

## OVERVIEW

All disinfectants **must** undergo rigorous testing regimes before commercial use, as stipulated by governing bodies worldwide.

**EN 14885** provides a framework for testing the antimicrobial activity of chemical disinfectants and antiseptics.

The test methods listed within **EN 14885** cover bactericidal, yeasticidal, fungicidal, virucidal, mycobactericidal, and sporicidal claims.

The standards within EN 14885 are categorised into different phases of testing:

- Phase 2, Step 1 (2,1): Suspension tests to establish a product's efficacy appropriate to its intended use.
- Phase 2, Step 2 (2,2): Surface/Carrier tests to establish a product's efficacy when applied to a surface under practical conditions (e.g., surface, instrument).

EN 14885 defines Surface Disinfection as the chemical disinfection of a solid surface, including those of certain medical and veterinary instruments which cannot be immersed, by the application of a product with or without mechanical action.

## SUSPENSION TESTS - PHASE 2, STEP 1

- The microorganism and desired soiling (i.e., simulating clean or dirty conditions) are added to a test tube.
- The disinfectant solution is added to the test tube and neutralised after a specified time (contact time).

### DID YOU KNOW?

**EN 17126** is the first standard for evaluating the sporicidal activity of a chemical disinfectant in the **medical area**. Sporocidal claims following **EN 13704** are no longer valid for products used in the medical area. **Tristel Duo ULT**, **Tristel Duo OPH** and **Tristel Sporocidal Wipe (part of the Tristel Trio Wipes System)** are sporicidal according to **EN 17126**.

## SURFACE TESTS WITHOUT MECHANICAL ACTION - PHASE 2, STEP 2

- The microorganisms and interfering substance are dried onto a carrier.
- The disinfectant is then applied directly onto the carrier to simulate its application directly onto a surface without wiping or mopping.
- The disinfectant is neutralised after the contact time.

### DID YOU KNOW?

This type of test is performed without mechanical action and relies solely on the antimicrobial activity of the disinfectant.

**EN 16777** is the only virucidal surface test for surface disinfectants applied without mechanical action. When claiming virucidal activity with **EN 16777**, the product **must** also have **EN 14476** virucidal activity with Poliovirus, Adenovirus and Murine Norovirus.

## SURFACE TESTS WITH MECHANICAL ACTION - PHASE 2, STEP 2

This test concept determines if microorganisms are killed or transferred from one area to another when mechanical action (wiping) is applied.

- Considers the effect of wiping or mopping.
- Evaluates activity against bacteria and yeast.
- For disinfectants applied to surfaces (including medical devices) in the **medical area**.

Relates to:

- Ready-to-use impregnated wipes (e.g., Tristel Sporocidal Wipe).
- Disinfectants that are applied with a wipe or mop (e.g., Cache Collection).

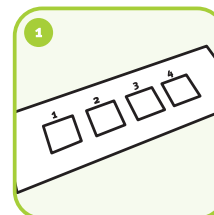


### DID YOU KNOW?

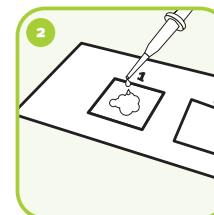
When attached to a surface, microorganisms are often less susceptible to disinfectant action. Therefore, surface tests are generally more difficult to pass than suspension tests.

**EN 16615** is the first standard for evaluating bactericidal and yeasticidal activity using mechanical action in the medical area.

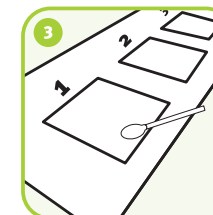
**Tristel Duo ULT**, **Tristel Duo OPH** and **Tristel Sporocidal Wipe (part of the Tristel Trio Wipes System)** are bactericidal and yeasticidal following **EN 16615**.



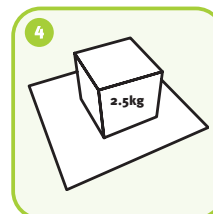
A vinyl test area is prepared, replicating the surface to be disinfected.



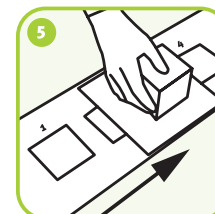
The first field is inoculated with a measured amount of the microorganism to be tested.



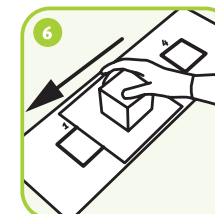
The microorganisms are dispersed evenly over the first test field and the surface is left to dry.



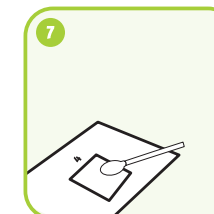
A 2.5kg block is placed on top of the test wipe pre-soaked with the disinfectant to simulate the physical downward force of a person wiping a surface.



