UNDERSTANDING EN 14885:2018

APPLICATION OF EUROPEAN STANDARDS FOR CHEMICAL DISINFECTANTS AND ANTISEPTICS

All disinfectants must undergo vigorous testing regimes before being put onto the market as stipulated by governing bodies worldwide.

EN 14885:2018 provides a framework for testing the activity of chemical disinfectants and antiseptics intended for use in human medicine, veterinary or food, industrial, domestic, and institutional areas for the European market. Standards within EN 14885:2018 may also be used to demonstrate efficacy in other countries where appropriate, for example, Australasia.

The standards referenced within EN 14885:2018 can support bactericidal, yeasticidal, fungicidal, virucidal, mycobactericidal, and sporicidal claims.

A disinfectant or antiseptic's efficacy claim is dependent on mandatory testing parameters such as microorganisms, contact time, interfering substance, and log reduction. An activity claim will only be successful if testing against all mandatory requirements as per the respective standard is achieved with the required log reduction and within the contact times allowed.

Tristel fuse for Stella, the high-level disinfection solution used within the Stella System, meets the requirements of instrument disinfectants for medical devices within EN 14885:2018 and the latest published regulatory standards, as detailed in Table 1.

TRISTEL FUSE FOR STELLA TICKS ALL THE BOXES:

- **Compliant with all EN standards** in the medical field for surface disinfection with mechanical action.
- Adherent to the requirement of **EN 17111:2018** the new simulated in use testing.
- Tristel Fuse for Stella is sporicidal, mycobactericidal, virucidal, fungicidal and bactericidal according to EN standards.
- **One universal contact time of five minutes,** with one concentration.

<table>
<tr><th>TYPE OF ACTIVITY</th><th>SPORICIDAL</th><th colspan="2">MYCOBACTERICIDAL / TUBERCULOCIDAL</th><th colspan="2">VIRUCIDAL</th><th colspan="2">FUNGICIDAL / YEASTICIDAL</th><th>BACTERICIDAL</th><th colspan="2">BACTERICIDAL</th></tr>
<tr><td>EN STANDARD</td><td>EN 17126*</td><td>EN 14348</td><td>EN 14563</td><td>EN 14476</td><td>EN 17111**</td><td>EN 13624</td><td>EN 14562</td><td>AOAC 955.17***</td><td>EN 13727</td><td>EN 14561</td></tr>
<tr><td>PHASE, STEP</td><td>2,1</td><td>2,1</td><td>2,2</td><td>2,1</td><td>2,2</td><td>2,1</td><td>2,2</td><td>N/A</td><td>2,1</td><td>2,2</td></tr>
<tr><td rowspan="3">REQUIRED MICROORGANISMS</td><td rowspan="3">Bacillus cereus
Bacillus subtilis</td><td colspan="2">Mycobacterium avium
Mycobacterium terrae</td><td>Poliovirus type 1
Adenovirus type 5
Murine Norovirus
(Full virucidal activity)</td><td>Murine Parvovirus
(Virucidal activity when temperature is ≥ 40◦C)</td><td colspan="2">Candida albicans
Aspergillus brasiliensis</td><td rowspan="3">Trichophyton interdigitale</td><td rowspan="3" colspan="2">Staphylococcus aureus
Pseudomonas aeruginosa
Enterococcus hirae</td></tr>
<tr><td rowspan="2" colspan="2">Mycobacterium terrae
(Tuberculocidal activity only)</td><td>Adenovirus type 5
Murine Norovirus
(Limited spectrum virucidal activity)</td><td>Adenovirus type 5
Murine Norovirus
(Virucidal activity when temperature is ‹ 40◦C)</td><td colspan="2" rowspan="2">Candida albicans
(Yeasticidal activity only)</td></tr>
<tr><td>Vaccinia virus
(Virucidal activity against enveloped viruses)</td><td>Vaccinia virus
(Virucidal activity against enveloped viruses)</td></tr>
<tr><td>REQUIRED LOG $_{10}$ REDUCTION</td><td colspan="7">≥4</td><td>No growth</td><td colspan="2">≥5</td></tr>
<tr><td rowspan="2">CONTACT TIME</td><td>≤ 60 mins</td><td colspan="2">5, 15, 30 or 60 mins</td><td colspan="2">≤ 60 mins</td><td>≤ 60 mins</td><td>5, 15, 30 or 60 mins</td><td>10 mins</td><td>≤ 60 mins</td><td>5, 15, 30 or 60 mins</td></tr>
<tr><td colspan="10">≤ 60 mins</td></tr>
</table>

*EN 17126:2018 is the first standard for the evaluation of sporicidal activity in the medical area. Compliance with this new test norm is mandatory by June 2020 to make sporicidal activity claims.
**To claim virucidal activity with EN 17111:2018, the product must pass EN 14476:2013+A2:2019 full virucidal activity with Poliovirus, Adenovirus and Murine Norovirus. Compliance with this new test norm is mandatory by April 2020 to make virucidal activity claims.
***Other harmonised standard, such as AOAC Official Method 995.17 Fungicidal Activity of Disinfectants, may be used to claim efficacy where appropriate.

Table 1. European regulatory compliance for surface disinfectants for medical devices used in the medical area with mechanical action, adapted from BS EN 14885:2018 and the latest regulatory efficacy standards published.

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