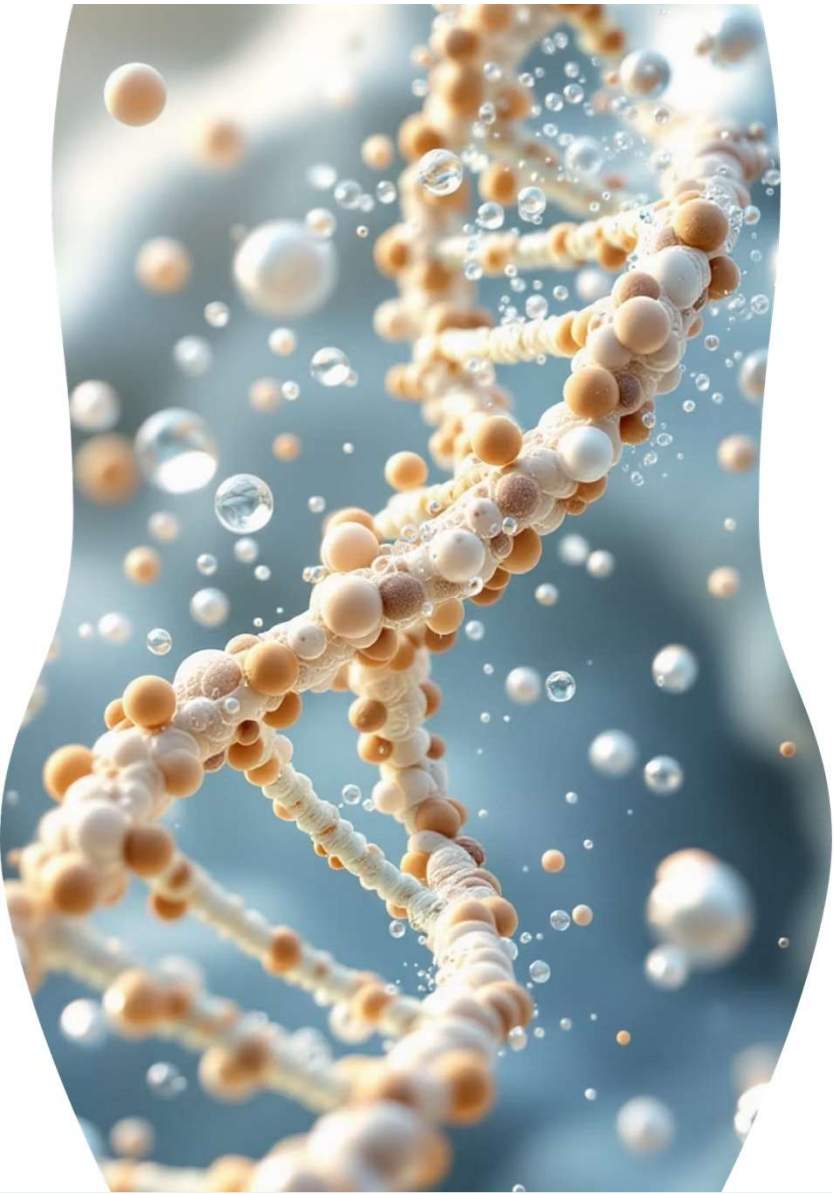


Decontamination by UV LED in a controlled environment: towards an alternative to ionizing radiation

Presented by **Janyce Franc**, General Manager of Sterixene

A comprehensive exploration of advanced UV decontamination technologies and their applications in healthcare and industrial sterilization environments.

About Me: Janyce Franc



Academic Foundation

- PhD in Optics
- Engineer in Material Science
- Technician in Chemistry

Industry Leadership

- 21 years in optical innovation
- 15 years focused on decontamination technologies
- 15+ years managing microbiology teams
- General Manager of Sterixene and Bacchustorm
- President of EHEDG (European Hygienic Engineering & Design Group)

With over two decades of expertise in optical innovation and decontamination technologies, I bring specialized knowledge in UV-based sterilization methods to help organizations transition from traditional ionizing radiation to advanced UV LED solutions.

Corporate Overview: Sterixene

Strategic Partnership

Since May 2024, Sterixene has been 51% owned by the Hoenle Group, creating a powerful alliance in UV decontamination technology.

Enhanced Capabilities

- Enhanced R&D capabilities
- Expanded global market reach
- Combined expertise in UV technologies

hoenle

STERIXENE
Member of Hönle group

This acquisition strengthens our market position and expands our technological capabilities in advanced decontamination solutions for pharmaceutical and industrial applications.



Hoenle Group - Key Facts

Founded in Germany

Established in 1976, Hoenle has built a 48-year legacy of innovation and excellence in specialized lighting technologies.

Global Expansion

Operations in 17 countries worldwide, creating a robust international presence and distribution network.

Technical Expertise

Strong specialization in UV technologies, industrial curing systems, and high-performance adhesives.

Strategic Restructuring

Recent 2023-2024 business optimization to streamline operations and enhance market competitiveness.



UV Disinfection Technologies Comparison

Low Pressure UV (254 nm)

Targeted wavelength treatment for standard decontamination applications with moderate efficacy levels.

LED UV (275 nm)

Energy-efficient solution with enhanced sustainability profile and reduced power consumption for modern applications.

Medium Pressure UV

High-intensity treatment across multiple UV wavelength peaks for more intensive industrial applications.

Pulsed Light

Premium high-intensity disinfection across broad spectrum, offering superior microbial reduction capabilities.

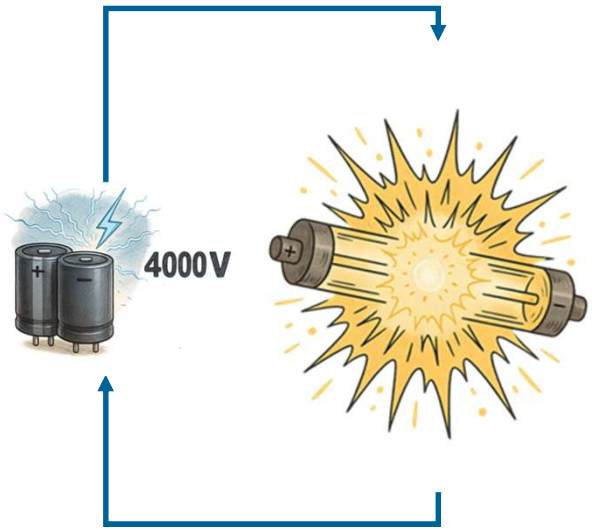


Comparative Analysis of UV Technologies

Examining performance metrics across different UV decontamination solutions reveals significant variations in efficacy, wavelength profiles, and operational characteristics.

Technology	Microbial Reduction	Wavelength Profile	Treatment Time	Ecological Impact	Cost Factor
UV Techno Excimer	1-2 log reduction	Monowavelength	Several seconds	Low (●)	Low (●)
Low Pressure UV	1-4 log reduction	Monowavelength	Several seconds	Low (●)	Low (●)
UV LED	**1-4 log reduction**	**Monowavelength**	**Several seconds**	**Medium (●●)**	**Medium (●●)**
Medium Pressure UV	3-4 log reduction	Multiwavelengths	1-3 seconds	Low (●)	Medium (●●)
Pulsed Light	4-7 log reduction	Total spectrum	Instantaneous	High (●●●)	High (●●●)

