

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

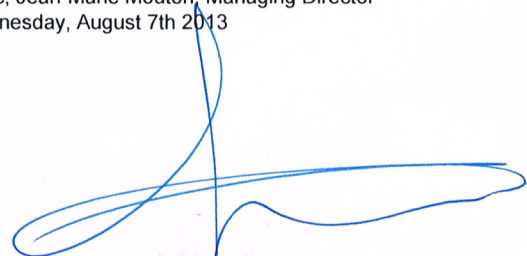
Cycle	Test n°	Reference T°	Duration	Analysis of sterilization holding time							Fo total	Fo during sterilization plateau	Load integrity
				Duration at T°>134° (B&D)	Duration	Minimum T°	Maximum T°	Range of every probe	Difference between probes	Difference in P / as per Regnault tables			
Cartography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




Société Hospitec
 BP 20

57560 ABRESCHVILLER

Tél. : 03 87 07 00 11 Fax: 03 87 07 00 29

Siret: 413 822 974 00015

N° TVA intracommunautaire : FR78 413 822 974



Tesalys
 Making biomedical waste safe
 P.A. du Cassé - 7 rue du Cassé
 31240 SAINT JEAN
 Tél : +33(0)5 62 10 18 91
 E-mail : info@tesalys.fr
 www.tesalys.fr
 Siret 750 475 527 00032 - TVA intracom. FR 42 750 475 527