless steel alloy 1.4435 (AISI 316L). This alloy is recommended by EHEDG for the food contact and resistent against common cleaning detergents [2]. The roughness of the product contact surface is Ra = 0,3 µm (12 micro inches) (tactile stylus method) and thus the surface is smoother than the maximum roughness recommended by EHEDG of 0,8 µm (32 micro inches).

The following Figure shows the pipe coupling with the sealing in detail,

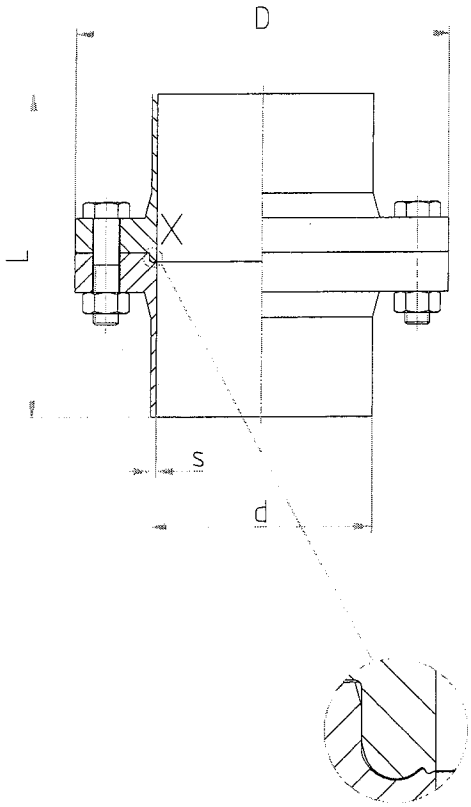

Fig. 1: pipe coupling Connect S®

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 *Bacillus 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.

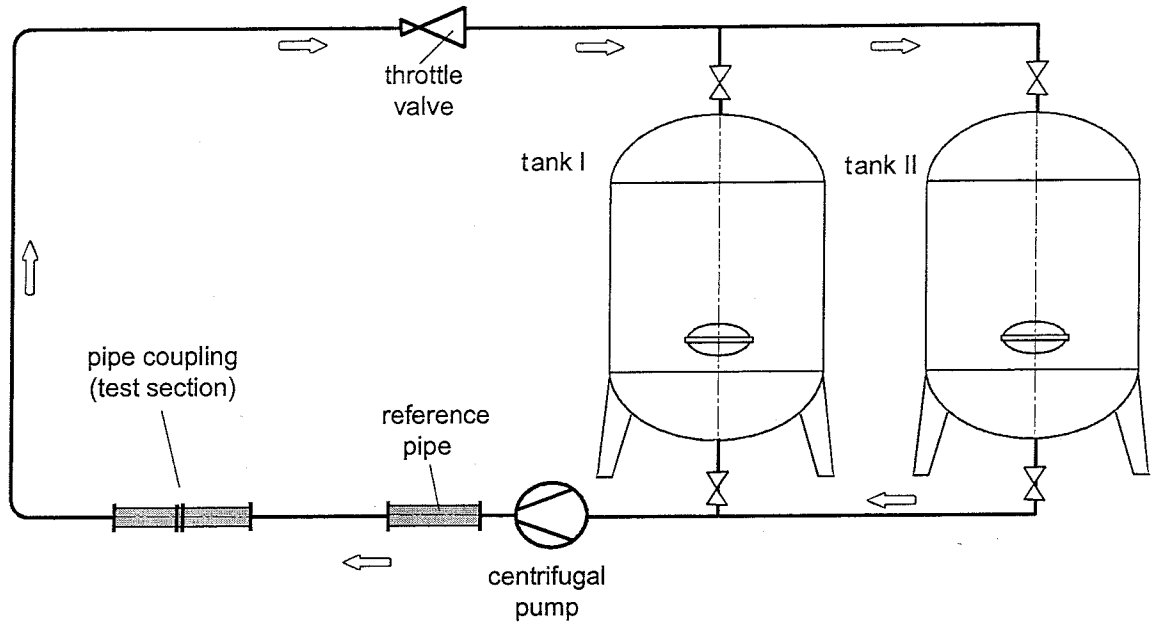

Fig. 2: test rig for cleanability tests

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

All test parameters were set according to the EHEDG-Cleanability method [1]. The previous sterilisation of the reference pipe and the pipe coupling 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 pipe was pressurised 3 times with 5 bar for each 2 minutes. After the soiling matrix has dried, the pipe coupling was installed with auxiliary pipes in the test rig. The reference pipe was installed into the pipeline with adapters upstream of the test section. During cleaning, a centrifugal pump supplied a pressure of p = 1.5 bar to the test piece. The flow velocity was set to 1.5 m/s (5 ft/s) referring to the diameter of the reference pipe (DN 50). For detection of the residues the pipe coupling was incubated in a sloped position.

The test on antibacterial properties of O-rings is not necessary because no elastomers are used.

