

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 various 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 purpose of EN 14885:2018 is to:

- ✓ enable the selection of appropriate standards by the disinfectant manufacturer in respect to the claims they wish to make.
- ✓ enable end-user assessment on the product information provided by the manufacturer.
- ✓ assist regulatory authorities in the assessment of claims made by the manufacturer for the product on the market.

The standards within EN 14885:2018 are categorised into different phases/steps of testing. Phases of relevance are:

- **Phase 2, step 1 tests (2,1):** these are quantitative suspension tests that establish a product's activity under simulated practical conditions.
- **Phase 2, step 2 tests (2,2):** these are quantitative laboratory tests that establish a product's activity when applied to inanimate surfaces or skin under simulated practical conditions (e.g. surface, insto-prument, handwash and hand rub tests).

The different phases of testing are used in combination to support efficacy claims for disinfectants.

The product efficacy claims are dependent on mandatory parameters such as *:

- **Microorganisms:** The microorganism species, chosen by scientists for testing under each regulatory standard within EN 14885:2018, are representative of the most resistant microorganisms to disinfectants in the medical area. Efficacy against these mandatory organisms infers efficacy against species of non-tested microorganisms, including emerging pathogens. For example, efficacy against mandatory viruses Poliovirus T1, Adenovirus T5 and Murine Norovirus in accordance with EN 14476:2013 + A2:2019 infers virucidal activity against other enveloped and non-enveloped viruses.
- **Contact Time:** The product contact time for each claim, is governed by the time it takes the product to inactivate or kill the mandatory microorganisms. However, the standards within EN 14885:2018 do stipulate expected efficacy contact times. Refer to table for specific norm contact time information.
- **Interfering Substance:** This refers to soiling conditions of surfaces expected within the field. Within the medical area, it is categorised as "clean conditions" (surfaces cleaned satisfactorily or are known to have minimal levels of organic and inorganic substances) or "dirty conditions" (surfaces known to or may contain organic and inorganic substances). This parameter is used to determine if a disinfectant claim regarding pre-cleaning (the removal of visible heavy soiling before disinfection) is necessary. I.e. If the product is tested in clean conditions only, then pre cleaning is necessary.
- **Log Reductions:** This is the reduction of the microorganism(s) stipulated [and any additional microorganisms tested]. A product which fails to meet these mandatory log reductions cannot make a claim against the specific activity tested for.

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.

* NB. Information above is specific to the medical area.

TYPE OF ACTIVITY	MYCOBACTERICIDAL / TUBERCULOCIDAL			VIRUCIDAL			FUNGICIDAL / YEASTICIDAL		BACTERICIDAL	
	SPORICIDAL	EN 14348	EN 14563	EN 14476	EN 17111**	EN 16777***	EN 13624	EN 14562	EN 13727	EN 14561
EN STANDARD	EN 17126*	EN 14348	EN 14563	EN 14476	EN 17111**	EN 16777***	EN 13624	EN 14562	EN 13727	EN 14561
PHASE, STEP	2,1	2,1	2,2	2,1	2,2	2,2	2,1	2,2	2,1	2,2
REQUIRED MICROORGANISMS	<i>Bacillus cereus</i> <i>Bacillus subtilis</i>	<i>Mycobacterium avium</i> <i>Mycobacterium terrae</i>		Poliovirus type 1 Adenovirus type 5 Murine Norovirus (Full virucidal activity)	Murine Parvovirus (Virucidal activity when temperature is $\geq 40^{\circ}\text{C}$)	Adenovirus type 5 Murine Norovirus (Virucidal activity)	<i>Candida albicans</i> <i>Aspergillus brasiliensis</i>			<i>Staphylococcus aureus</i> <i>Pseudomonas aeruginosa</i> <i>Enterococcus hirae</i>
				Adenovirus type 5 Murine Norovirus (Limited spectrum virucidal activity)	Adenovirus type 5 Murine Norovirus (Virucidal activity when temperature is $\geq 40^{\circ}\text{C}$)	Adenovirus type 5 Murine Norovirus (Limited spectrum virucidal activity)				
		<i>Mycobacterium terrae</i> (Tuberculocidal activity only)		Vaccinia virus (Virucidal activity against enveloped viruses)	Vaccinia virus (Virucidal activity against enveloped viruses)	Vaccinia virus (Virucidal activity against enveloped viruses)	<i>Candida albicans</i> (Yeasticidal activity only)			
REQUIRED LOG ₁₀ REDUCTION	≥ 4								≥ 5	
CONTACT TIME	≤ 60 mins	5, 15, 30 or 60 mins		≤ 60 mins	5 or 60 mins		≤ 60 mins	5, 15, 30 or 60 mins	≤ 60 mins	5, 15, 30 or 60 mins
<p>*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.</p> <p>**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.</p> <p>*** To claim virucidal activity with EN 16777:2018, the product must also pass EN 14476:2013+A2:2019 full virucidal activity with Poliovirus, Adenovirus and Murine Norovirus. Compliance with this new test norm is mandatory by June 2020 to make virucidal activity claims.</p>										

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