How Pulsed Light Works



1 Electric pulse

2 Conductive lamp

3 Discharge until 4000V

4 Flash

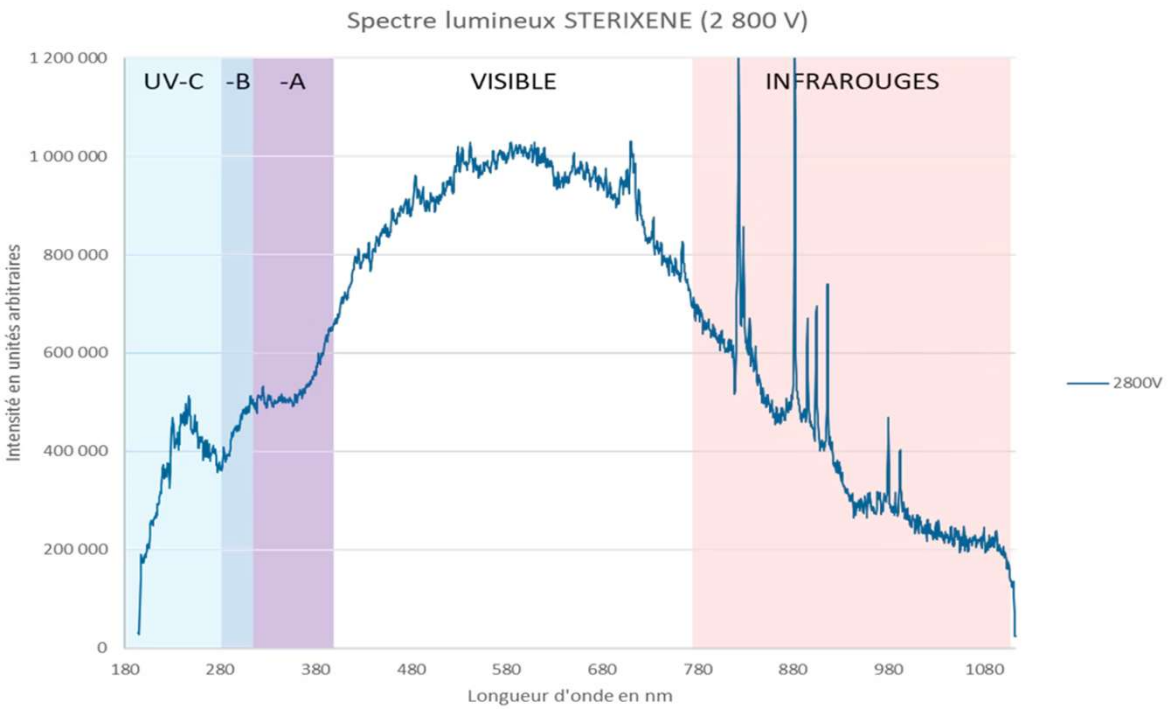
4 Immediate decontamination



A flash:

- With a power of 2 MW
- Broad spectrum reproduction (180 nm to 1100 nm)

Light Spectrum in Pulsed Technology



The Spectrum:

Comprehensive Range

UV to Infrared (180 nm to 1100 nm)

Balanced Distribution

20% UV – 45% Visible – 35% NIR

Germicidal Power

UV portion provides most effective microbial deactivation

Universal Application

Wide spectrum ensures effectiveness against diverse microorganisms

The broad spectral profile of pulsed light technology enables it to target multiple cellular components simultaneously, providing more comprehensive microbial inactivation than narrower-spectrum UV technologies.

Comparison: UV LED, Low and Medium Pressure Systems



UV LED

- No preheating phase required
- Instantaneous activation
- Targeted single wavelength emission
- Longer operational lifespan
- Lower power consumption



Low Pressure UV

- One to five minutes preheating phase
- Monowavelength (254nm) output
- Continuous operation design
- Lower intensity than medium pressure
- Cost-effective solution

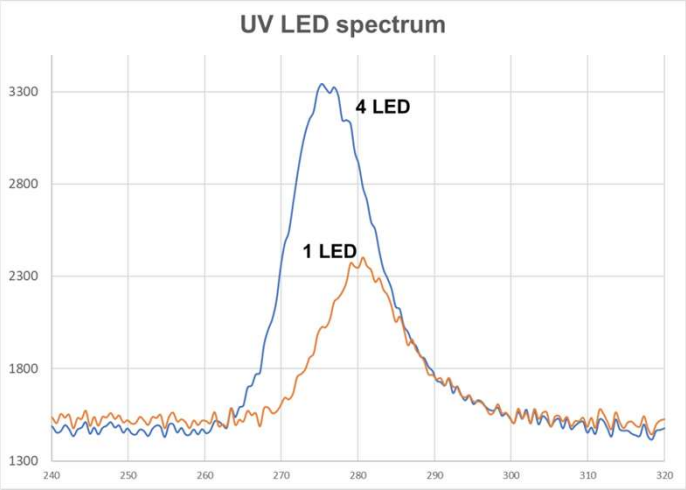


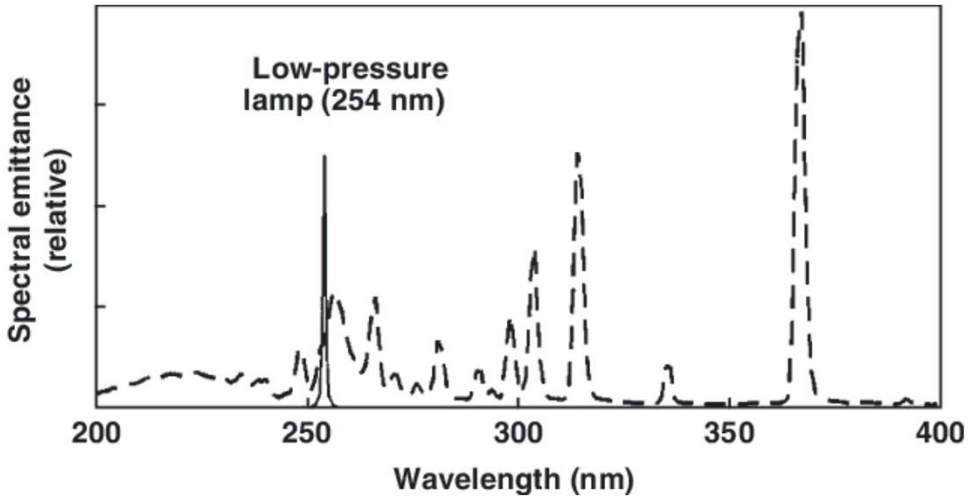
Medium Pressure UV

- Two-minute preheating phase
- Multiple wavelength emission
- Higher intensity output
- Greater power consumption
- Shorter lamp lifespan

The warm-up phase of UV lamps is important before optimal operation. Lasting 1-5 minutes depending on lamp model and power, this phase stabilizes the electric arc and temperature. UV output remains unstable during this period, not yet reaching peak intensity or optimal spectral distribution.

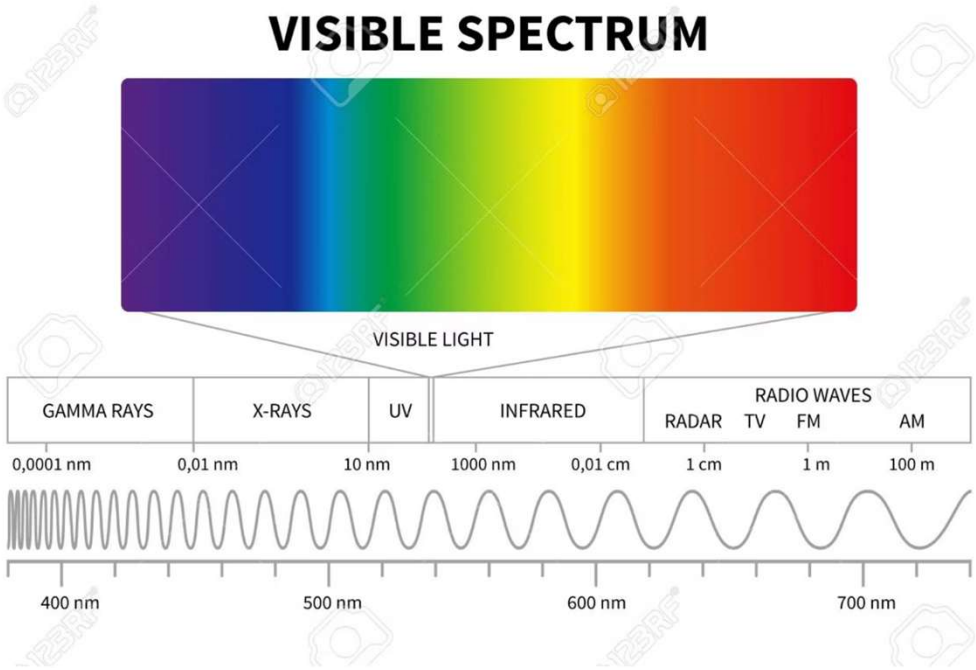
Spectrum of UV LED and Mercury lamps (low and medium pressure)





Electromagnetic spectrum showing the relationship between wavelength, frequency, and energy levels across different light categories from gamma rays to radio waves.

Visible Spectrum Comparison



Wavelength Comparison

Type of Light	Number of Wavelengths
Pulsed Light	~950
UV Medium Pressure	Some tens
UV Low Pressure	1
UV LED	1

Pulsed Light's extensive wavelength coverage provides comprehensive microbial targeting across diverse cellular structures, creating multiple inactivation mechanisms simultaneously.

