Evaluation of products for disinfection in Danish healthcare

A guidance document on the evaluation procedure, requirements for documentation and legislation
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Evaluation of products for disinfection in Danish healthcare

The National Center for Infection Control (CEI) has many years of experience in the evaluation of products for disinfection in Danish healthcare.
This guidance document explains the aspects, which are included in the evaluation, the requirements for documentation, and the procedure for the evaluation.

NB! It is voluntary to request CEI for an evaluation of a disinfection product and CEI does not charge for the evaluation.

An evaluation will include:

- The name of the product.
- The name of the company applying for the evaluation.
- Indication of the active substance(s) in the product with approx. concentrations.
- A short description of the task(s) of disinfection intended for the product.
- A summarization of the documented antimicrobial efficacy.
- Conclusion with:
    - An evaluation of the product's antimicrobial efficacy.
    - A statement of whether or not CEI finds the product suitable for the disinfection task(s).
    - Possible remarks CEI may have.

NB! CEI emphasizes, that CEI is not a national authority in Denmark on approval of disinfection products and therefore the evaluation from CEI is not an approval of a product. The evaluation from CEI is only an evaluation and a recommendation.

The evaluation procedure

If a company wishes CEI to evaluate a disinfection product, the company has to send a formal application to CEI. When applying for an evaluation, CEI's guidance document has to be used in a word format. On request CEI will mail the guidance document in word format and the applicant will fill-in the document (page 24 onwards) and mailed it to the CEI in a digitized format including all the required documentation.
CEI will prepare a written evaluation, in which CEI reserves the right to formulate the final wording. The evaluation will be published on CEI's website and should only be used in its entirety.

Aspects included in the evaluation

CEI's evaluation includes several aspects that have an impact on whether CEI finds a given product suitable for disinfection in the healthcare sector.
CEI's evaluation is primarily based on the information and documentation submitted by the manufacturer/market company.
In an evaluation, CEI reserves the right to exchange information and seek specific professional expertise from relevant partners, including the Danish Environmental Protection Agency, the Danish Medicines Agency, the Regions' Chemical Cooperation (REKS), The Regional Chemical Counselling in the Capital Region, the Danish Working Environment Authority and more.
CEI will also seek further information by the use of relevant chemical/toxicological databases and peer-reviewed journals using biological, chemical, toxicological and health literature databases.

NB! The detailed list of ingredients in the product that CEI requires for the evaluation (see later) will be treated confidentially, but as CEI sometimes request advice from the REKS and The Regional Chemical Counselling in the Capital Region on toxicological and occupational aspects, REKS and The Regional Chemical Counselling in the Capital Region will be shown the list of ingredients and any other relevant documentation regarding working environment and/or environmental aspects.

NB! Test results according to relevant EN standards are not considered confidential information and will be summarized in the evaluation.

NB! CEI does not, in principle, sign confidentiality agreements.

Legislation

The product has to be legal according to EU and Danish legislation:

- The Biocidal Products Regulation[1]

  and/or

- The Medical Devices Regulation[2]

and other Danish legislation

- Danish Chemicals from the Danish Ministry of Environment[3]
- Act concerning medical devices from the Danish Ministry of Health[4]
- The Danish Product Safety from the Danish Ministry of Health [5]
- The Working Environment from the Danish Ministry of Employment[6]
- Consolidated Act on a pesticides' duty from the Danish Ministry of Taxation[7].

[1] REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products
[2] REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
[3] Bekendtgørelse af lov om kemikalier, LBK nr 115 af 26/01/2017.
[4] Bekendtgørelse af lov om medicinsk udstyr. LBK nr 139 af 15/02/2016.
[5] Bekendtgørelse af lov om produktsikkerhed. LBK nr 3 af 03/01/2019.
[6] Bekendtgørelse af lov om arbejdsmiljø. LBK nr 1084 af 19/09/2017.
[7] Bekendtgørelse af lov om afgift af bekæmpelsesmidler. LBK nr 232 af 26/02/2015.

NB! CEI emphasizes, that it is the company's responsibility to ensure, that the product is legal before submitting documentation for an evaluation.

