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TNO report

V7942

Validation of the in-line steam sterilisability of
the Knick SensoGate® WA 130H Sensor Lock-Gate
according to the EHEDG procedure

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No. of copies	12
Number of pages	8
Number of appendices	2
Customer	Knick Elektronische Messgeräte GmbH & Co, Berlin, Germany
Projectname	In-line Steam Sterilisability SensoGate® WA130
Projectnumber	031.11513/01.18

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Summary

At the request of Knick Elektronische Messgeräte GmbH & Co, Berlin, Germany the in-line steam sterilisability of their SensoGate® WA 130H Sensor Lock-Gate was assessed according to the test procedure of the European Hygienic Engineering & Design Group (EHEDG) [Ref 1].

The test results show that no bacteria remained in the internal (SensoLock circuit) and external (process side circuit) parts of the SensoGate® WA 130H Sensor Lock-Gate after steam sterilization in-line at 121 °C for 30 minutes. The in-line steam sterilisability tests were conducted three times. The results of the independent tests were comparable with each other. The SensoGate® WA 130H Sensor Lock-Gate is classified as steam-sterilisable in-line according to the EHEDG test procedure.

The SensoGate® WA 130H Sensor Lock-Gate is available in the following sizes and process connector variants: Tri-Clamp 1-3,5 inch, VariVent® DN50-125 and Dairy Fitting DN50-80 according DIN 11851 in combination with Siersema gasket.

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1 Introduction

At the request of Knick Elektronische Messgeräte GmbH & Co, Berlin, Germany the in-line steam sterilisability of their SensoGate® WA 130H Sensor Lock-Gate was assessed according to the test procedure of the European Hygienic Engineering & Design Group (EHEDG) [Ref 1].

2 Description of the test object

Name of test object	: SensoGate® WA 130H Sensor Lock-Gate
Type	: WA 130H / WA130MH
Process connection	: process unit DN 25 Tri-Clamp connection
Materials of construction	: 1.4404 (316L) for the wetted parts
Surface finish	: < 0.8µm Ra
Applied seal /gaskets	: EPDM / FKM / FFKM / VMQ
TNO numbers	: 3119-07-0778 / 3119-07-0779 / 3119-07-080.

In Appendix A the build-up of the SensoGate® WA 130H Sensor Lock-Gate is visualized in more detail.

Figure 1 shows the test object in both working positions, meaning with retracted and slide-out immersion tube.

A detailed sectional cross view of the internal parts of the test object is given in Figure 2.

3 Time schedule

The test objects (three identical SensoGate® WA 130H Lock-Gates) arrived at TNO Quality of Life on November 26, 2008 and were registered under TNO numbers 3119-07-0778, 3119-07-0779 and 3119-07-080. The investigations were carried in period December 2007 – January 2008.



Figure 1 The SensoGate® WA 130H Sensor Lock-Gate with retracted (photo left) and slid-out (photo right) immersion tube

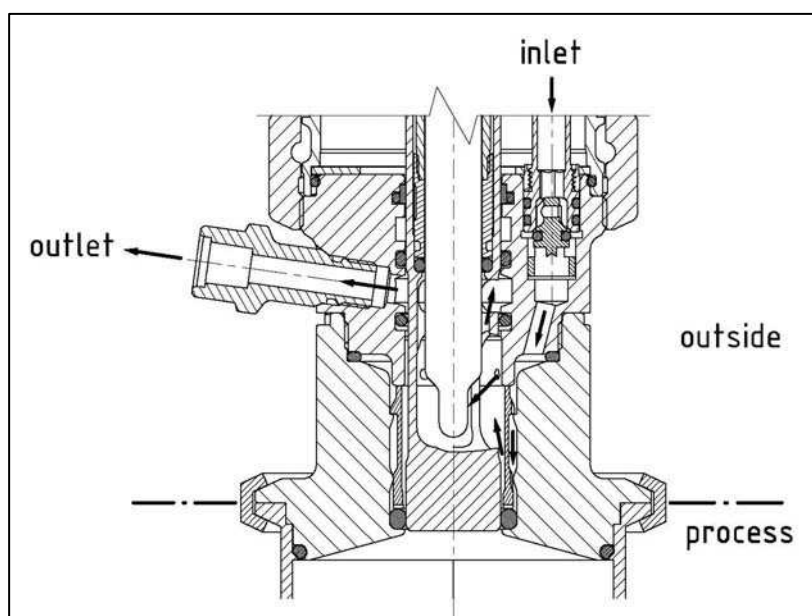


Figure 2 Sectional cross view of the internal of the SensoGate® WA 130H Sensor Lock-Gate