UV Technologies at Labrobot: The good choice in 2023

UV LED

Traditional single-wavelength approach with established protocols and moderate efficacy levels for standard applications.

PULSED LIGHT

Advanced broad-spectrum technology offering superior decontamination performance with rapid treatment cycles.

Microbiological Testing Protocol

- Representative germ selection
- Standardized exposure conditions
- Quantitative efficacy measurement

Treatment Parameters

- Optimized time treatment protocols
- Dose-response relationship analysis
- Performance validation studies



Where Does UV LED Technology Come From?

1

1900-1980: Early Discovery

Discovery of the **germicidal effect** of UVC and first developments of **UV lamps (with mercury vapour)**. Industrial adoption across various sectors.

2

1960-1970s: LED Innovation

Invention of the first light-emitting diodes (LEDs), initially limited to visible light spectrum (red, then green, then blue).

3

1990s: Material Breakthrough

Major breakthrough with **gallium nitride (GaN) – 365 nm to 405 nm but not enough**, enabling the fabrication of blue LEDs and opening the path to UV applications.

4

2000s: UV-C Development

First UV-C LEDs (below 280 nm) appear, but with very low power, <1% efficiency, and limited operational lifetime.

5

2000-2015: Rapid Progress

Significant advancement in efficiency and reliability through advances in semiconductor materials and manufacturing processes.

Where Does Pulsed Light Technology Come From?

1

1900-1980: Foundation Era

Discovery of the **germicidal effect** of UVC and first developments of **UV lamps**. Industrial adoption across various sectors.

2

1980-1990: Patent Pioneering

Pioneering patents for pulsed light technology developed in Japan (Hiramoto, 1984), establishing foundational intellectual property.

3

1990-2000: Industrial Development

First **applications** of pulsed light technology emerge. Industrial development by **PurePulse (USA)** in collaboration with **Tetra Pak**. **FDA approval** secured for food applications.

4

2000-2018: Market Growth

Significant growth of UV and pulsed light adoption in **industrial environments** across pharmaceutical and food processing sectors.

5

Today: Sterixene Era

Creation of Sterixene in 2018 marks new phase. International development of UV technologies accelerated through partnership with the Hoenle Group.

Pulsed Light vs UV LED: Feature Comparison

Feature	Pulsed Light ⚡	UV LED 💡
Emission Type	🌈 Broad spectrum → UV + visible + IR	🎯 Targeted UV-C (265–280 nm)
Treatment Duration	⏱️ Short pulses	📏 Continuous, adjustable dose
Noise	🔊 Audible noise	🤫 **Silent operation**
Integration	⚙️ Harder integration → less flexibility	🤖 **High flexibility - Easily programmable & automated**
Lamp Life / Maintenance	🔄 Lamp lifetime: 10 million flashes, High voltage requirement	⏳ **Long lifetime → 20,000 hours**
Safety Precautions	⚠️ Special safety precautions (be careful with light leakage)	✅ **Compatible with cleanroom standards (No light leakage)**

Key Advantage: UV LED = precise, silent, safe, no light leakage and fully compatible with pharma cleanrooms, offering integration flexibility for modern manufacturing environments.

UV Microbiology Lab

Research & Development Excellence

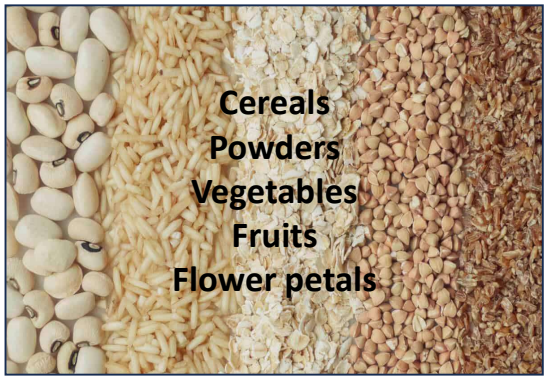
- **R&D partner for industry** - Leading collaborative research initiatives
- **Recognized expertise in France** - Established authority in UV microbiology
- **Pioneering UV decontamination research** - Advancing next-generation technologies

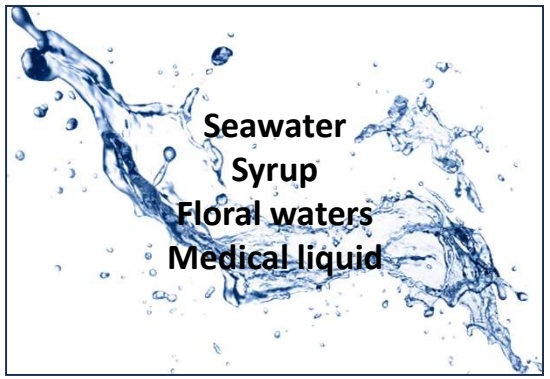
Our state-of-the-art microbiology laboratory serves as a cornerstone for UV decontamination research and development. We provide comprehensive testing services and validation protocols that support industry leaders in implementing effective UV-based sterilization solutions.



Microbiological Expertise Across All Matrices







AMORIM CORK



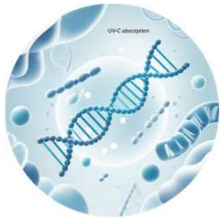
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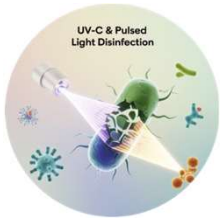
How Light Inactivates Microorganisms



Absorption of Light by Key Cellular Components

Certain wavelengths, particularly **UV-C (200–280 nm)**, are strongly absorbed by:

- DNA and RNA
- Proteins
- Cell membranes



DNA Damage: Blocking Replication

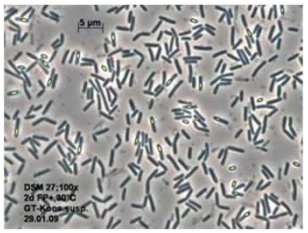
When microbial DNA absorbs UV-C light, it leads to:

- Formation of **pyrimidine dimers** (e.g. thymine-thymine dimers)
- **Strand breaks** or structural distortions
- Replication and transcription errors

Result: As a result, the microorganism **cannot reproduce** = it is **inactivated**. This mechanism ensures reliable sterilization without the need for chemical agents or ionizing radiation.



Bacillus pumilus as Reference Germ



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High UV-C Resistance

Bacillus pumilus spores are among the most UV-resistant microorganisms. Their DNA repair mechanisms and spore structure confer enhanced tolerance to UV-C wavelengths, especially around 254–280 nm.

Conservative Challenge Organism

Because of their resistance, *B. pumilus* spores represent a "worst-case" challenge. Demonstrating effective inactivation provides strong evidence that less resistant microorganisms will also be inactivated under the same conditions.

Standardized and Well-Characterized

Commercially available *B. pumilus* spore suspensions are standardized in terms of concentration and resistance, allowing reproducible and comparable validation studies.

Regulatory Acceptance

The use of *Bacillus pumilus* as a biological indicator is well established in pharmaceutical validation protocols. Its acceptance by regulatory agencies supports its use as a benchmark organism.

As UV LED systems can be tuned to specific wavelengths (265–280 nm), using a highly resistant indicator such as *B. pumilus* ensures that validation demonstrates robust microbial inactivation even under demanding conditions.