Depending on the disinfection areas the product is intended to be used for, a disinfectant product may fall under either the Biocidal Product Regulation or the Medical Devices Regulation or both. In the latter case, the requirements of both laws must be met.
The Danish Environmental Protection Agency is the national authority in Denmark that evaluates and approves disinfection products defined by the Biocidal Product Regulation when all active substances in a disinfection product (product type (PT) 1 and 2) have been evaluated and approved at EU level. In this context, the manufacturer/marketing company of a product defined by the Biocidal Product Regulation must ensure that the active substance(s) of the product is approved or under evaluation within the scope(s) specified. This will primarily be PT 1, which includes products for hand disinfection and surgical hand disinfection, and PT 2, which includes products for general surface disinfection. See more about this on the Danish Environmental Protection Agency's website under "Biocides" and on the approval of active substances on the European Chemicals Agency's (ECHA) website by searching for "Approval of active substances" and "Biocidal Active Substances".
A disinfection product specifically intended for disinfection of medical devices may be defined as an accessory of medical devices, which is defined by the Medical Devices Regulation[1]. The product should be CE marked and classified within the Medical Devices Regulation which is regulated by the Danish Medicines Authority. For more information see the Danish Medicines Authority's website.
Furthermore, all chemical products have to be registered in the Product Registry administered by the Danish Working Environment Authority. For more information see the Danish Working Environment Authority's website.

Working environment, patient safety and environmental considerations

CEI includes "The Substitution Principle" from the Danish Working Environment Authority in an evaluation. This states that hazardous substances and materials are to be replaced by less hazardous substances if possible to ensure a safer working environment. "The Substitution Principle" is an important principle in the Danish working environment legislation and is also now included in EU chemicals legislation from ECHA. For more information see ECHA's website by searching for "Potential candidate for substitution".

CEI includes relevant information about possible side effects of a disinfection product:

- To humans, concerning working environment and patient safety (e.g. irritation, allergy, toxicity, mutagenicity, teratogenicity, carcinogenicity, endocrine disrupting)
- On the environment (e.g. issues on waste removal)
- On bacteria (e.g. selection (resistance/tolerance/cross resistance to antibiotics), formation of biofilm).

[1] REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Consensus on rational use of disinfection

An expert group with representatives from the regional infection control units, the Society of Infection Control Nurses, The Danish Society for Infection Prevention (formerly the Danish Society for Central Sterilization and Hospital Hygiene), Danish Society of Clinical Microbiology, the primary healthcare, the Danish Environmental Protection Agency and CEI have prepared a consensus statement on the principles for the use of disinfection in Danish healthcare. Among other things, the consensus statement describes the consensus on rational use of disinfection products. CEI includes these principles in the evaluation.

Instructions for use and product description in Danish

If the marketing of a disinfection product is in Danish, the instructions for use must also be in Danish, unless it is clearly stated in the marketing that the instructions for use are in English. Such instructions for the product/product description will be included in CEI's evaluation.

NB! CEI recommends that the manufacturer/the marketing company of a product follow ECHA's guidance in legislation on biocidal products. For more information see ECHA's website by searching for "Guidance on biocides legislation".

The user instruction for the product and/or the product description should include:

- Information about the active substance(s), as well as other relevant ingredients in the product with approx. concentrations.
- Information on the ease of use of the product (e.g. a ready-to-use product vs. a product, which has to be mixed).
- A description of the of intended disinfection task(s) in healthcare.
- A description of how the product should be used, including how the product should be dispersed (and rinsed off if necessary) and the contact time(s) required for the product to have the antimicrobial efficacy found in tests according to relevant EN standards.
- Shelf life/durability of the product before and after it has been opened documented by the use of ECHA's guidelines.
- Information on possible odours or other side effects from the product.
- Information on possible corrosive effects or other kind of impact on materials.
- Possible interaction of the product with organic materials or with other materials or chemicals.
- Possible requirements for use of protective equipment when using the product.

NB! CEI emphasizes, that disinfection products containing chemicals which are or suspected to be seriously dangerous to humans (e.g. toxic, mutagenic, teratogenic, carcinogenic or endocrine disrupting) will NOT be recommended for use in Danish healthcare. Additionally, disinfection products containing ingredients suspected of causing an allergic skin reaction will generally NOT be recommended for hand and skin disinfection in Danish healthcare. However, exceptions can be made.

In addition, the use of active substances suspected of selecting for resistance or cross-resistance to antibiotics should be limited, as stated in the consensus statement on the principles for the use of disinfection in Danish healthcare.

