Certificate

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Standard	**ISO 9001 : 2015**
Certificate Registr. No.	MS20 Q 11159
ID No:	9000010750

Certificate Holder:

TESALYS SAS
Parc d'activités du Cassé I
7-8 rue du Cassé
31240 Saint Jean
France

Tesalys
Making biomedical waste safe

Scope :

Design, manufacturing, marketing and sales of equipment (shredder/sterilizers) and accessories for the treatment of healthcare and laboratory waste, particularly those with infectious risk, as well as their associated after-sales services (training, installation, qualification, maintenance).

Proof has been furnished by means of an audit that the requirements of ISO 9001 : 2015 are met.

Certification decision on: 27.12.2023
Valid from 15.01.2024 to 14.01.2027
Expiry of previous certificate: 14.01.2024.

Edited on 27.12.2023

TÜV Rheinland France
20ter rue de Bezons
92400 COURBEVOIE

www.tuv.com

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CERTIFICATION DE SYSTEMES DE MANAGEMENT
ACCREDITATION N° 4-0530 PORTÉE DISPONIBLE SUR WWW.COFRAC.FR

TÜVRheinland®
Precisely Right.

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

Société Hospitec
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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

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

Tesalys
Making biomedical waste safe
P.A. du Cassé - 7 rue du Cassé
31240 SAINT JEAN
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Référence : certificat 20242901

TESALYS
7, rue du Cassé
31240 SAINT-JEAN

The undersigned, on behalf of:

BIORISK EXPERTISE
1 rue Jeanne d'Arc – 59350 Saint-André-lez-Lille, France

Hereby **certifies** that the following TESALYS devices:

STERIPLUS™ range:
STERIPLUS 20/STERIPLUS 40/STERIPLUS 80

STERISHRED® range:
STERISHRED®250/STERISHRED®700

Have been designed to process "Waste from human or animal healthcare and/or related research" (mainly categories 18 01 01, 18 01 03, 18 02 02, 18 02 02 of the European Waste Catalogue, excluding waste containing BSL4 pathogens).

These devices render healthcare waste unrecognizable and non-infectious.

Tests have been carried according to the NFX 30-503 standards to prove that healthcare waste processed with the above-mentioned devices can be considered as non-hazardous waste and can be collected and disposed of without special techniques and without risk to people and the environment. The treated waste can be considered as "Municipal wastes (household waste and similar commercial, industrial and institutional waste)" category 20 of the European Waste Catalogue.

Signed in Saint-André, France, on July 17, 2024

Dr Marie-Florence Gireaudot, PhD
Microbiologist, Risk Management Expert

Référence :Déclaration 20242902

DECLARATION OF ENVIRONMENTAL AEROSOL EMISSIONS FROM THE TREATMENT OF TESALYS BIOMEDICAL WASTE TREATMENT SYSTEM STERIPLUS™ AND STERISHRED®

The technology uses saturated steam under pressure as a disinfecting agent. The heat combined with humidity aims to reduce the intrinsic microflora of medical waste.

The analyzes show that the operation of the device:

- No increase in the microbiological contamination of air, during operation of the device

Signed in Saint-André-lez-Lille (France), July 17, 2024

Marie-Florence GIREAUDOT, PhD
Microbiologist, Risk Management Expert at AFNOR,
Former head of Service at Louis Pasteur

Référence : Déclaration 20242904

DECLARATION OF MICROBIOLOGICAL EFFICIENCY OF TESALYS STERIPLUS™ AND STERISHRED® BIOMEDICAL WASTE TREATMENT SYSTEM

We undersigned, Dr. Marie-Florence GIREAUDOT, PhD, Microbiologist, risk management expert of the independent laboratory BioRisk Expertise, declare that we have tested the antimicrobial efficacy of the HCW treatment system **Tesalys STERISHRED®250 STERISHRED®700, STERIPLUS™80, STERIPLUS™40** and **STERIPLUS™20**, with the following results:

Regarding antimicrobial effectiveness, the test results show that the cycle parameters (shredding, air extraction by vacuum, steam autoclaving at 135°C ± 0,5°C during 10 minutes, under 3,145 ± 0,028 bar) allow:

- **A reduction of 6 log_{10} spores of *Geoacillus stearothermophilus***,
- **A reduction at least of 8 log_{10} spores of *Bacillus Atrophaeus*,**

Considering these results, we hereby **CERTIFY**:

That the HCW treatment systems Tesalys, STERIPLUS™ and STERISHRED®, comply with the requirements of the French standard NFX 30-503-1 (February 2016) **with regards to the carrier test (bacterial spores) requirements.**

Signed in Saint-André-lez-Lille (France), July 17, 2024

Dr. Marie-Florence GIREAUDOT, PhD
Microbiologist, Risk Management Expert
BioRisk Expertise

Référence : Déclaration 20242903

DECLARATION OF WATER DISCHARGES FROM THE TREATMENT OF TESALYS BIOMEDICAL WASTE TREATMENT SYSTEM STERIPLUS™ AND STERISHRED®

The technology uses saturated steam under pressure as a disinfecting agent. The heat combined with humidity aims to reduce the intrinsic microflora of medical waste.

The analyzes show that the discharges from the treatment:

- are free from specific bacterial indicators (*E. coli*, *P. aeruginosa*, *S. aureus*),
- have a physico-chemical composition (pH, BOD, COD, MES, metals, ..) variables that strictly depends on the nature of the medical waste introduced into the device.

Signed in Saint-André-lez-Lille (France), July 17, 2024

Marie-Florence GIREAUDOT, PhD
Microbiologist, Risk Management Expert at AFNOR,
Former head of Service at Louis Pasteur