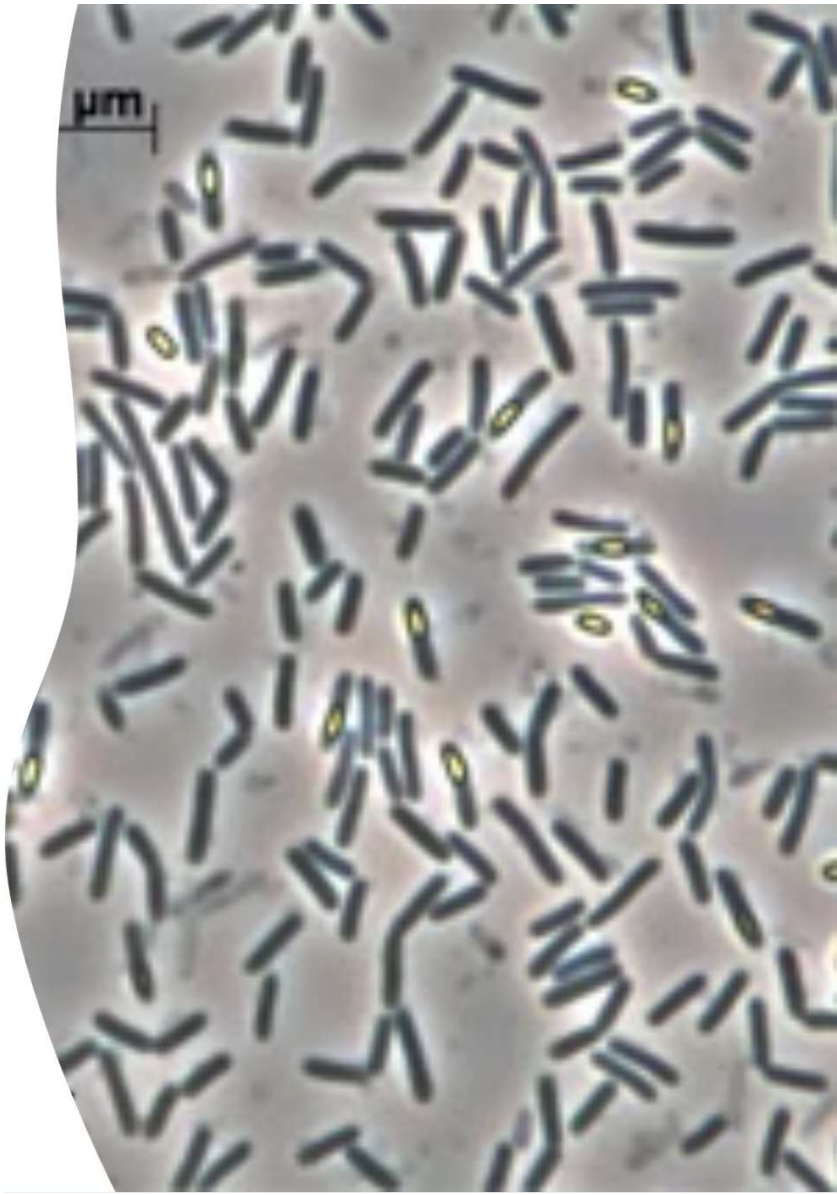
Regulatory Framework for *Bacillus pumilus*

Ph. Eur. 5.1.6 – Validation of Disinfection Processes

This European Pharmacopoeia monograph outlines the principles for validating disinfection processes, including the use of biological indicators such as *Bacillus pumilus* spores to assess the efficacy of decontamination methods.

USP <1227> – Validation of Microbiological Control and Monitoring Systems

The United States Pharmacopeia recommends the use of resistant biological indicators, like *Bacillus pumilus* spores, to validate UV-C decontamination systems in pharmaceutical environments.



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These regulatory frameworks provide the foundation for standardized validation protocols, ensuring that UV decontamination systems meet the stringent requirements of pharmaceutical and healthcare applications. Compliance with these standards is essential for regulatory approval and operational validation.

Other Reference Germs for UV Validation

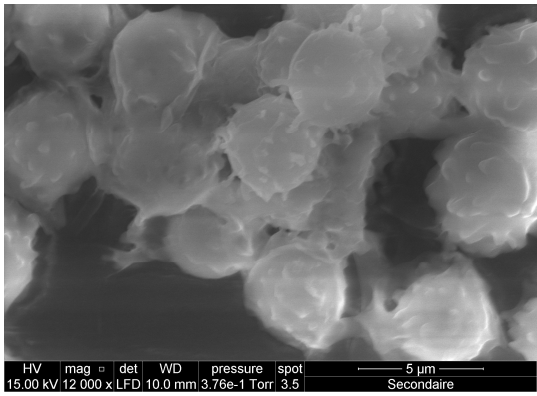
Bacterial Spores

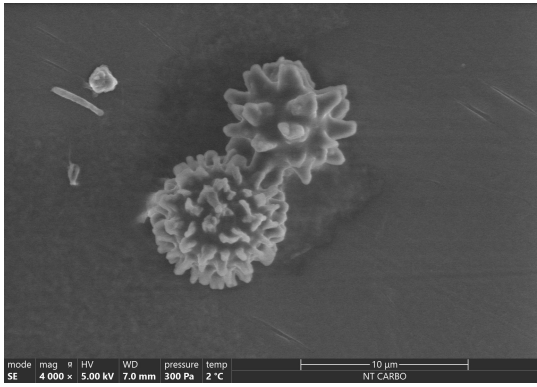
- *Bacillus atrophaeus*
- *Geobacillus stearothermophilus*

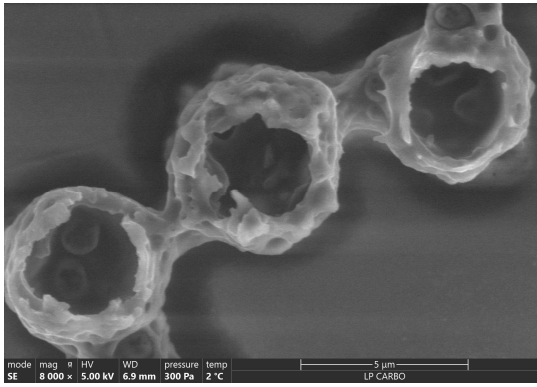
Fungal Species

- *Aspergillus brasiliensis*
- *Penicillium rubens*
- *Aspergillus carbonarius*

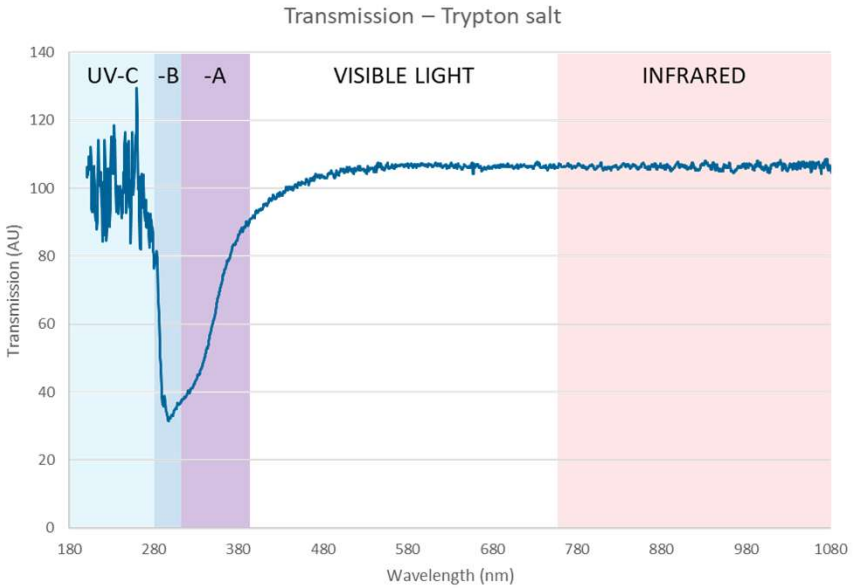
These diverse reference microorganisms provide comprehensive validation coverage across different resistance profiles and morphological characteristics. Each species represents specific challenges that UV systems must overcome, ensuring robust validation protocols that address real-world contamination scenarios in pharmaceutical and industrial environments.