Documentation of antimicrobial efficacy

CEI's evaluation of a product's antimicrobial efficacy is primarily based on harmonized European standards (EN standards) for testing of disinfection products for the medical area prepared by the TC216 working group under the European standardization organization Le Comité Européen de Normalization (CEN). Table 1 and EN 14885 summarizes the EN standards for the medical area.

Requirements for documentation of antimicrobial efficacy

According to the consensus statement, disinfection products are categorized according to their antimicrobial efficacy.
Table 1 is a modification of the EN 14885 standard, which summarizes the minimum requirements for documentation by testing of antimicrobial efficacy by the use of relevant EN standards, according to the intended task of disinfection for a product (hand disinfection and surgical hand disinfection, surface disinfection, disinfection by submersion or room disinfection) and how the disinfection product will be categorized.

Important considerations regarding tests by relevant EN standards

When designing tests, it is important to take into account how the disinfection product is intended to be used. The time a disinfection product in a practical situation has to react with microorganisms (the contact time) and at which temperature the product will be used in practice are important factors.
It is extremely important that the tests are performed with the exact prescription of the product including all active substances, excipients, preservatives etc.
Any deviations from the protocol for a test by a relevant EN standard must be described in detail.
Products tested by a phase 3 test design ("in field-tests") will have an advantage in the evaluation. However, at the moment no EU standards for phase 3 testing have been designed and harmonized. In EN 14885 an annex describing the overall principles for the design of the phase 3 tests ("in field-tests").

Table 1. Overview of EN standard according to which disinfection products for the medical area must be tested (modified after EN 14885)

Requirements for categorisation	Antimicrobial efficacy	Phase step	Hand disinfection	Surgical hand disinfection	Surface disinfection		Disinfection by submersion	Room disinfection
					Without mechanical treatment	With mechanical treatment		
Low-level Intermediate-level High-level	Bactericidal	2,1	EN 13727		EN 13727		EN 13727	
		2,2	EN 1500	EN 12791	EN 17387	EN 16615	EN 14561	EN 17272
Low-level Intermediate-level High-level	Yeasticidal	2,1	EN 13624		EN 13624		EN 13624	
		2,2	***		EN 17387	EN 16615	EN 14562	EN 17272
Low-level Intermediate-level High-level	Fungicidal **a)**	2,1	***		EN 13624		EN 13624	
		2,2	***		EN 17387	*prEN 16615 **d)**	EN 14562	EN 17272
Low-level Intermediate-level High-level	Virucidal **b)**	2,1	EN 14476	***	EN 14476		EN 14476	
		2,2	EN 17430	**	EN 16777	modified EN 16615 **c)**	EN 17111	EN 17272
Intermediate-level High-level	Mycobactericidal	2,1	EN 14348	***	EN 14348		EN 14348	
		2,2	***		**	*prEN 16615 **d)**	EN 14563	EN 17272
High-level	Sporicidal	2,1	***		EN 17126		EN 17126	
		2,2	***		**	EN 17846	*	EN 17272

a) For products to be categorized as a product with antimicrobial efficacy against certain types of microorganisms (low-level and intermediate-level disinfection, respectively) the tests are required to show "limited" antimicrobial efficacy over for the test organism *Aspergillus brasiliensis*. “Limited” efficacy can either be in the form of a lower log reduction (for EN 13624 and EN 17387 <4 log) or that the antimicrobial efficacy specified in the test is achieved by a longer contact time (up to 15 min.).
b) For products to be categorized as a product with antimicrobial efficacy against certain types of microorganisms (low-level disinfection) the requirement is that tests by EN 14476 and EN 16777 must show the antimicrobial efficacy specified in the standard against enveloped viruses (vaccinia virus). For products categorized as a product with antimicrobial efficacy against certain types of microorganisms (intermediate-level disinfection), the requirement is that tests by EN 14476 and EN 16777 must show the antimicrobial efficacy specified in the standard against enveloped viruses (vaccinia virus) or one or more of the mandatory non-enveloped viruses (murine norovirus, adenovirus and/or poliovirus). For products that are to be categorized as a product with antimicrobial efficacy against all types of microorganisms (high-level disinfection), tests by EN 14476 and EN 16777 or modified EN 16615 must show antimicrobial efficacy against all viruses. As poliovirus does not tolerate desiccation, it cannot be used in EN 16777 or modified EN 16615.
c) When modifying EN 16615, the mandatory test organisms and test criteria from EN 16777 are to be used. As poliovirus does not tolerate desiccation, it cannot be used in a modified EN 16615.
d) prEN 16615 is preliminary, i.e. it is available as a draft which has not yet been finalized. The standard is therefore not included as a mandatory requirement in CEI’s evaluations before a final version is available, but it is recommended to test according to the standard.

