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TNO report

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Validation of the in-line steam sterilisability of the Knick SensoGate® type WA131H/WA131MH according to the EHEDG procedure

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Summary

At the request of Knick Elektronische Messgeräte GmbH & Co. KG, Berlin, Germany the in-line steam sterilisability of their SensoGate® type WA131H/WA131MH 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® type WA131H/WA131MH after steam sterilization in-line at 121°C for 30 minutes. The in-line steam sterilization tests were conducted three times. The results of the independent tests were comparable with each other. The SensoGate® type WA131H/WA131MH is classified as steam-sterilisable in-line according to the EHEDG test procedure.

The SensoGate® type WA131 (M)H is available in the following sizes and process connections: Knick DN25 hygienic, Tri-Clamp 1-3.5 inches, Varivent® DN50-125, BioControl® DN50-65 and Dairy Fitting according to DIN11851 DN50-80 in combination with the Siersema gasket.

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Appendices
A Drawing of the SensoGate® WA131H/WA131MH

1 Introduction

At the request of Knick Elektronische Messgeräte GmbH & Co. KG, Berlin, Germany the in-line steam sterilisability of their SensoGate® type WA131H/WA131MH 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®
Type	:	WA131H / WA131MH
Process connection	:	Tri-clamp 1" and Knick DN25 hygienic
Materials of construction	:	1.4404 (316L) for the wetted parts
Surface finish	:	< 0.8μm Ra
Applied seal /gaskets	:	EPDM / FKM / FFKM / VMQ
TNO numbers	:	3119-11-0052 / 3119-11-0053.

A the build-up of the SensoGate® is visualized in figure-1.
A detailed sectional cross view of the internal parts of the test objects is given in Appendix-1.

Figure-1, photograph of the test objects.

3 Time schedule

The test objects arrived at TNO Quality of Life on March 2011 and were registered under TNO numbers 3119-11-0052 and 3119-11-0053. The investigations were carried in period March 2011 – July 2011.

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® type WA131H / WA131MH 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. $5x10^7$ 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,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.

5 Results

The tests were conducted three times on the two test objects. In all three test runs a double circuit was used, 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® type WA131H/WA131MH

SensoGate® type WA131H/131MH 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® type WA131H/131MH 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® type WA131H/WA131MH 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® type WA131H/WA131MH is classified as steam-sterilisable in-line according to the EHEDG test procedure.

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7 Records

The test objects are registered under TNO numbers 3119-11-0052 and 3119-11-0053. The results are recorded and archived under TNO's project code 031.20996/01.01. 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 Signature

Zeist, September 2011

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