Tesalys

HAZARDOUS BIOMEDICAL WASTE TREATMENT AT SOURCE

INNOVATION MADE IN FRANCE

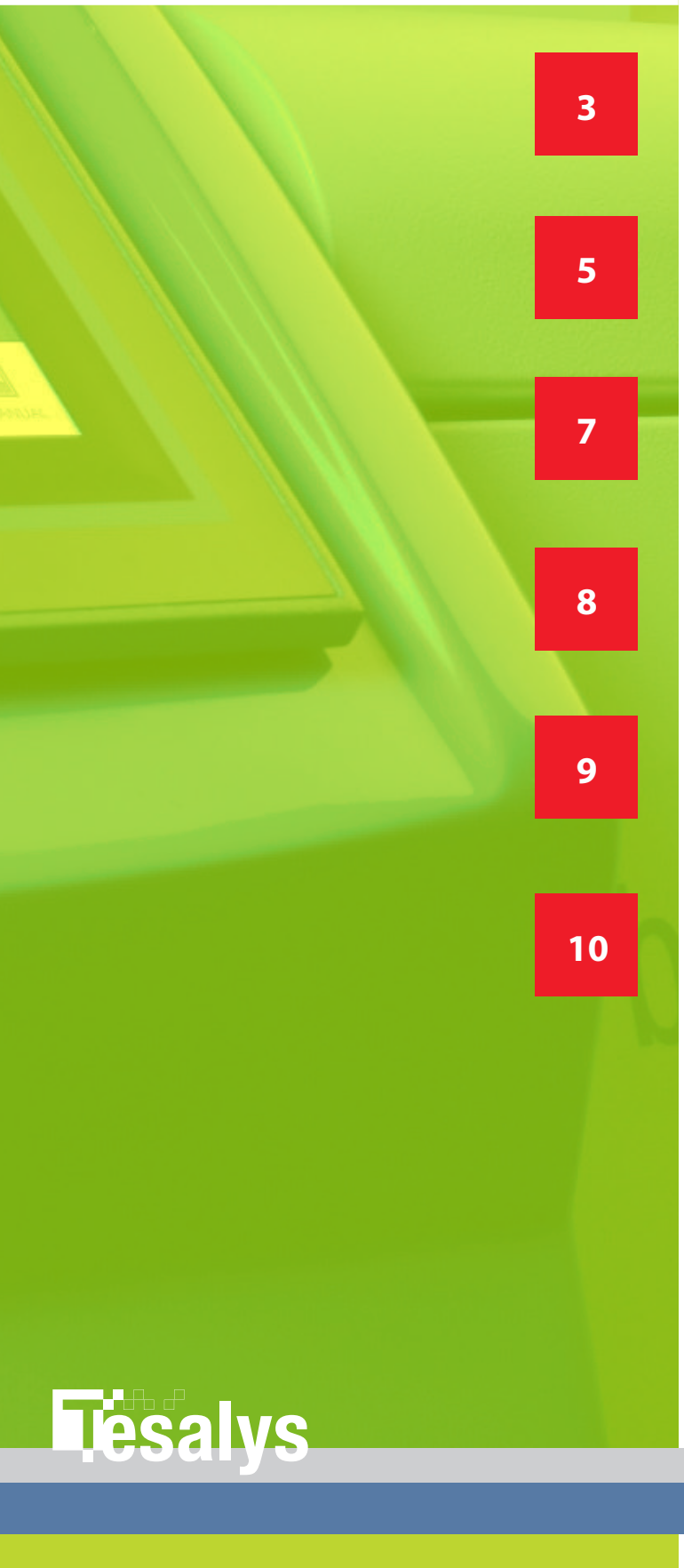
BIOMEDICAL WASTE TREATMENT EQUIPMENTS

STERIPLUS™ 20
4/5 kg/h (8-11 lbs.)

STERIPLUS™ 40
8/10 kg/h (17-22 lbs.)

STERIPLUS™ 80
16/20 kg/h (35-44 lbs.)