* In preparation. ** Not yet in preparation, but relevant standards that probable will be prepare in the future. *** No plan to draft a standard.

Requirements for contact times in Tests by relevant EN standards

Hand disinfection and surgical hand disinfection

The recommendation to achieve a sufficient hand disinfection is that hands and wrists should be rubbed for 30 seconds. When testing products for hand disinfection, a contact time of 30 seconds must therefore be used. When testing products for surgical hand disinfection, a contact time of 1-5 minutes must be used.
The documented contact time used in the tests for hand disinfection and/or surgical hand disinfection should be stated in the instruction for the product and/or the product description.

Surface disinfection

When testing products intended for surface disinfection of surfaces that are likely to come into contact with patients or staff close to the patient and “multi-touch” contact points, the contact time in the tests should be maximum 5 minutes (according to EN 14885). Testing with shorter contact times can be conducted and claimed. However, when testing products to be categorized as a product with antimicrobial effect against certain types of microorganisms (intermediate-level disinfection) or a product with antimicrobial effect against all types of microorganisms (high-level disinfection) for antimicrobial efficacy against *Aspergillus brasiliensis* or bacterial spores a contact time of 10-15 minutes can be used. The contact time represents the time from when a disinfectant have been added to a surface to the time the "surface is taken into use". This does not mean that the surface has to be visibly wet during this period, as the added disinfectant may evaporate. The documented contact time used in the tests for surface disinfection should be stated in the user instruction for the product and/or the product description.

Disinfection by submersion

When testing products for disinfection by submersion, testing must be performed by a mandatory contact time of 60 minutes according to EN 14885. CEI's recommendation is a maximum contact time of 60 minutes to ensure optimal disinfection. Testing with shorter contact times can be conducted and claimed. The documented contact time used in the tests for disinfection by submersion should be stated in the user instruction for the product and/or the product description.

Room disinfection

There is no requirement for a mandatory contact time when testing products for room disinfection. The documented contact time used in the tests for room disinfection should be stated in the user instruction for the product and/or the product description.

Requirements for test concentrations used in tests according to relevant EN standards

The concentration of the product used and found to have sufficient antimicrobial efficacy in the tests should be the same concentration in the in-use product and specified in the instructions for the product and/or the product description.

Requirements for alcohol-based disinfection products

According to the consensus in Denmark an alcohol-based disinfection product in a liquid form must have a concentration of 70-85 vol/vol %, corresponding to approx. 63-80 weight/weight %. The

recommendation is based partly on the existing literature on the antimicrobial efficacy of alcohol, partly on requirements from the Danish fire authorities.
According to “The Substitution Principle” from the Working Environment Authority in Denmark, REKS and The Regional Chemical Counselling in the Capital Region products based on ethanol should be preferred to products based on isopropanol (isopropyl alcohol/2-propanol) for disinfection. Ethanol is less of an irritant to the mucous membrane, ethanol is not significantly absorbed through the skin and ethanol has a lower MAL-factor than isopropanol (isopropyl alcohol/2-propanol). The MAL-factor (“Måleteknisk Arbejdshygiejnisk Luftbehov”) is a technical measure which the Working Environment Authority uses in setting the level the requirement for ventilation when working with organic solvents. However, isopropanol (isopropyl alcohol/2-propanol) can or must be added to a disinfection product, as SKAT (the Danish Tax Authority) requires denaturation of ethanol for a product to be tax deductible. The consensus is that the amount of isopropanol (isopropyl alcohol/2-propanol) in an ethanol-based product may not be more than 10 % of the total alcohol concentration in an alcohol-based disinfection product.
According to REKS, hand rubs should not contain organic solvents other than ethanol and isopropanol (isopropyl alcohol/2-propanol), as these other organic solvents pose a greater health risk for the working environment, skin contact and inhalation of aerosol.