The block is pushed from the side in a smooth, one second, motion across the whole test area.



This wiping motion is then reversed, with the block and wipe pushed back over all four fields in another smooth one second motion.



After the requested contact time, all four fields are swab tested to measure the presence and level of the test microorganism.

# UNDERSTANDING EN 14885 – Surface Disinfectants (including the surface of medical devices) in the Medical Area Test Standards

**Table 1. UK & European Regulatory Compliance for Surface Disinfectants Applied with Mechanical Action Used in the Medical Area.**

Activity	SPORICIDAL	MYCOBACTERICIDAL / TUBERCULOCIDAL	VIRUCIDAL	FUNGICIDAL	YEASTICIDAL		BACTERICIDAL	
EN Standard	EN 17126	EN 14348	EN 14476	EN 13624		EN 16615	EN 13727	
Phase, Step	2,1	2,1	2,1	2,1	2,1	2,2	2,1	
Test Type	Suspension	Suspension	Suspension	Suspension		Surface with mechanical action	Suspension	
Test Microorganism	<i>Bacillus cereus</i> <i>Bacillus subtilis</i>	<i>Mycobacterium avium</i> <i>Mycobacterium terrae</i>	Poliovirus type 1 Adenovirus type 5 Murine Norovirus	<i>Candida albicans</i> <i>Aspergillus brasiliensis</i>	<i>Candida albicans</i>		<i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Enterococcus hirae</i>	<i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Enterococcus hirae</i>
Minimum Required Log <sup>10</sup> Reduction	≥4	≥4	≥4	≥4	≥4	≥4 ≥5	≥5	
Interfering Substance	<b>CLEAN:</b> 0.3 g/l Bovine albumin <b>and/or DIRTY:</b> 3.0 g/l bovine albumin + 3.0 ml/l sheep erythrocytes							
Contact Time	≤ 15 mins for surfaces near patients and staff	≤ 5 mins for surfaces near patients and staff						
		≤ 60 mins for other surfaces						

Source: Adapted from BS EN 14885 and the latest efficacy standards published for surface disinfectants.

\*Efficacy claims against *Clostridioides difficile* require test data against that specific spore as *C. difficile* efficacy claims are not substantiated using sporicidal activity against the *Bacillus spp.*

# UNDERSTANDING EN 14885 – Surface Disinfectants (including the surface of medical devices) in the Medical Area Test Standards

**Table 2. UK & European Regulatory Compliance for Surface Disinfectants Applied WITHOUT Mechanical Action Used in the Medical Area.**

Activity	SPORICIDAL	MYCOBACTERICIDAL / TUBERCULOCIDAL	VIRUCIDAL		FUNGICIDAL/YEASTICIDAL		BACTERICIDAL	
EN Standard	EN 17126	EN 14348	EN 14476	EN 16777	EN 13624	EN 17387**		EN 13727
Phase, Step	2,1	2,1	2,1	2,2	2,1	2,2		2.1
Test Type	Suspension	Suspension	Suspension	Surface	Suspension	Surface		Suspension
Test Microorganism	<i>Bacillus cereus</i> <i>Bacillus subtilis</i>	<i>Mycobacterium avium</i> <i>Mycobacterium terrae</i>	Poliovirus type 1 Adenovirus type 5 Murine Norovirus	Adenovirus type 5 Murine Norovirus	<i>Candida albicans</i> <i>Aspergillus brasiliensis</i>		<i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Enterococcus hirae</i>	<i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Enterococcus hirae</i>
	<i>Clostridioides difficile</i> *	<i>Mycobacterium terrae</i> <b>(Tuberculocidal activity only)</b>			<i>Candida albicans</i> <b>(Yeasticidal activity only)</b>			
Minimum Required Log <sup>10</sup> Reduction	≥4	≥4	≥4	≥4	≥4	≥4	≥5	≥5
Interfering Substance	<b>CLEAN:</b> 0.3 g/l Bovine albumin <b>and/or DIRTY:</b> 3.0 g/l bovine albumin + 3.0 ml/l sheep erythrocytes							
Contact Time	≤ 5 mins for surfaces near patients and staff							
	≤ 15 mins for surfaces near patients and staff	≤ 60 mins for other surfaces						

Source: Adapted from BS EN 14885 and the latest efficacy standards published for surface disinfectants.

\*Efficacy claims against *Clostridioides difficile* require test data against that specific spore as *C. difficile* efficacy claims are not substantiated using sporicidal activity against the *Bacillus spp.*

\*\*EN 17387 is the first standard for the evaluation of bactericidal and fungicidal/yeasticidal activity in the medical area for disinfectants applied without mechanical action. Bactericidal and fungicidal/yeasticidal activity following EN 13697 is no longer valid for products used in the medical area.