4 Method and material

4.1 In-line steam sterilisability

The test object was dismantled and thoroughly cleaned and degreased by hand. After reassembling the process unit of the SensoGate® WA 130H Sensor Lock-Gate test object was connected with adapters on a T-pieces DN 50 pipe. The process site (mentioned process side circuit) and the SensoGate body (mentioned SensoLock circuit) were both connected to a steam line and both circuits were steam-sterilised in-line at 121°C for 30 minutes.

A spore suspension of *Bacillus subtilis* (Bac 1-12) with a concentration of approx. 5×10^7 spores/ml was used to wet the inner surface of the dismantled test object, including all surfaces that are in contact with each other after reassembly. The test object was allowed to dry at 20 °C for 4 hours. After reassembling the test object was remounted in the double test rig circuit (process side circuit and SensoLock circuit) and both circuits were simultaneously steam-sterilised in-line by saturated steam at 121 °C for 30 minutes. During the 30 minutes lasting sterilisation cycle the immersion tube was actuated downwards 10 times during 5 seconds.

After steam sterilization, the both test object circuits were aseptically connected to the two sterile test circuits with sterile Trypticase Soy Broth (TSB). The flow rate of the TSB was set to give two circuit volume exchanges within both circuits during a 2-hour circulation period each day. The test circuit was kept at ambient temperature for at least 5 days.

If the broth remains clear during 5 days the test object is classified as steam-sterilisable in-line. If the broth becomes turbid, a sample is taken and examined microscopically for the presence of *Bacillus subtilis*. If there is any doubt as to the identity of the micro-organisms a further sample is pour-plated with Trypticase Soy Agar (TSA) and incubated at 37 °C for 3-5 days. Colonies of sporulated *Bacillus subtilis* are greyish-green.

A detailed description of the test procedure including a schematic drawing of the test circuit is enclosed in appendix B.

5 Results

The tests were conducted three times on three identical test objects. In all three test runs a double circuit has been run, meaning a circuit for the internal of the Sensolock body (Sensolock circuit) and one for the process connection side (process side circuit).

The results of the independent tests were comparable with each other. The applied seals showed no antimicrobial properties. In Table 1 the test results are summarized.

Table 1 Survey of the test results for the SensoGate® WA 130H Sensor Lock-Gate

SensoGate® WA 130 circuit	circuit sterile during at least 5 days (yes /no)		
	test 1	test 2	test 3
SensoLock circuit	yes	yes	yes
process side circuit	yes	yes	yes

The test results show that no bacteria remained in the internal and external parts of the SensoGate® WA 130H Sensor Lock-Gate after steam sterilization in-line at 121 °C for 30 minutes.

6 Conclusions

The test results show that no bacteria remained in the internal (SensoLock circuit) and external (process side circuit) parts of the SensoGate® WA 130H Sensor Lock-Gate after steam sterilization in-line at 121 °C for 30 minutes. The in-line steam sterilisability tests were conducted three times. The results of the independent tests were comparable with each other. The SensoGate® WA 130H Sensor Lock-Gate is classified as steam-sterilisable in-line according to the EHEDG test procedure.

The SensoGate® WA 130H Sensor Lock-Gate is available in the following sizes and process connector variants: Tri-Clamp 1-3,5 inch, VariVent® DN50-125 and Dairy Fitting DN50-80 according DIN 11851 in combination with Siersema gasket.

7 Records

The test objects are registered under TNO numbers 3119-07-0778, 3119-07-0779 and 3119-07-080 and the results are recorded and archived under TNO's project code 031.11513/01.18. Original data sheets, protocols and the final report will be filed in the archives of TNO for 5 years after completion of the study.


8 References

- 1 A method for the assessment of in-line steam sterilisability of food processing equipment (second edition), European Hygienic Engineering & Design Group, Doc. 5, July 2004.

9 Authentication

We, the undersigned, herewith declare that the studies reported here were carried out according to the agreed protocols, that this report contains an accurate description of the results obtained and that the results relate only to the tested object.

Date: February 25, 2008



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