CEI’s recommendations for alcohol-based disinfection products for disinfection in Danish healthcare

- The total concentration of alcohol in a liquid product must be 70-85 vol/vol %, corresponding to approx. 63-80 weight/weight %.
- The product must be based on ethanol, but may contain isopropanol (isopropyl alcohol/2-propanol)
- The content of isopropanol (isopropyl alcohol/2-propanol) must not be more than 10 % of the total alcohol concentration in a product.
- Products must not contain propane-1-ol (n-propanol/1-propanol or butanone).
- Hand rubs must contain skin care ingredients
- Hand rubs must not contain allergens

Requirements for high-level disinfection products

For a product to be categorized as product with antimicrobial efficacy against all types of microorganisms (high-level disinfection), the requirement is that the product has been tested against all the relevant EN standards and show antimicrobial efficacy against all the microorganisms specified in the standards; vegetative bacteria, fungi, virus, mycobacteria and bacterial spores.
Currently, there is two EN standard for testing for efficacy against bacterial spores within the medical area (EN 17126 and EN 17846). EN 17126 is a suspension test and EN 17846 is a surface test (carrier test) for testing of sporicidal efficacy of surface disinfectants with mechanical action.
For CEI to evaluate whether a product has antimicrobial efficacy against bacterial spores and can be categorized as a product with antimicrobial effect against all types of microorganisms (high-level disinfection), CEI must have the previously mentioned documentation for antimicrobial efficacy and

additional documentation for all ingredients as well as *in situ* generated active ingredients in the product with exact concentration.
For chlorine-based products (where the active substances are hypochlorous acid/hypochlorite) documentation is required for *in situ* concentration of free chlorine in ppm (including the concentration of hypochlorous acid and hypochlorite) and the pH value in the in-use product within the specified time for which the product can be used and for the claimed shelf life.
For products based on other active substances, documentation of active substances (possibly *in situ* generated) with concentration in ppm is required, as well as the pH value in the in-use product within the specified time for which the product can be used and for the claimed shelf life.
There is now an EN standard (EN 17272) for testing of products for room disinfection, which must show antimicrobial efficacy against all types of mandatory microorganisms i.e. vegetative bacteria, fungi, viruses, mycobacteria and bacterial spores.

Requirements for products for hand disinfection and surgical hand disinfection

The following are CEI's requirements for the testing of antimicrobial efficacy of a product for hand disinfection and surgical hand disinfection.
CEI's recommendation is that disinfection products for hand disinfection and surgical hand disinfection should be products categorized as a product with antimicrobial efficacy against certain types of microorganisms (intermediate-level disinfection).
In addition to be tested according to relevant EN standards, hand disinfection and surgical hand disinfection products must also comply with the Danish National Guidelines for hand disinfection. This implies, among other things, that a hand disinfection product must contain a skin care product and not contain known allergens or ingredients suspected of causing allergy.

Documentation for antimicrobial efficacy against vegetative bacteria

For CEI to evaluate whether a product has antimicrobial efficacy against vegetative bacteria, the requirement is that the following tests have to be conducted:

- Tests performed by EN 13727 must as a minimum show the required bactericidal efficacy specified in the standard against all the mandatory bacteria.
- Tests performed by EN 1500 must as a minimum show the required antimicrobial efficacy specified in the standard against the mandatory bacteria and meet the requirements defined in the standard.
- For a product intended for surgical hand disinfection, tests performed by EN 12791 must as a minimum show the required antimicrobial efficacy specified in the standard against the mandatory bacteria and meet the requirements defined in the standard.

Documentation for antimicrobial efficacy against fungi

For CEI to evaluate whether a product has antimicrobial efficacy against fungi, the requirement is that the following tests have to be conducted:

- Tests performed by EN 13624 must as a minimum show the required yeasticidal efficacy specified in the standard against yeast (*Candida albicans*).

For a product for hand disinfection and surgical hand disinfection antimicrobial efficacy against mold (*Aspergillus brasiliensis*) is not considered relevant.

Documentation for antimicrobial efficacy against virus

For CEI to evaluate whether a product has antimicrobial efficacy against viruses, the requirement is that the following tests have to be conducted:

- Tests performed by EN 14476 must as a minimum show antimicrobial efficacy specified in the standard against the enveloped viruses (vaccinia virus) or one or more of the mandatory non-enveloped viruses (murine norovirus, adenovirus and/or poliovirus) depending on how the product is to be categorized (see below) and how the virucidal efficacy of the product is claimed.
- Tests performed by EN 17430 must as a minimum show the required antimicrobial efficacy specified in the standard against the mandatory virus (murine norovirus) and meet the requirements defined in the standard.