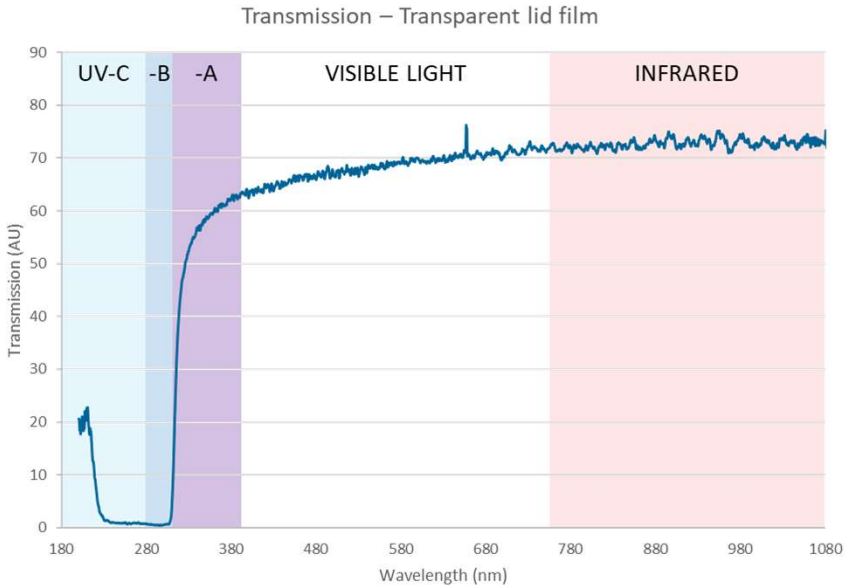






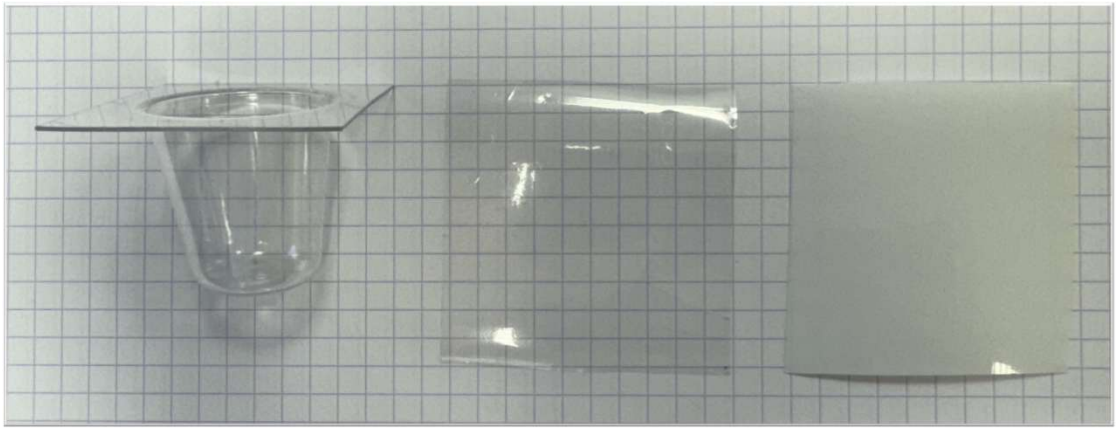
Transmission of liquid and material





- **Critical Finding:** The study demonstrated that transparent film allows almost no transmission in the tested light spectrum, especially UV wavelengths. As a result, it cannot reduce bacterial contamination, and TS liquid cannot be effectively decontaminated through this film barrier.

Materials decontamination study



Comprehensive materials decontamination studies evaluate the effectiveness of UV technologies across diverse substrate types and surface characteristics.

These investigations provide critical data for optimizing treatment parameters and ensuring consistent decontamination performance across different material compositions, surface roughness levels, and geometric configurations encountered in real-world applications.

Materials decontamination – Laborobot study in 2023

Films		Treatment	CFU/sample*	Average CFU/sample*	Log CFU/sample*	Reduction Log	Reduction %
White film	Control	Ø	3,55E+04 3,33E+04 5,18E+04	4,02E+04	**4,6**		
	UV LED 6s	15 mm	1,09E+01 1,09E+0,1 8,18E+00	9,99E+00	1,0	3,6	99,98%
Transparent rigid cups	Control	Ø	5,84E+04 6,35E+04 4,45E+04	5,55E+04	**4,7**		
	UV LED 6s	15 mm	8,18E+00 1,09E+01 1,09E+01	9,99E+00	1,0	3,7	99,98%
Transparent lid	Control	Ø	4,36E+04 4,55E+04 3,74E+04	4,22E+04	**4,6**		
	UV LED 6s	15 mm	2,12E+00 2,12E+00 2,73E+01	1,05E+01	1,0	3,6	99,98%

		Treatment	CFU/sample*	Average CFU/sample*	Log CFU/sample*	Reduction Log	Reduction %
Transparent opercule	Control	Ø	3,57E+04 3,52E+04 2,18E+04	3,09E+04	**4,5**		
	Pulsed light 10 mm	1F	2,12E+00 2,12E+00 2,12E+00	2,12E+00	0,3	>4,2	100%
		2F	2,12E+00 2,12E+00 2,12E+00	2,12E+00	0,3	>4,2	100%

Liquid Decontamination and Impact

Trypton-Salt	Treatment	CFU/cup*	Average CFU/cup*	Log CFU/cup*	Reduction Log	Reduction %
Control	Ø	5,65E+03 4,45E+03 5,37E+03	5,15E+03	**3,7**		
LED-UV 6s	10 mm	2,65E+03 2,48E+03 2,97E+03	2,70E+03	3,4	**0,3**	48%
	15 mm	2,65E+03 2,51E+03 3,90E+03	3,02E+03	3,5	**0,2**	41%

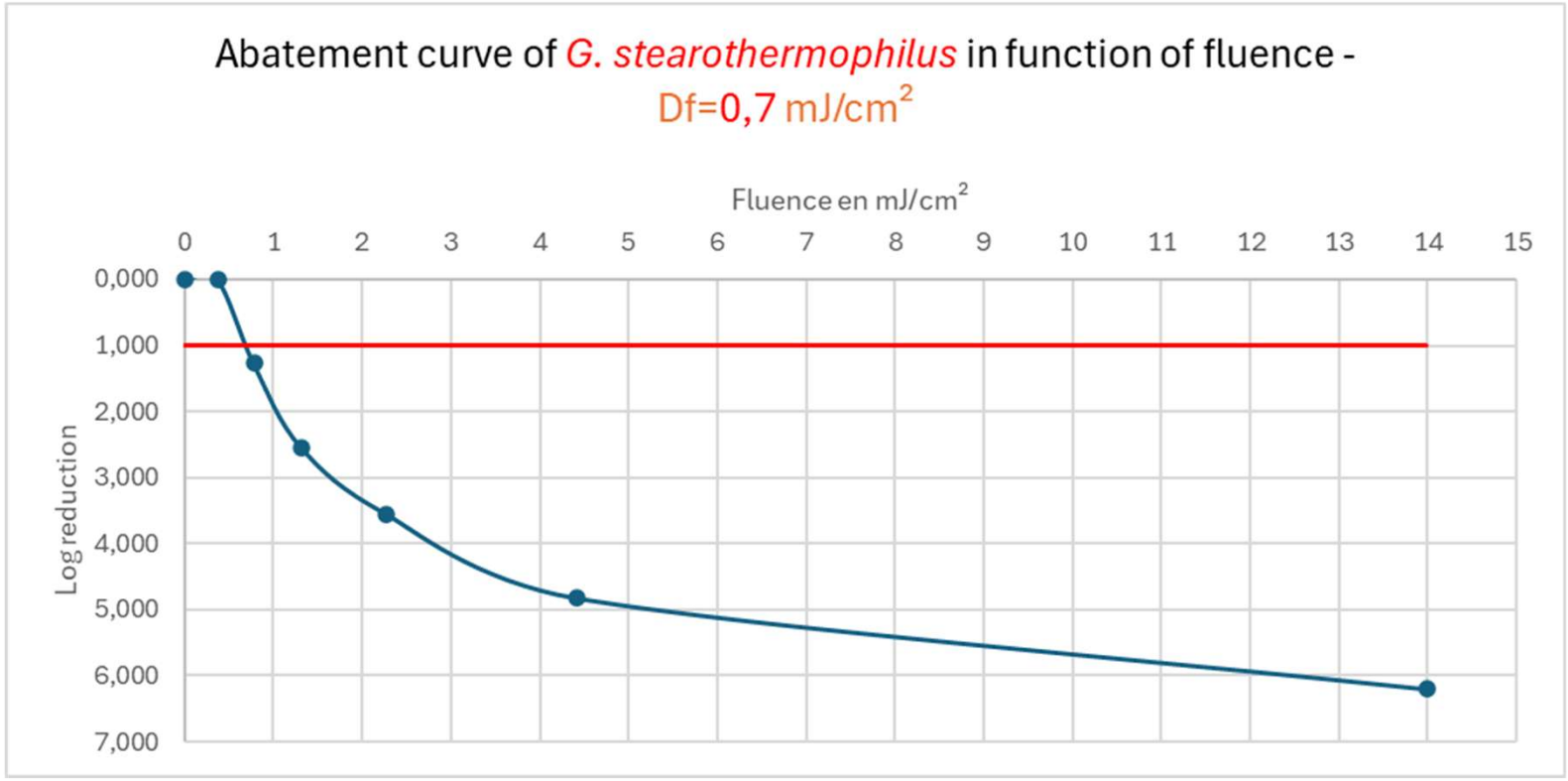
Penetration Analysis

UV light penetration depth and effectiveness in liquid media varies significantly based on optical properties and contamination levels.

