# Validated, Certified, and Supported by Clinical Research

The UV Smart D25 disinfection system is the **first medically certified UV-C disinfection device** (with a class IIa CE marking) for non-invasive medical equipment.

The disinfection efficacy of the UV Smart D25 has been demonstrated and supported by numerous comprehensive studies conducted in clinical settings at academic medical centers (**University Medical Center Groningen**, **University Medical Center Amsterdam**, and **Radboud University Medical Center** in the Netherlands) and laboratories (**Eurofins** and **Streeklab Haarlem**, the Netherlands).

These comprehensive studies have shown that the UV Smart D25 is highly effective against the full spectrum of microorganisms, achieving at least log-4 reductions in microorganism counts in 25 seconds on the hard, nonporous surfaces of non-invasive medical devices. The UV Smart D25 was also able to achieve significant log reductions in methicillin-resistant **Staphylococcus aureus**, *Vancomycin-resistant enterococci* (*VRE*), the family of Coronaviruses, Norovirus, and Escherichia coli. However, UV-C technology has not been proven effective against prions, which are highly resistant proteins that cannot be disinfected by ordinary physical and chemical disinfection methods. They are therefore considered indestructible.

#### Medical requirement Results Source Microorganisms<sup>6,7</sup> (NEN-EN-14885:2018) UV Smart (surfaces and instruments) Staphylococcus aureus (ATCC 6538) ≥ Log 5 ≥ Log 6 Streeklab Haarlem Pseudomonas aeruginosa (ATCC 15442) ≥ Log 5 ≥ Log 6 Streeklab Haarlem Bactericidal Enterococcus hirae (ATCC 10541) \*\* ≥ Log 5 ≥ Log 6 Streeklab Haarlem Escherichia coli (ATCC 10536) ≥ Log 4 ≥ Log 7 Streeklab Haarlem Sporicidal Bacillus subtillis (ATCC 6633) \*\*\* ≥ Log 4 ≥ Log 6 Streeklab Haarlem Yeasticidal & Fungicidal Candida albicans (ATCC 10231) ≥ Log 4 ≥ Log 7 Streeklab Haarlem Fungicidal Aspergillus brasiliensis (ATCC 16404) Streeklab Haarlem ≥ Log 4 ≥ Log 6 Yeasticidal Candida auris (DSM 21092 Streeklab Haarlem ≥ Log 4 ≥ Log 7 Mycobactericidal Streeklab Haarlem Mycobacterium avium (ATCC 15769) ≥ Log 4 ≥ Log 7 Mycobactericidal & Mycobacterium terrae (ATCC 15755) Streeklab Haarlem ≥ Log 4 ≥ Log 7 Tuberculocidal Poliovirus type 1, LSc-2ab $\geq Log 4$ ≥ Log 4 Eurofins Biolab Srl\* Adenovirus Type 5, strain Adenoid 75 (ATCC VR-5) Eurofins Biolab Srl\* $\geq Log 4$ ≥ Log 4 Virucidal Bovine coronavirus type 1 ≥ Log 4 ≥ Log 4 Eurofins Biolab Srl\* Polyomavirus SV40, Stam 777 ≥ Log 4 ≥ Log 4 Eurofins Biolab Srl\* Murine Norovirus, strain S99 Berlin ≥ Log 4 ≥ Log 4 Eurofins Biolab Srl\*

This overview is merely for your information, the intended use shall always be leading.

#### Intended use

The UV Smart D25 is intended to reduce micro-organism count by at least log-4 on hard, non-porous outer surfaces of non-invasive medical devices.

Chart 1: Microbiological efficacy of UVC-disinfection with UV Smart D25

\* Tests not yet included in the intended use

\*\* Test done on Enterococcus faecium (ATCC12952)

\*\*\* Test done on Bacillus cereus (ATCC 12826)

### Log Reduction:

 I log reduction = 99,99% fatality (1 in 10.000 survives)

 <sup>5</sup> log reduction = 99,999% fatality (1 in 100.000 survives)

 <sup>6</sup> log reduction = 99,9999% fatality (1 in 1.000.000 survives)

 <sup>7</sup> log reduction = 99,9999% fatality (1 in 10.000.000 survives)

## **UV Smart D25 Microbiological Efficacy Chart**