Tesalys - France

Integrated shredder / sterilizer for infectious healthcare waste Tesalys

Performance Qualification

Date of qualification tests : August 2, 2013

Installation of instruments for measurement has been carried out by M. Ludovic Bonnin, Validation Engineer
supervised by M. Jean-Marie Mouton, Managing Director of Hospitec
All tests have been carried out with more than 12 measurement points/m3, distributed in all spots in the chamber

Summary of qualification tests

				Analysis of sterilization holding time									
Cycle	Test n°	Reference T°	Duration	Duration at T°>134° (B&D)	Duration	Minimum T°	Maximum T°	Range of every probe	Difference between probes	Difference in P / as per Regnault tables	Fo total	Fo during sterilization plateau	Load integrity
Cartography of temperatures, empty ch	Test 1/3	134°C	00:35:08	Non applicable	00:20:00	135.1°C	135.8°C	0.7°C	0.1°C	17 mbar	644.1 minutes	548.4 minutes	Non applicable
	Test 2/3	134°C	00:33:30	Non applicable	00:20:00	135.1°C	135.9°C	0.7°C	0.2°C	16 mbar	642.2 minutes	549.7 minutes	Non applicable
	Test 3/3	134°C	00:31:54	Non applicable	00:20:00	135.1°C	135.9°C	0.8°C	0.2°C	15 mbar	639.2 minutes	551.3 minutes	Non applicable
Decontamination/Sterilization cycle	Test 1/3	134°C	00:32:36	Non applicable	00:20:00	135°C	135.9°C	0.8°C	0.3°C	24 mbar	637.9 minutes	544.5 minutes	Non applicable
	Test 2/3	134°C	00:33:28	Non applicable	00:20:00	135.1°C	135.8°C	0.7°C	0.3°C	16 mbar	644.3 minutes	549.2 minutes	Non applicable
	Test 3/3	134°C	00:32:30	Non applicable	00:20:00	135.1°C	135.8°C	0.7°C	0.2°C	15 mbar	639 minutes	549.9 minutes	Non applicable

Remarks

By Hospitec	By Tesalys
The sterilization cycle parameters measured in the unit conform to the requirements of the following standards : NF EN ISO 14937, EN ISO 17665-1, EN 285, EN ISO 11140-3 ,EN 554 and therefore guarantee the sterility of the goods treated by the device. **The above tested sterilizer is capable to carry out repeatedly the sterilization cycles within the limits and tolerances required**	**The qualified device is marketed under the model names** STERISHRED AND STERIPLUS **It has been specifically designed to treat infectious healthcare/biomedical waste**

By Hospitec, Jean-Marie Mouton, Managing Director
Date : Wednesday, August 7th 2013

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By Tesalys, Miquel Lozano, President
In acceptance of this report

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