5 TEST RESULTS

	Test 1	Test 2	Test 3	Test 4	Test 5
Reference pipe (yellow dis-coloration)	15 %	18 %	8 %	5 %	5 %
pipe coupling Connect S®					
connecting pipe (in- and out-let)	single yellow spots	purple	purple	purple	purple
metal to metal sealing surface	two small yellow spots	purple	purple	one yellow spot	purple

Table 1: Summary of test results

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, L = 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.

6 DRAWING

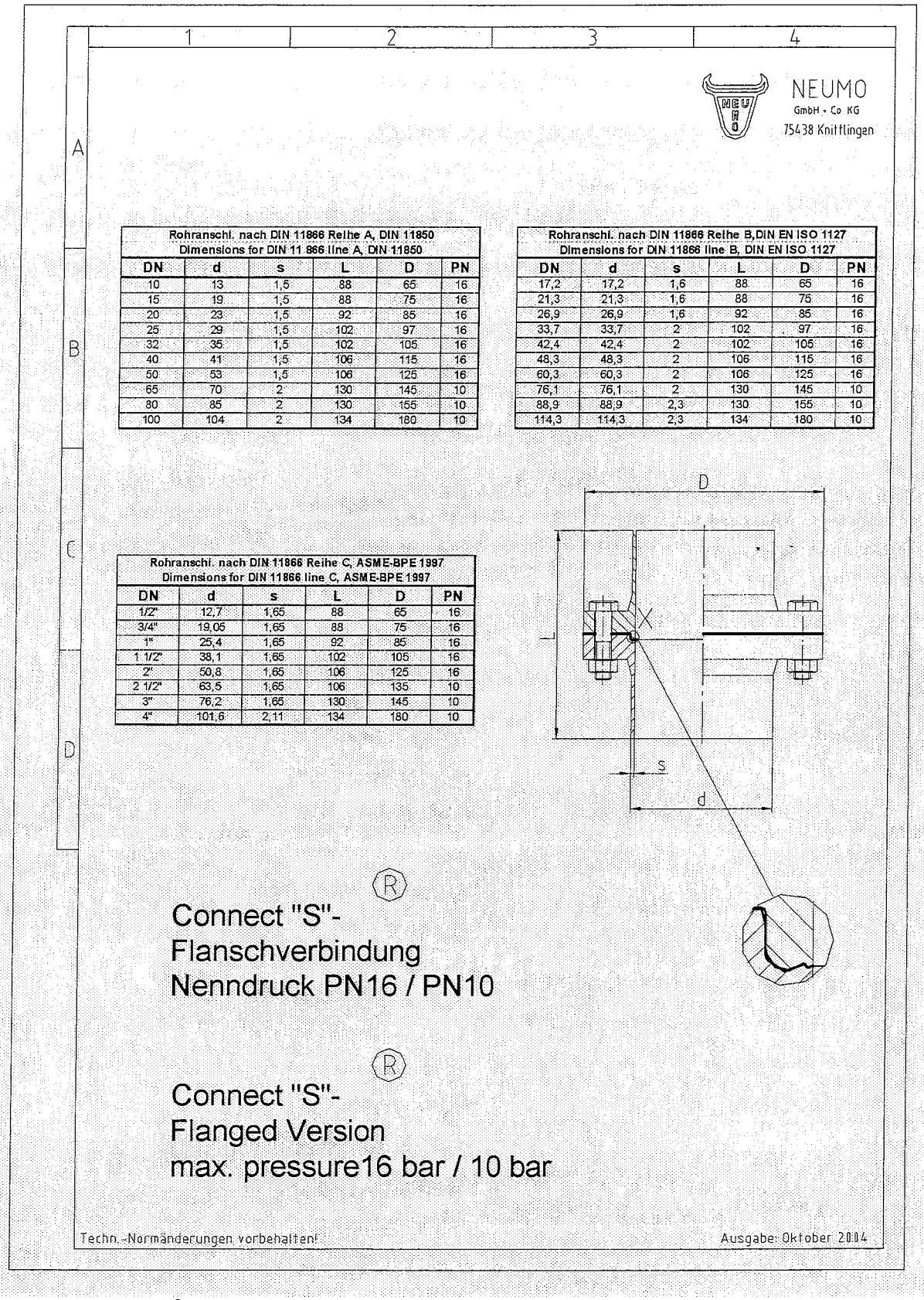

Fig. 3: Connect S®

7 REFERENCES

[1] A method for the assessment of in-place cleanability of food processing equipment, EHEDG-Doc. 2, 2nd edition, 2000.

[2] Hygienic equipment design criteria, EHEDG-Doc. 8, 2nd 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.

APPENDIX TO THE REPORT

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A1 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.

A2 CONCLUSION

The test results of the EHEDG cleanability test show that the ***pipe coupling, type Connect S®*** in the size of DN 50 (2 inch) is deemed to be easily cleanable. The cleanability of the pipe coupling is better in comparison with the one of the reference pipe. The surface of the metal to metal sealing was nearly always completely cleaned so that there is no poor hygienic design present.
Although all criteria of the Hygienic Design of EHEDG for functional reasons could not be fulfilled (avoidance of direct metal to metal joints other than welding), by this test the proof was led that the metal to metal pipe coupling Connect S® is easy to clean.