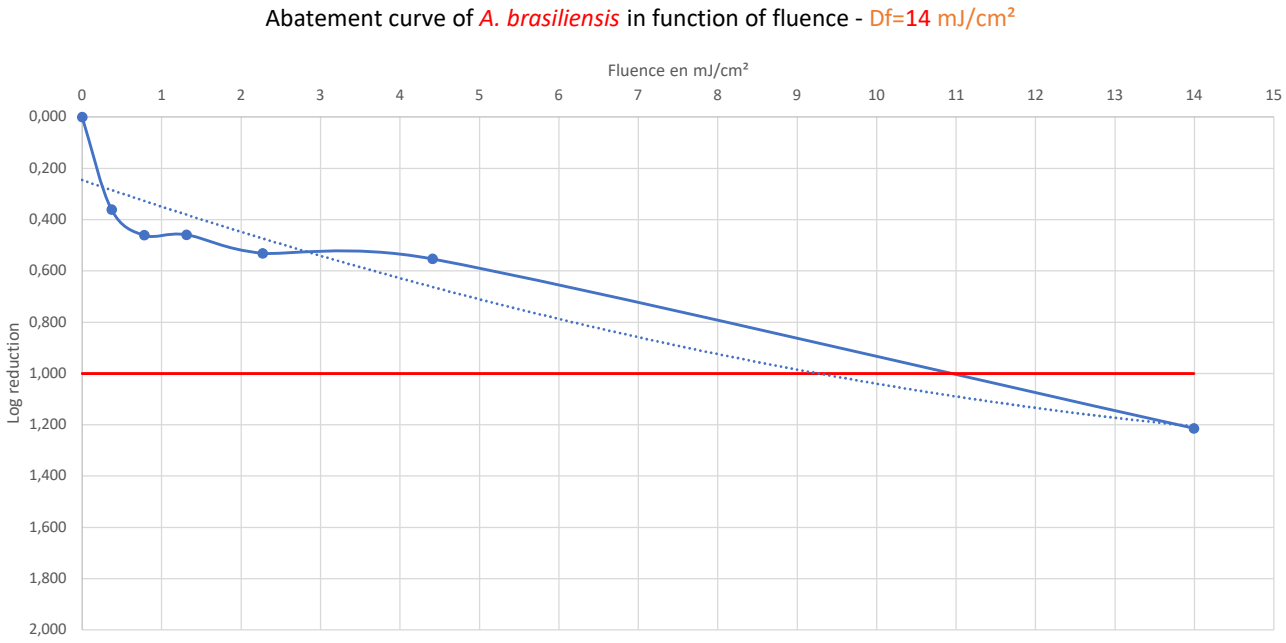
Results

There is no decontamination because of the absorption of the film.
But no impact on liquid.

New decontamination results in 2025 with UV LED *Geobacillus stearothermophillus* (treatment – 2s)



New decontamination results in 2025 with UV LED *Aspergillus brasiliensis* (treatment – 2s)



To conclude : Advantages of UV LED

Compact Design

Their **small size** enables integration into space-constrained environments and mobile applications.

Mercury-Free Operation

The absence of mercury eliminates environmental hazards and simplifies disposal procedures.

Precise Wavelength Control

The ability to target **specific wavelengths** (265–280 nm for DNA) optimizes germicidal effectiveness.

Instant Response

Instant on/off capability eliminates warm-up time and enables precise control.

Easy Integration

Simple integration into mobile and connected devices for automated systems.

Continuous Evolution

Ongoing technological advancement steadily improves decontamination performance and efficiency.

UV LED vs Ionization

Feature	Ionization ⚡	UV LED 💡
Mode of Action	☢️ Radioactive / chemical sources	🎯 Targeted UV-C light
Decontamination Location	🚚 Off-site, requires transport	🏭 On-site, direct in cleanroom
Effect on Product	🟡 TS liquid turns yellow	✅ No color change, preserves quality
Operational Complexity	⚙️ Complex handling, regulatory restrictions	🤖 Easy to operate, programmable
Environmental & Safety Impact	♻️ Radioactive/chemical waste	🌱 No hazardous waste, mercury-free
Integration in Production	⏳ Batch processing	🔄 Can be integrated in-line, automated
Energy & Maintenance	💡 High operational cost, safety checks	⚡ Low energy, long lifetime, low maintenance
Regulatory & Compliance	📑 Heavily regulated, transport licenses	✅ Standard electrical device, pharma cleanroom compatible

Summary: UV LED enables on-site decontamination avoiding logistics and transport risks, prevents yellowing or degradation of TS liquid unlike ionization, offers environmentally friendly & energy-efficient operation with strong CSR advantages, and is fully compatible with cleanrooms and automated production lines.

Application Sectors of UV LED












UV decontamination technology finds application across diverse industries, including pharmaceuticals, food processing, beverage production, medical devices, cosmetics, and packaging. Each sector benefits from specialized implementation of pulsed light and other UV technologies to address unique contamination challenges.

Pharmaceuticals

Critical surface decontamination for clean rooms, packaging, and production equipment.

Food Processing

Pathogen reduction on packaging materials, conveyor systems, and product surfaces.

Tourism

Prevention and reduction of conveyor contamination during production, of lugages contamination or virtual reality mask.

Application Sectors - Regulatory & Testing Frameworks

Reference Germs

- ***Bacillus atrophaeus spores*** — Reference indicator in dry heat/UV sterilization (packaging, cleanrooms)
- ***Aspergillus brasiliensis conidia*** — Tests surface effectiveness against fungi (packaging, cosmetics)
- ***Geobacillus stearothermophilus spores*** — Standard indicator for moist heat and UV validation
- ***Bacillus pumilus*** — Standard indicator for ionization

Standards

- **EN 62471** — Photobiological safety of UV sources
- **ISO 15858** — UV-C safety guidelines for occupied spaces
- **EN 61010** — Safety of electrical laboratory equipment
- Machinery Regulation (EU) 2023/1230
- Low Voltage Directive (2014/35/EU)
- EMC Directive (2014/30/EU)

R&D Protocols

- **Microbiological testing** — Assessing reduction of target pathogens
- **Neoformed compound analysis** — Monitoring potentially harmful by-products
- **Organoleptic testing** — Evaluating impact on taste, texture, or appearance

For each sector, it's essential to understand the applicable regulations and to stay up to date with changes depending on the country and specific application requirements.

Swedish System Standards and Regulations

Authority / Source	Domain	Regulation / Recommendation	Application / Notes
Strålsäkerhetsmyndigheten (SSM)	Radiation protection	All UV-C exposure must respect dose limits for skin and eyes; interlocks and warning signage mandatory	Operator safety: warning signs, PPE, interlocks, ventilation if ozone is produced
Livsmedelsverket (Swedish Food Agency)	Food safety	UV-C can be used as a decontamination barrier within HACCP; assess chemical and organoleptic side effects	Apply on surfaces and equipment; ensure doses do not cause unwanted effects (taste alteration, toxic compounds)
ISO 15858:2016	UV-C technical standard	Minimum requirements for UV-C devices: interlocks, physical barriers, leakage tests	Mandatory for all industrial or laboratory UV-C equipment for decontamination
IEC/EN 62471	Photobiological safety	Photobiological risk classification; exposure limits for skin and eyes	Used to evaluate risk and select PPE
SS-EN 14255-1:2005	Exposure measurement	Methods for measuring and assessing artificial UV exposure in the workplace	Useful to document actual operator exposure doses
HACCP Best Practices	Food decontamination	Define microbiological targets (≥3–5 log), dose mapping, testing with biological indicators	Documentation required for traceability and process validation
Ozone management & ventilation	Health & safety	UV-C <240 nm can generate O_3; ventilation mandatory if ozone is produced	Monitoring and sensors recommended



EU Mercury Regulation Impact

The revised European Union Mercury Regulation represents a landmark shift toward environmental protection and sustainable technology adoption. This comprehensive regulatory framework eliminates mercury-containing technologies across multiple sectors, creating unprecedented opportunities for UV LED adoption.

1 — ## Immediate Impact

Dental amalgam ban effective January 1, 2025, with temporary derogations until June 30, 2026 for specific member states.

2 — ## Lamp Regulations

Mercury-containing lamps banned by December 31, 2025-2026, depending on lamp type, creating massive replacement market.

3 — ## Market Opportunity

UV LED technology positioned as primary mercury-free alternative for decontamination applications across all affected sectors.

