

DECLARATION OF CONFORMITY OF TESALYS STERIPLUS™ BIOMEDICAL WASTE TREATMENT SYSTEM TO NFX 30-503-1 STANDARD

According to French NFX 30-503-1 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 30-503-1 standard (February 2016).

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™80, STERIPLUS™40** and **STERIPLUS™20**, in accordance with NFX 30-503-1(February 2016), with the following results:

Regarding antimicrobial effectiveness, the test results show that the cycle parameters (shredding, air extraction by vacuum, steam autoclaving at $135^{\circ}\text{C} \pm 0,5^{\circ}\text{C}$ during 10 minutes, under $3,145 \pm 0,028$ bar) allow:

- **A reduction of at least 6 log₁₀ of contaminated HCW (vegetative bacteria),**
- **A reduction of at least 8.8 log₁₀ spores of *Bacillus atrophaeus*, of at least 6 log₁₀ spores of *Geococcus stearothermophilus*, 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 30-503-1 (February 2016) 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), April 09, 2019

A handwritten signature in blue ink, appearing to be "MFG", located below the text of the declaration.

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