Table of Contents



Tesalys

Why use Steriplus for treatment of Biomedical Waste

1

Biomedical waste is hazardous in nature and needs to be handled and disposed off after treatment as prescribed in the Biomedical Waste Rules 2016.

2

Producer of the waste i.e. healthcare facility is responsible for the waste it generates.

3

Higher risk of infection spreading if the chain of people handling hazardous biomedical waste is long.

4

Biomedical waste implies very high risk on the environment and the personnel handling the waste.

5

The longer duration for which the hazardous waste remain untreated the more are the chances of infection spreading.

6

The Central Pollution Control Board and State Pollution Control Board Committees have the authority to cancel the consent to operate the authorisation of healthcare facilities under the Biomedical Waste Management Rules 2016 for non compliant hospitals.

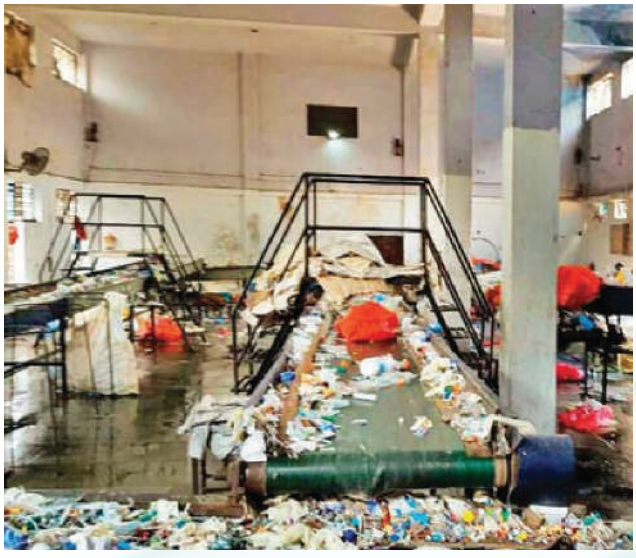
7

The hazardous biomedical waste is not to be transported to the common biomedical waste facility without prior treatment at source of its generation i.e. the healthcare facilities. It has been made mandatory for all the healthcare facilities to treat its highly infectious biomedical waste at source by the Central Pollution Control Board of India. The method of disposal must be in compliance to the Biomedical Waste Rules 2016.

8

Please find attached individual case studies where institutions have been found to be on the wrong side of the law.

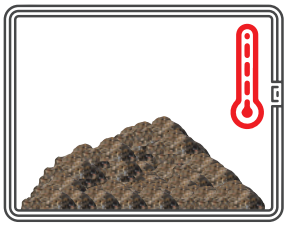
People affected because of mishandling of hazardous biomedical waste.



Advantages of Steriplus

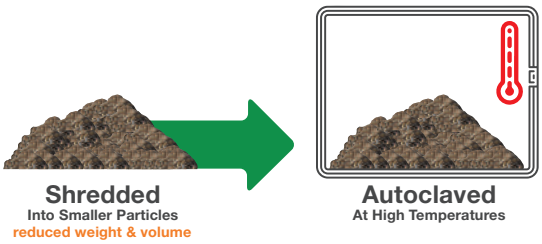
1

Steriplus reduces the weight of the waste by upto 50% and volume of medical waste by upto 80% thus making it easier to handle after disinfection.



2

The waste is shredded prior to being autoclaved in our equipment Steriplus. This ensures that the waste is fully processed as shredding increases the exposure to microorganisms to the sterilising steam. This process ensures that the core of infection is treated.



3

The process of shredding and autoclaving is integrated in the equipment, which reduces user exposure to hazardous medical waste.

4

Steriplus changes the appearance of biomedical waste by turning it into 8-10 mm small pieces.

5

Steriplus is effective for all types of waste, for e.g. dry solid, semi solid etc.

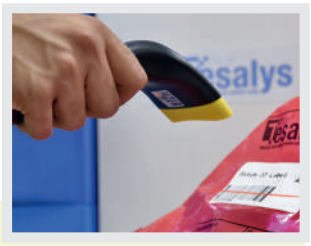
6

Zero dioxin and furan emissions in the entire procedure.