Strategic Significance: This regulation accelerates the transition to UV LED technology, providing regulatory support for organizations investing in sustainable decontamination solutions.

Towards a Mercury-Free Environment – Revised Mercury Regulation



Objective:

- Protect people and the environment from toxic mercury
- Contribute to the EU's **Zero Pollution** and toxic-free ambitions

Key Measures:

- **Ban on dental amalgam use and export** from 1 January 2025
- Temporary derogation for some Member States until 30 June 2026
- Mercury-free dental fillings except for specific medical needs

Ban on certain mercury-containing lamps

Effective 31 December 2025 or 31 December 2026 depending on lamp type. Replaced by less toxic, energy-efficient alternatives (LEDs).

Next Steps:

- Regulation is **directly applicable in all EU Member States**
- Guidance on mercury emission abatement from crematoria by 31 December 2025

Context:

Mercury is **highly toxic**, harmful to humans and the environment. Regulation complements the 2017 Mercury Regulation covering the **entire mercury lifecycle**.

UV Exposure Limits: ISO 62471 Standard

Types of UV and Associated Risks

UV-C (200–280 nm)

High risk, eye and skin burns

UV-B (280–315 nm)

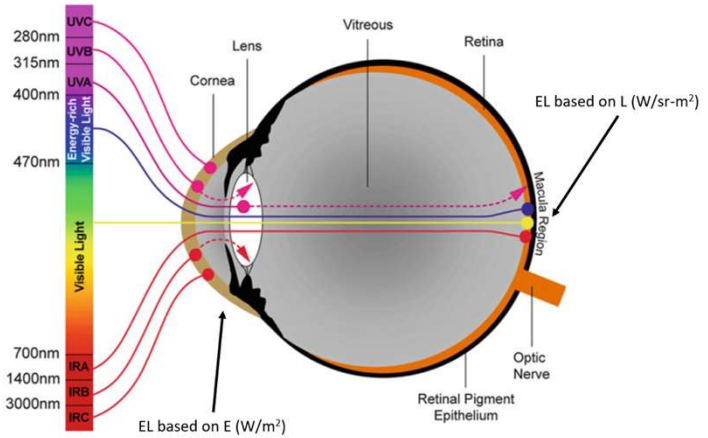
Moderate risk

UV-A (315–400 nm)

Long-term risks (phototoxicity, skin aging)

Key Exposure Limits

- **UV-C:** Maximum exposure dose of **30 J/m²** weighted over 8 hours
- Max permissible irradiance at 254 nm: ~0.001 W/m² (8h exposure)



Practical Implications

- Need for on-site exposure measurement
- Use of appropriate instruments: UV dosimeters, spectrometers
- Implementation of protective measures: PPE, shielding, training

Protecting Yourself from UV Exposure

Protection against Low-Pressure UV (254 nm) and UV LED (275 nm)

Typical sources: mono-wavelengths technologies



Protection:

- Standard safety glasses provide sufficient protection
- Laboratory safety goggles compliant with UV standards

Why? UV-C intensity is relatively low and continuous, so well-tested glass filters absorb effectively.

Protection against Pulsed UV and Medium-Pressure UV Lamps

Typical sources: multiwavelengths technologies



Protection:

- Glasses or goggles with **high UV protection index** (e.g., "Alpinist" type or equivalent)
- Materials designed to absorb higher intensity and broader UV spectrum, including UV-B and UV-A components

Why? Pulsed and medium-pressure UV have **higher peak intensities** and broader spectra, needing enhanced filtering and impact resistance.

General Protective Measures

(When you have a risk of overexposure during maintenance)

- Use **full-face shields** or barriers when exposure is unavoidable or intense
- Wear **protective clothing** covering exposed skin (lab coats, gloves)
- Implement **engineering controls** (enclosures, interlocks) to limit exposure time and direct contact
- Ensure **training and awareness** on UV hazards and correct use of PPE



The client who promises they didn't bypass the safety protections! :)

UV Light Decontamination:

Standards, Reference Microorganisms & Validation

Key Standards & Guidelines

- ISO 15714: Validation method for UV disinfection systems (mainly for water)
- EHEDG Guidelines: Hygienic design and UV decontamination best practices
- VDMA

Reference Microorganisms for Validation

- *Bacillus subtilis* spores (high UV resistance)
- Geobacillus stearothermophillus spores (high UV resistance and thermoresistant)
- Bacillus atrophaeus spores (high UV resistance)
- *Aspergillus brasiliensis* spores (fungal spores, highly resistant)



Some information about Dose measured in mJ/cm^2

⚠ Typical doses for 3-log (99.9%) reduction:

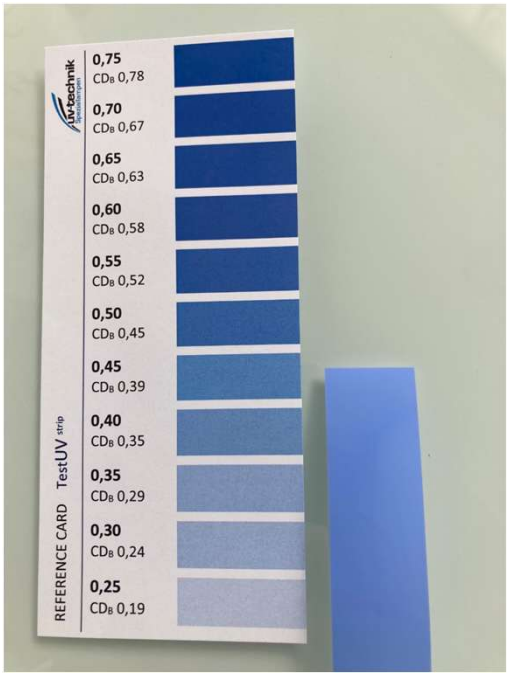
- *E. coli*: 10-20 mJ/cm^2
- *B. subtilis* spores: 40-60 mJ/cm^2
- *A. brasiliensis* spores: >100 mJ/cm^2

Validating UV Systems Using Colorimetric Indicators



What are colorimetric UV indicators?

- Strips or cards that change color based on UV dose received
- Provide a quick, visual confirmation of UV exposure



How to use them:

1. Place indicators at critical points in the UV system
2. Run the UV cycle
3. Compare color change to reference scale indicating dose levels

Advantages:

- Easy to use on-site
- Immediate feedback
- Non-biological, no lab needed

Validating UV Systems Using Biological Indicators

What are biological UV indicators?

- Microorganisms with known UV resistance (e.g., *Bacillus subtilis* spores)
- Serve as a "worst-case" challenge for UV disinfection

Validation process:

1. Inoculate test carriers with spores of molds or bacteries
2. Expose carriers to the UV system
3. Recover and culture microorganisms to assess survival
4. Calculate log reduction to confirm system efficacy

Advantages:

- Quantitative microbiological proof of disinfection
- Standard method recognized by regulatory agencies





Advantages of Sterixene's Patented UV Biological Indicators



Specialized Design

Custom-engineered specifically for UV validation applications, with optimal exposure surface and consistent microbial loading

Standardized Performance

Batch-to-batch consistency with certified population and resistance values for reliable validation protocols

Comprehensive Results

Provides quantifiable log reduction values that directly correspond to decontamination efficacy

Regulatory Compliance

Meets international standards for biological indicator performance and validation methodologies

