Dr. Schumacher

We protect your health.

UNDERSTANDING NORMS FOR BEST PRACTICES

Understanding EN 14885

EN 14885:
Meaning, Application and Verificaiton

WHAT IS EN 14885? WHY IT IS RELEVANT IN HEALTHCARE? HOW DOES IT INCREASES SAFETY IN THE SELECTION & APPLICATION OF DISINFECTANTS?

EN 14885 is considered the gold standard in the healthcare sector, especially for authorities, notified bodies, and healthcare facilities. It serves as a benchmark in audits and inspections and supports effective product selection as well as safe application and documentation.

What is EN 14885?

EN 14885 is the **European standard for the efficacy testing** of chemical disinfectants and antiseptics. It is mandatory for manufacturers and suppliers of these products. It also plays an important role for regulatory authorities, for example, within the framework of the Biocidal Products Regulation (EU 528/2012) and the Medical Devices Regulation (EU 2017/745).

It specifies:
- which ***individual testing standards*** (e.g. EN 13727, EN 14476) must be applied and
- which ***tests a product must pass*** to be considered effective against bacteria, fungi, viruses, spores or other microorganisms

Why and for whom is the norm important?

The goal: to ensure independent, standardized and replicable testing.
This is important for:
- ***Manufacturers –*** it sets clear requirements for demonstrating efficacy
- ***Authorities –*** it provides a uniform basis for registration approvals
- ***Users –*** it documents confirmation of the effectiveness of the products

Where is EN 14885 applicable?

All hygiene-relevant areas:
- Human and veterinary medicine (hospitals, medical practices, nursing homes)
- Food industry
- Public and private institutions
- Households

What testing methods are defined in EN 14885?

1. Quantitative Suspension Test (Phase 2, Step 1)
Test tube test: under laboratory conditions, the product's effectiveness against specific microorganisms is tested.

2. Quantitative Carrier Test (Phase 2, Step 2)
Practical test: under realistic conditions (e.g., wiping, immersion), the product's effectiveness against specific microorganisms is tested. It simulates real world application of the products..

Both tests must be passed!

How does EN 14885 apply in practice and what does this mean for the selection of disinfectants?

EN 14885 is not a legal requirement, but it plays a crucial role in practice. It describes which **European testing standards** (EN standards) must be used to demonstrate the **antimicrobial efficacy of chemical disinfectants.**

What must the user consider when reviewing or evaluating their processes?

When testing and evaluating their own disinfection and hygiene measures, users must consider several normative, regulatory, and practical aspects. **Tests according to EN 14885 demonstrate the effectiveness of a product under defined laboratory conditions.**

However, this does not automatically mean that its actual use in everyday practice is also effective. The user is responsible for ensuring that the product is used correctly – with the right concentration, contact time, and appropriate application in the defined area.

The effectiveness of the process must therefore be evaluated and documented separately. Process validation at the point of use remains a vital and necessary step.

How can you tell if a product meets the required EN standard?

Compliance with the standard cannot be determined from a single piece of evidence. The **decisive factor**, and therefore the most important document of proof, is a **test report from an independent, accredited testing laboratory.** Compliance with the standard always refers to the tested application under specified conditions – not the product itself.

A typical confirmation of conformity with an EN standard usually reads:
„Tested according to EN 14885 in conjunction with EN 13727 (bactericidal) and EN 13624 (fungicidal and yeasticidal).“

How should products that do not comply with EN 14885 be handled in an institutional setting?

The use of products that do not comply with the requirements of EN 14885 **is not generally prohibited**, but it is associated with an increased risk. An institution may only use them if their effectiveness has been demonstrated in an equivalent way and their use is professionally justified.

This decision must be documented. The responsibility lies entirely with the institution or its operator.

Use of noncompliant products is **not recommended** in sensitive areas such as hospitals, operating rooms, or intensive care units. In the long term, such products should be replaced.

May products that do not meet the standard be used up?

Yes, existing stocks of non-compliant products do not automatically have to be disposed of. **EN 14885 allows for their use to depletion under certain conditions.** The norm is the **currently valid standard** in healthcare and a central benchmark for demonstrating effectiveness. Therefore, remaining stocks should only be used up if the risk is assessed as low, the use is professionally justified and temporary, and the use is documented in a traceable manner. In critical or patient-facing areas, continued use without prior assessment is not permitted.

How long can remaining stocks be used?

There is **no specified deadline** to deplete noncompliant stock. The duration is determined solely by the facility's individual risk assessment. This decision must be **transparent, time-limited, and documented.**

Where can users find the necessary information?

Product Information Sheets (PIFs) from Dr. Schumacher products
https://www.schumacher-online.com/en/downloads/data-sheets

Dr. Schumacher Website
https://www.schumacher-online.com/en

check with your local regulatory agencies

EN 14885 in Practice:
Responsibility and Accountability

Manufacturer

Ensures quality and effectiveness during product manufacturing and testing.

Institution

Selection of the correct disinfectant and adherence to the corresponding required process.

Facility Management

Organizes and ensures compliance with relevant processes.

Personnel

Correct application of products and implementation of and adherence to the processes.

From selection to application:
Dr. Schumacher is here to support you

To ensure the safe selection of disinfectants and proper use in everyday practice, we offer support beyond the product itself.

Dr. Schumacher can help you identify suitable products for each application, correctly interpret efficacy data, and ensure proper application within your team.

We provide relevant product information and appropriate documentation or work instructions. We also offer product training and instruction, allowing decisions to be documented transparently.

Dr. Schumacher

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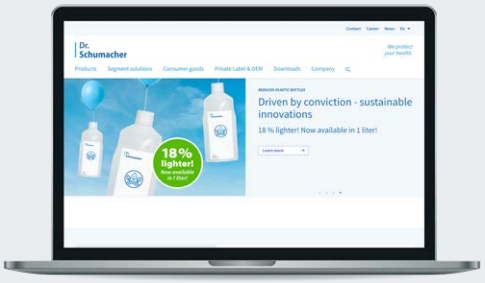

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