7

Compact equipment, does not require a lot of space in the healthcare facility.

Advantages of Steriplus

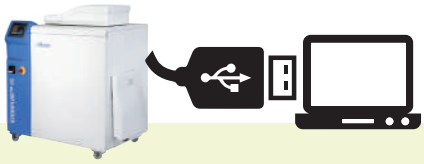


8

The Equipment comes with a 'barcode scanner' that can scan waste bags and user badges. This way the authorities can monitor what waste is being treated and who is running the treatment cycles.

9

Steriplus gives print ticket after every cycle for data recording, the print ticket displays the temperature and pressure maintained by the Equipment at every minute of the treatment cycle.



10

User can access the cycle details and store all the data on their computers by data logging using a USB pen drive.

By using Steriplus our clients can be 100% sure that the waste generated by them is being treated properly and is absolutely safe for disposal.

11

The Equipment can be connected to a wi-fi and all the data of the Equipment can be accessed by the concerned authorities online.

12

Clean ambient air by filtration at 0.2 microns

13

Energy savings by integrated heat recovery system

14

Steriplus is being used across the globe and has proven to be effective for treatment of hazardous biomedical waste.

15

Steriplus has been approved by the Ministry of Health in France.

16

Steriplus has been designed as per WHO Recommendations for treatment of health care waste.

17

One of our prestigious installation is in European Union's Ebola Testing Laboratory.

Effectiveness in fight against highly contagious diseases

Current Procedure in Healthcare Facilities for Handling Medical Waste of Isolation Wards

Step 1

Waste Generation

Step 2

Segregation & Storage

Step 3

Waste Collection from Authorised Waste Collectors

Step 4

Transportation to Treatment Facility

Step 5

Final Treatment and Disposal

Drawbacks of Current Practices

- Higher risk of infection spreading if the chain of people handling hazardous biomedical waste is long.
- The longer duration for which the hazardous waste remains untreated the more are the chances of infection spreading.

Solution and Special Corona Virus Cycle

Solution

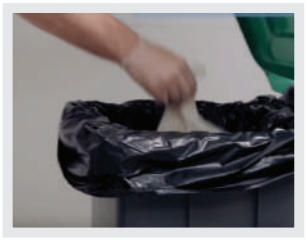
STERIPLUS™ - Waste is treated at the point of its generation i.e. healthcare facilities.

Step 1

Waste Generated

Step 2

Treatment on Site



Step 3

Safe Disposal

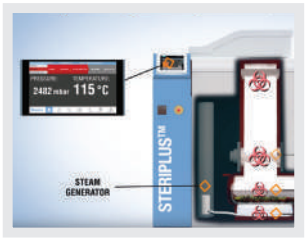
Special Corona Virus Cycle

Step 1

Loading Waste

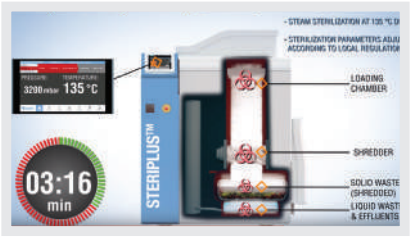
Step 2

Shredding



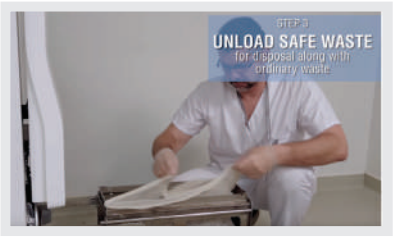
Step 3

Pre-decontamination at 80 degrees celsius



Step 4

Decontamination Cycle at 135 degrees celsius for 30 mins



Step 5

Unloading Waste Safe for Disposal

As per Schedule I of Government of India, Ministry of Environment, Forest and Climate Change Notification dated 28th March 2016 our Equipment Steriplus can treat the following categories of waste:




1

Soiled Waste: Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components. Discarded linen, mattresses, beddings contaminated with blood or body fluid.