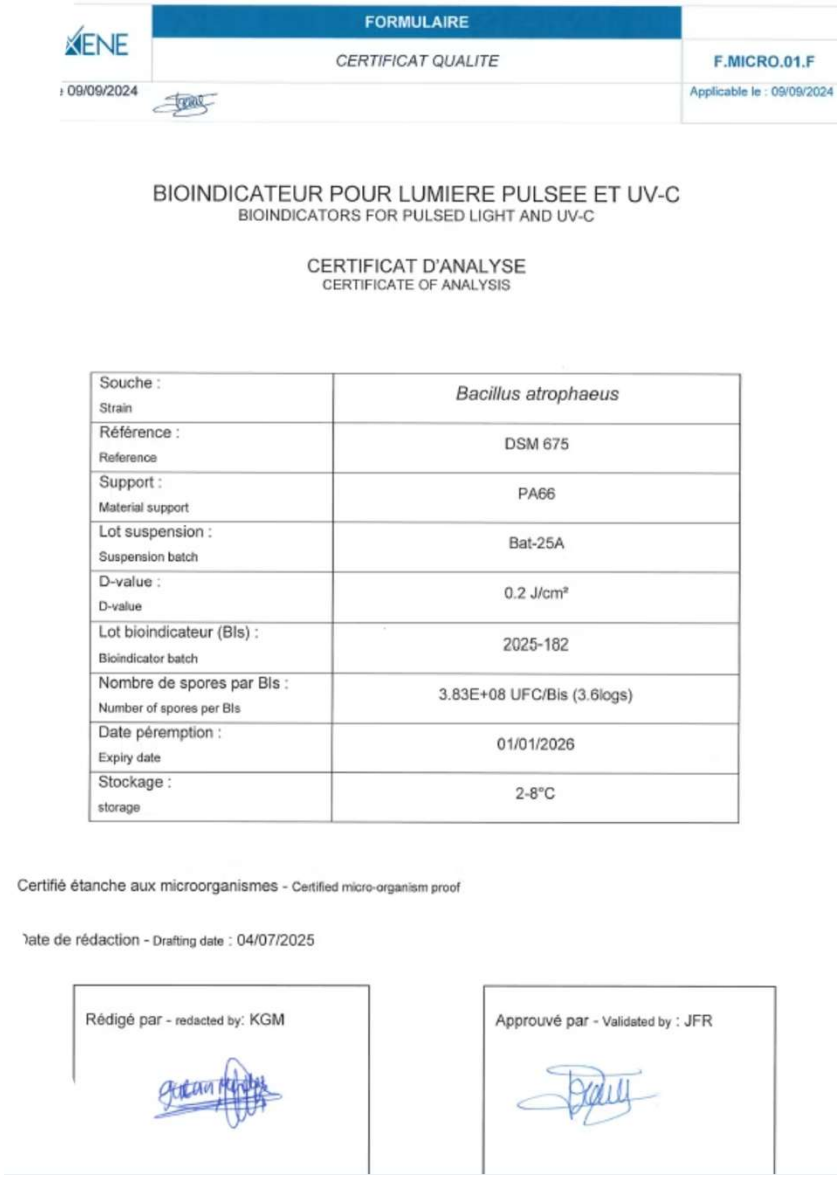
Adaptable System

Compatible with various UV technologies including pulsed light, low-pressure, and medium-pressure systems

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Example of Certificate

This certificate documents the quality and specifications of biological indicators, including population, D-value, and batch validation information required for regulatory compliance.



FORMULAIRE		
ENE	CERTIFICAT QUALITE	F.MICRO.01.F
: 09/09/2024		Applicable le : 09/09/2024

BIOINDICATEUR POUR LUMIERE PULSEE ET UV-C
BIOINDICATORS FOR PULSED LIGHT AND UV-C

CERTIFICAT D'ANALYSE
CERTIFICATE OF ANALYSIS

Souche : Strain	*Bacillus atrophaeus*
Référence : Reference	DSM 675
Support : Material support	PA66
Lot suspension : Suspension batch	Bat-25A
D-value : D-value	0.2 J/cm²
Lot bioindicateur (BIs) : Bioindicator batch	2025-182
Nombre de spores par BIs : Number of spores per BIs	3.83E+08 UFC/BIs (3.6logs)
Date péremption : Expiry date	01/01/2026
Stockage : storage	2-8°C

Certifié étanche aux microorganismes - Certified micro-organism proof

)ate de rédaction - Drafting date : 04/07/2025

Rédigé par - redacted by: KGM

Approuvé par - Validated by : JFR

Domazan, France – 18/07/2025

ANALYSIS REPORT UV DECONTAMINATION	[redacted]
Order number: CV25020001 Analysis date: 15/07/2025	Report intended to : Whom It May Concern

Samples :	Bioindicators germs placed on: PA66
Inoculation :	- *Bacillus subtilis* DSM 4181: spot of 100 µL at 4,6 log (3.85E+04UFC/BIs) concentration
Treatment :	Unknown
Observations :	Biological indicators were placed in a completely UV transparent ACLAR bag. This bag is hermetically sealed alowing risk-free handling of the indicator.

The reduction potential is calculated using the following equation (VDMA) :

$$Log\ reduction = LOG\ [((1/nber\ sample\ NT) * \Sigma\ nber\ UFC\ NT)] - LOG\ [((1/nber\ sample\ TT) * \Sigma\ nbre\ UFC\ TT)]$$

STERIXENE	FORMULAIRE	Ref.
	Analysis report	F.MICRO.12.A
Approved the : 08/09/2024		Applicable the : 09/09/2024

Results :

Treatment	UFC/BI	Mean UFC/BI	Log UFC/BI	Log reduction	% reduction
NT1	±8.55E+03				
NT2	±7.65E+03	±7.20E+03	3.86±0.10		
NT3	±5.40E+03				
A1	±3.00E+00		0.48±0.30	3.38±0.30	99.96%
A2	±0.00E+00		0.00±0.1	3.86±0.1	100.00%
A3	±0.00E+00		0.00±0.1	3.86±0.1	100.00%
B1	±3.00E+00		0.48±0.30	3.38±0.30	99.96%
B2	±3.00E+00		0.48±0.30	3.38±0.30	99.96%
B3	±0.00E+00		0.00±0.1	3.86±0.1	100.00%

Results marked in green indicate that no colonies were found, the measurement uncertainty is considered.

Example of Report

Video Demonstration

Video produced by one of our interns in 2023 @melissanougaret.



Equipment Validation Schedule

Annual Biological Validation

Validate equipment at least **once a year** using biological indicators

- Provides comprehensive efficacy assessment
- Measures actual microbial reduction
- Documents system performance for regulatory compliance

Quarterly Colorimetric Checks

Validate equipment **every 3 months** using colorimetric indicators

- Ensures consistent performance between biological validations
- Quickly identifies potential issues or performance degradation
- Provides visual documentation of system operation

Quality Manager Responsibility

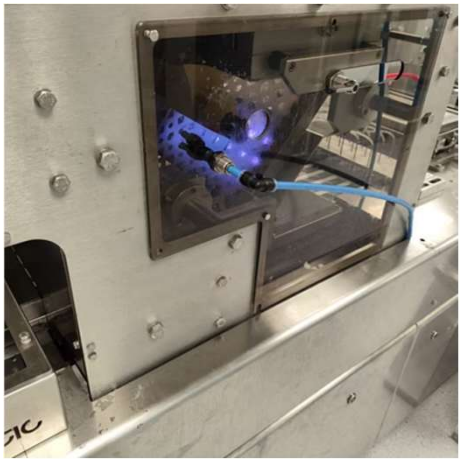
This responsibility belongs to the **Quality Manager**

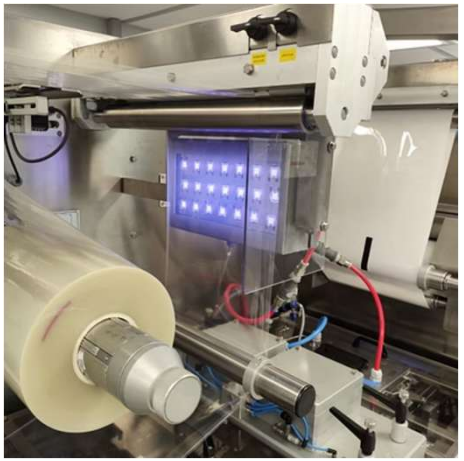
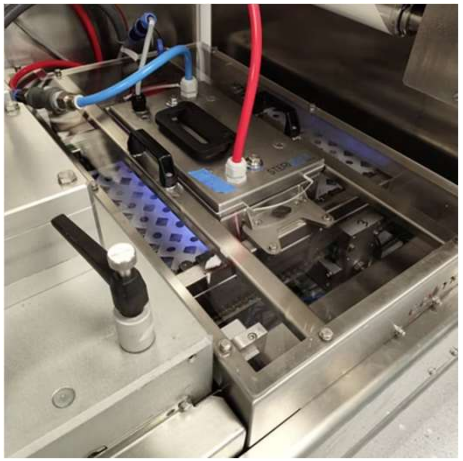
- Maintains validation records and documentation
- Ensures adherence to validation schedule
- Coordinates with maintenance team for corrective actions

Validation frequencies should be increased for critical applications, after system maintenance, or following any UV lamp replacement. Always follow industry-specific regulatory requirements which may mandate more frequent validation.



Machine Gallery





Thank You for Your Attention

Contact Information

j.franc@sterixene.com

+33 620173927

We appreciate your attention and interest in UV LED decontamination technology.

Let’s discuss!

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