

# European standards for ensuring the sporicidal efficacy of surface disinfectants

## Understanding how to demonstrate compliance in the medical area

Published in 2023 to strengthen the existing EN 17126 framework, EN 17846 is a European standard used to validate sporicidal efficacy claims against *Clostridioides difficile* (*C. diff*) for surface disinfectants and pre-soaked wipes used with mechanical action (wiping) in the medical area.

Given the link between *C. difficile* and healthcare-associated infections, EN 17846 completes the sporicidal framework by enabling full Phase 2 evaluation on non-porous surfaces with mechanical action, ensuring disinfectant performance is demonstrated under conditions representative of clinical use.

## EN sporicidal standards in the medical area

EN standards apply to surface disinfectants and ready-to-use wipes pre-soaked with disinfectant. It is organised into phases and steps, each addressing a different level of evidence:

- × **EN 17126 (Phase 2, Step 1): suspension tests.**  
Demonstrate intrinsic sporicidal activity under controlled laboratory conditions.
- × **EN 17846 (Phase 2, Step 2): practical tests.**  
Demonstrate efficacy under conditions that simulate real-life use, including surface type, organic soil, contact time, and mechanical action.

To be compliant with sporicidal requirements in the medical area, products must demonstrate a minimum 4 log<sub>10</sub> reduction in spores using defined test organisms. Both tests must be performed successfully to claim efficacy for *C. difficile*.

## EN 17126 (PHASE 2, STEP 1) suspension tests

EN 17126 (Phase 2, Step 1) evaluates the intrinsic sporicidal activity of a disinfectant under controlled laboratory conditions. The test is performed in suspension, without surfaces or mechanical action, and applies to products intended for surface disinfection, instrumentation, and linen.

Testing is conducted using three defined spore-forming organisms, depending on the claim being made:

× ***Bacillus subtilis***:

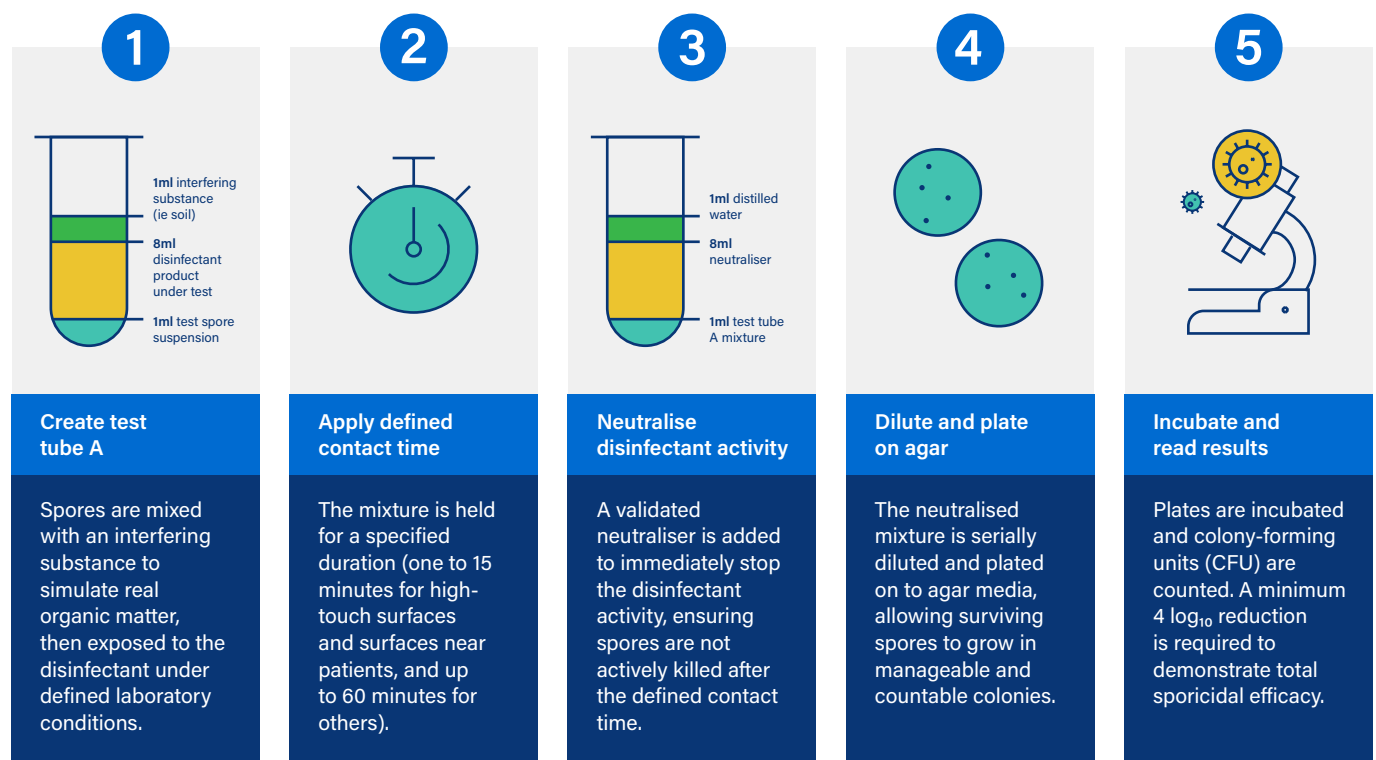
an aerobic, Gram-positive bacterium commonly found in the environment and the human gut. It is considered to be of minimal virulence and is used as a surrogate organism to demonstrate general sporicidal activity.