2

Microbiology, Biotechnology and other clinical laboratory waste: Blood bags, Laboratory cultures, stocks or specimens of micro- organisms, live or attenuated vaccines, human and animal cell cultures used in research, industrial laboratories, production of biological, residual toxins, dishes and devices used for cultures.

3

Contaminated Waste (Recyclable): Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and fixed needle syringes) and vaccutainers with their needles cut) and gloves.

4

Waste sharps including Metals: Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps

5

Glassware: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.

Steriplus now has a special cycle designed to treat the infected blood bags, it solidifies the bloods and shreds it making it easier for transportation to the common biomedical waste facility.

Certifications

Designed and manufactured in France
(in compliance with French standard NFX 30-503)

CE Conformity (European Directive 2006/42/EEC, harmonized standards for machinery safety)

In compliance with international standards (EN 554 and EN ISO 17665-1) and with the WHO recommendations

European patent 3104986 for the way the machine works with the loading chamber, the pressing plate, the shredder etc

European patent 3104987 for the design of the blades of the shredder.

CONFORMITY NFX 30-503 STANDARD

French standard for appliances to process HCW by non-burn technologies

STERIPLUS™ 20

4/5 kg/h (8-11 lbs.)

STERIPLUS™ 40

8/10 kg/h (17-22 lbs.)

STERIPLUS™ 80

16/20 kg/h (35-44 lbs.)

Tesalys

QUALITY STATEMENT

Ref. : LET-1507-0298

The undersigned, on behalf of :

TESALYS
7 rue du Cassé
31240 Saint-Jean (Toulouse), France

Declares that the product :

BIOMEDICAL WASTE TREATMENT SYSTEM
TESALYS STERIPLUS™

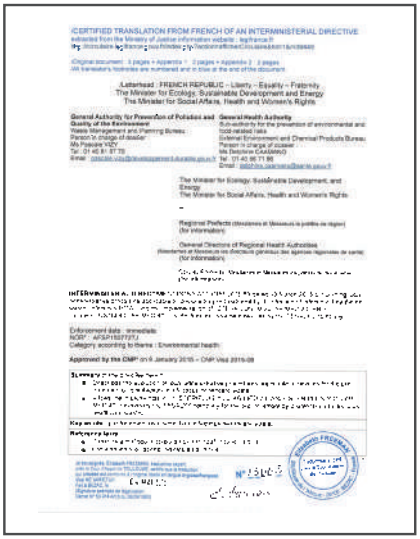
Is produced and assembled in a plant working in accordance to the following quality standards :

- ISO 9001 : 2008

Notified body : United Kingdom Accreditation Service UKAS, n° 043.

Place : Toulouse
Date : July 2nd, 2015

Miquel Lozano
President
Tesalys



CERTIFIED TRANSLATION FROM FRENCH OF AN INTERMINISTERIAL DIRECTIVE

BioRisk

DECLARATION OF CONFORMITY OF
TESALYS STERIPLUS™ BIOMEDICAL WASTE TREATMENT SYSTEM
TO NFX 30-503 STANDARD

According to French NFX 30-503 standard, any system designed for the treatment of Healthcare Waste (HCW) with infectious/sharp risk should involve both:

- *A change in the appearance and physical characteristics of HCW so as to reduce mechanical and psycho-emotional risks*
- *The reduction of the intrinsic microbial contamination of HCW to reduce the risk of contamination.*

The purpose of this treatment is to render HCW unrecognizable and non-infectious to be comparable to non-hazardous waste and be disposed of as such.

To be operated in France, any system for HCW treatment must comply with NFX 30-503 standard (December 2012).

