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 Duo ULT meets all the requirements of disinfectants for medical devices used with mechanical action within EN 14885:2018 and the latest published regulatory standards, as detailed in Table 1.

TRISTEL DUO ULT TICKS ALL THE BOXES:

- Compliant with all EN standards in the medical field for disinfection with mechanical action.
- Adherent to the requirement of less than 5/15 minutes contact time when used near patients and/or staff.
- Tristel Duo is sporicidal, mycobactericidal, virucidal, fungicidal and bactericidal according to EN standards.
- One universal contact time of 30 seconds, with one concentration. No dilution required.

Additional simulated use testing against HPV on medical devices has been performed with Tristel Duo ULT.

TYPE OF ACTIVITY	SPORICIDAL	MYCOBACTERICIDAL / TUBERCULOCIDAL		VIRUCIDAL	FUNGICIDAL/ YEASTICIDAL			BACTERICIDAL	
EN STANDARD	EN 17126*	EN 14348	EN 14563 **	EN 14476	EN 13624	EN 14562	EN 16615	EN 16615	EN 13727
PHASE, STEP	2,1	2,1	2,2	2,1	2,1	2,2	2,2	2,2	2,1
REQUIRED MICROORGANISMS	*Bacillus cereus* *Bacillus subtilis*	*Mycobacterium avium* *Mycobacterium terrae*		Poliovirus type 1 Adenovirus type 5 Murine Norovirus (Full virucidal activity)	*Candida albicans* *Aspergillus brasiliensis*			*Staphylococcus aureus* *Pseudomonas aeruginosa* *Enterococcus hirae*	
		Mycobacterium terrae (Tuberculocidal activity only)		Adenovirus type 5 Murine Norovirus (Limited spectrum virucidal activity)	*Candida albicans* (Yeasticidal activity only)				
				Vaccinia virus (Virucidal activity against enveloped viruses)					
REQUIRED LOG $_{10}$ REDUCTION	≥4						≥4 (f1) ≤50 cfu/25cm² (f2 to f4)	≥5 (f1)	≥5
CONTACT TIME	≤ 15 MINS FOR MEDICAL DEVICES USED NEAR PATIENT AND/OR STAFF	≤ 5 MINS FOR MEDICAL DEVICES USED NEAR PATIENT AND/OR STAFF							
	≤ 60 MINS FOR MEDICAL DEVICES NOT USED NEAR PATIENT AND/OR STAFF								

*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.
**According to EN 14885:2018, where no specific activity in an area exists (i.e. no mycobactericidal activity test norm in the medical area for disinfectants used with mechanical action) another standard may be used.

Table 1. European regulatory compliance for 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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