× ***Bacillus cereus***:

another aerobic, Gram-positive bacterium, more rarely described as a surface and food contaminant but still associated with infections in vulnerable populations such as newborns and elderly people.

× ***C. difficile***:

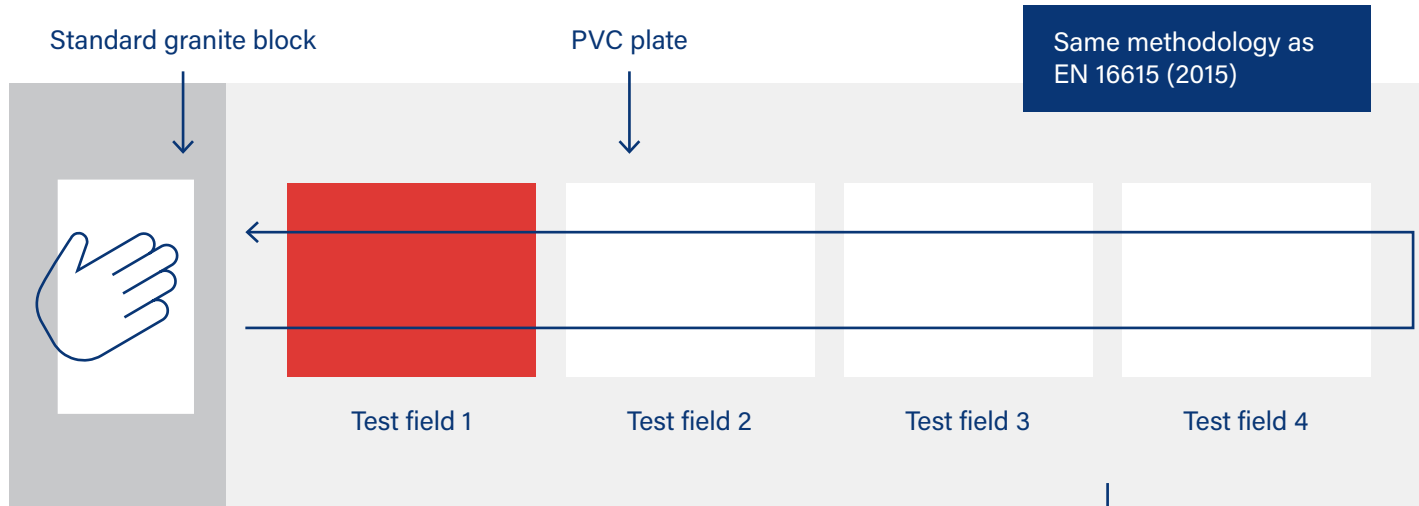
a strictly anaerobic, life-threatening pathogen and a leading cause of healthcare-associated infections, making it particularly relevant for substantiating sporicidal claims for surface disinfectants used in the medical area.



