

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

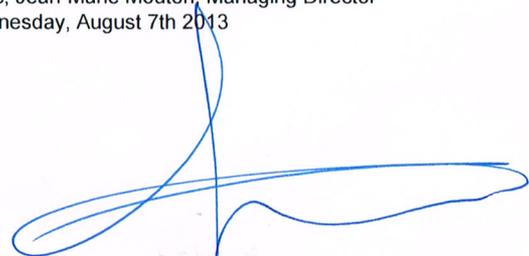
Cycle	Test n°	Reference T°	Duration	Analysis of sterilization holding time							Fo total	Fo during sterilization plateau	Load integrity
				Duration at T°>134° (B&D)	Duration	Minimum T°	Maximum T°	Range of every probe	Difference between probes	Difference in P / as per Regnault tables			
Cartography of temperatures, empty chamber	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

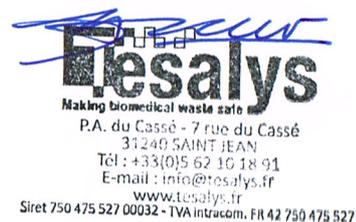
By Hospitec	By Tesalys
<p>The sterilization cycle parameters measured in the unit conform to the requirements of the following standards : NF EN ISO 14937, EN ISO 17665-1, EN 285, EN ISO 11140-3 ,EN 554 and therefore guarantee the sterility of the goods treated by the device. The above tested sterilizer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

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

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



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