We undersigned, Dr. Marie-Florence GIREAUDOT, PhD, Microbiologist, risk management expert of the independent laboratory BioRisk Expertise, declare that we have tested the antimicrobial and technical efficacy of the HCW treatment system **Tesalys STERIPLUS™40** and **STERIPLUS™20** , in accordance with NFX 30-503-December 2011, 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 at least 6 log10 of contaminated HCW (vegetative bacteria),**
- **A reduction of at least 8.8 log10 spores of bacterias** (*Bacillus anthropheaus*) , **), of at least 7 log10 of fungi** (*Aspergillus niger*), **of at least 5 log10 of virus** (*Adenovirus*) and of **at least 4log10 of parasites** (*Cryptosporidium parvum*).
- **No microbiological revival during time**; no microbial growth was observed (less than 1log10) after storage during 28 days at 20 °C of HCW treated.

On the technical efficiency of the **Tesalys STERIPLUS™**, the test result show:

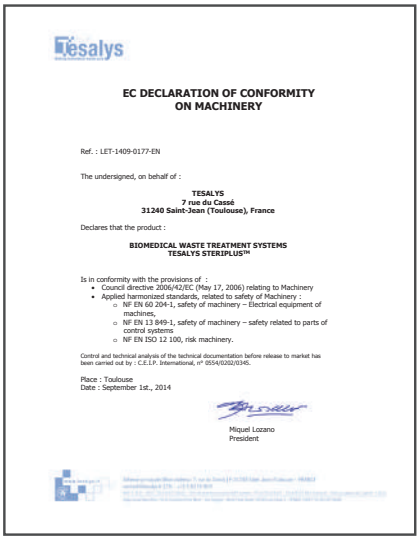
- The effectiveness of the shredder, which changes the HCW appearance : 100% of samples of shredded HCW have a particle size less than 30 mm,
- No increase in the microbiological contamination of air, during operation of the device,
- Liquid discharges from the apparatus are free of bacterial indicators (*E. coli, Enterococci sp, Staphylococci sp*).

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

That the HCW treatment system Tesalys STERIPLUS™, complies with the requirements of the French standard NFX 30-503-December 2011 and therefore is an efficient system to render HCW unrecognizable and non-infectious to be comparable to non-hazardous waste and be disposed of as such.

Signed in Saint-André-lez-Lille (France), November 5, 2014

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



Tesalys

EC DECLARATION OF CONFORMITY
ON MACHINERY

Ref. : LET-1409-0177-EN

The undersigned, on behalf of :

TESALYS
7 rue du Cassé
31240 Saint-Jean (Toulouse), France

Declares that the product :

BIOMEDICAL WASTE TREATMENT SYSTEMS
TESALYS STERIPLUS™

Is in conformity with the provisions of :

- Council directive 2006/42/EC (May 17, 2006) relating to Machinery
- Applied harmonized standards, related to safety of Machinery :
  - NF EN 60 204-1, safety of machinery – Electrical equipment of machines,
  - NF EN 13 849-1, safety of machinery – safety related to parts of control systems
  - NF EN ISO 12 100, risk machinery.

Control and technical analysis of the technical documentation before release to market has been carried out by : C.E.I.P. International, n° 0554/0202/0345.

Place : Toulouse
Date : September 1st., 2014

Miquel Lozano
President

Tesalys

Conveniences of Choosing Steriplus for the End User

Standards and Approvals
- NFX 30 503
- Approved by Ministry of Health France
- EN 554
- EN ISO 17665 - 1
- CE Conformity

Qualifications
- Tested by an independent body
- Institutional and operational performance qualification.
- Scientific tests - quality of shredding / microbiological efficacy / operator environment.

Installation

- Simple and fast
- By certified personnel across the world

User Training Guaranteed

- User training at client's facilities
- Support, documentation and software provided.
- Certification of Personnel - Periodic training for the entire team of hospital staff managing the hazardous biomedical waste.

Maintenance and Technical Support

- Original and consumable parts available.
- Fast delivery
- 24/7 Customer support
- Remote Surveillance and Remote Maintenance.
- Engineer visit every 3 months to ensure smooth and uninterrupted working of the Equipment.

User Training Guaranteed

- Certification of Personnel - Periodic training for the entire team of hospital staff managing the hazardous biomedical waste.

Q&A

Do you have any questions that you can't find answers to?

Tesalys