## EN 17846 (PHASE 2, STEP 2) practical steps

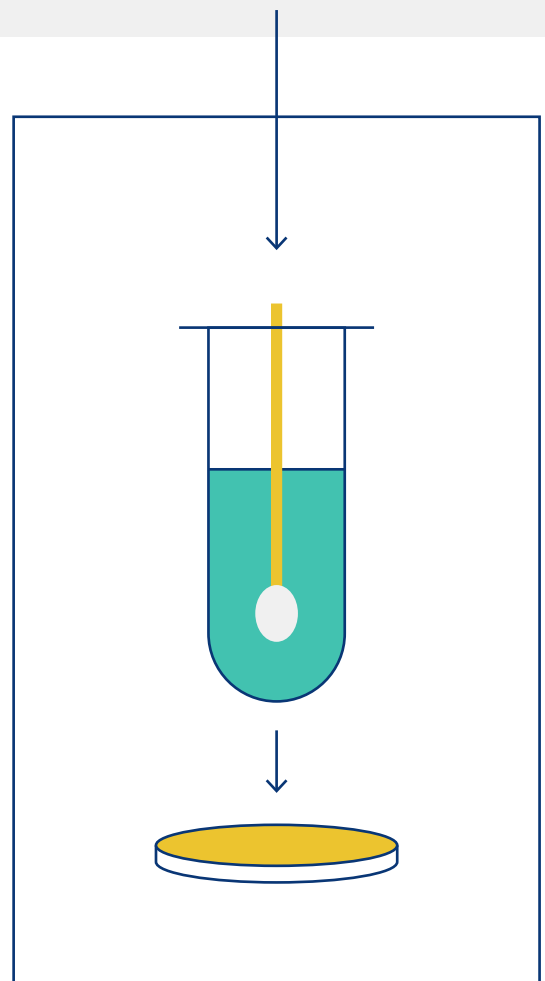
EN 17846 (Phase 2, Step 2) evaluates sporicidal efficacy under conditions representative of real clinical surface disinfection. Unlike suspension testing, this four-field method takes into account mechanical action, surface type, and product application, reflecting how disinfectants and pre-soaked wipes are used in the medical area.

The test is mandatory for surface disinfectants and ready-to-use wipes intended to be applied with mechanical action (wiping) and making sporicidal or sporicidal against *C. diff* claims.



1. A contaminated suspension containing spores of *C. diff* (mirroring EN 17126 spore production methodology for consistency) is placed on test field one and left to dry.
2. The wipe under test is moved across the surface from field one to four under a unitary force (granite block), without applying additional pressure to ensure reproducibility.
3. After the defined contact time (between one and 15 minutes for high-touch surfaces and surfaces near patients, and up to 60 minutes for other surfaces), each test field is sampled using cotton swabs soaked in a neutraliser.
4. Following neutralisation, 1ml of the recovered mixture is diluted, plated on agar, incubated, and colonies are enumerated to determine the number of surviving spores.

To demonstrate full sporicidal efficacy, test field one must achieve  $\geq 4 \log_{10}$  reduction in spores, while test fields 2–4 must achieve a mean of  $\leq 50$  CFU, confirming control of spore transfer during wiping.



# Product for surface (with wiping)

Surface (with wiping)	Concentrated Products	Spray Products	Ready to use/ Pre-impregnated wipes/Mops
 Reference Wipes from the standard	 Impregnation 16ml		
 Mop or wipe unspecified	 Soak in the amount of diluted solution recommended by the manufacturer		
 Pre impregnated wipes/mops			

## At-a-glance summary

### General sporicidal claim

Demonstrated using the EN 17126 (Phase 2, Step 1) suspension test with aerobic spore-forming organisms (*Bacillus subtilis* and *Bacillus cereus*), applicable to surface disinfectants with or without wiping, as no Phase 2, Step 2 practical surface standard exists for general sporicidal activity.

### Sporicidal against *C. diff* claim

Demonstrated using both EN 17126 (Phase 2, Step 1) suspension testing and EN 17846 (Phase 2, Step 2) practical surface testing, confirming sporicidal efficacy against *C. difficile* on non-porous surfaces applied with mechanical action (wiping) in the medical area.