For a product for surgical hand disinfection antimicrobial efficacy against virus is not considered relevant.

For a product for hand disinfection, which is to be categorized as a product with antimicrobial efficacy against certain types of microorganisms (intermediate-level disinfection) with limited antimicrobial efficacy against viruses, the requirement is that test performed by EN 14476 must show antimicrobial efficacy specified in the standard against enveloped viruses (vaccinia virus) or one or more of the mandatory non-enveloped viruses (murine norovirus, adenovirus and/or poliovirus). In addition, the requirement is that test performed by EN 17430 must show antimicrobial efficacy specified in the standard against the mandatory non-enveloped viruses (murine norovirus).
For a product for hand disinfection, which is to be categorized as a product with antimicrobial efficacy specified in the standard against certain types of microorganisms (intermediate-level disinfection) with full antimicrobial efficacy against viruses, the requirement is that tests performed by EN 14476 must show antimicrobial efficacy specified in the standard against murine norovirus, adenovirus and poliovirus. In addition, the requirement is that test performed by EN 17430 must show antimicrobial efficacy specified in the standard against the mandatory non-enveloped viruses (murine norovirus).
For a product for surgical hand disinfection, antimicrobial efficacy against virus is not considered relevant, as surgical hand disinfection is used to reduce the resident flora.

Documentation for antimicrobial efficacy against mycobacteria

For CEI to evaluate whether a product has antimicrobial efficacy against mycobacteria, the requirement is that the following tests have to be conducted:

- Tests performed by EN 14348 must as a minimum show the required mycobactericidal efficacy specified in the standard against both mandatory mycobacteria.

For a product for surgical hand disinfection antimicrobial efficacy against mycobacteria is not considered relevant.

Requirements for contact times in tests for products for hand disinfection and surgical hand disinfection

See under: Requirements for contact times in tests by relevant EN standards.

Evaluation of quaternary ammonium compounds in aqueous solution for hand disinfection

REKS has made an overall evaluation of 30 different substances from the active substance group quaternary ammonium compounds based on the substances' hazard classification (CLP) in relation to their use in products for hand disinfection. Only 6 quaternary ammonium compounds are under evaluation under the Biocidal Product Regulation under product type 1 at EU level. None of these substances have yet been approved.
REKS find that all 30 quaternary ammonium compounds will affect the skin, being classified as either irritating, corrosive or sensitizing in concentrations of 1%.
The overall evaluation and conclusion is that REKS cannot recommend a product for hand infection in the healthcare sector, where the active substance is an aqueous solution of quaternary ammonium compounds.
REKS' justification is:

- The use of products for hand disinfection that contain quaternary ammonium compounds in an aqueous solution will result in an increasing concentration in and on the skin, which potentially be either irritating/corrosive and/or allergenic.

- As hand disinfection is performed many times during a work day, quaternary ammonium compounds will be on the skin throughout the work day and result in an additive effect, which can cause irritative or allergic contact dermatitis on the hands.

CEI agree with REKS' evaluation and conclusion and therefore CEI cannot recommend the use of products for hand disinfection, which contain quaternary ammonium compounds in an aqueous solution for use in Danish healthcare.

Requirements for products for surface disinfection

The following are CEI's requirements for the testing of antimicrobial efficacy of a product for surface disinfection depending on how the product is to be categorized.

Documentation for antimicrobial efficacy against vegetative bacteria

For CEI to evaluate whether a product has antimicrobial efficacy against vegetative bacteria, the requirement is that the following tests have to be conducted:

- Tests performed by EN 13727 must as a minimum show the required bactericidal efficacy specified in the standard against all the mandatory bacteria.
- If the product is intended to be applied to a surface without mechanical treatment (i.e. the disinfectant is sprayed or poured over a surface without the use of cloth), tests performed by EN 17387 must as a minimum show the antimicrobial efficacy specified in the standard against all the mandatory bacteria.
- If the product is to be applied to a surface by mechanical treatment (e.g. by wiping with pre-impregnated disinfection wipes or wipes soaked with a disinfectant) tests performed by EN 16615 must as a minimum show antimicrobial efficacy specified in the standard against all the mandatory bacteria.

For products to be categorized within all three categories of disinfection products: antimicrobial efficacy against certain types of microorganisms (low-level disinfection), antimicrobial efficacy against certain types of microorganisms (intermediate-level disinfection) and antimicrobial efficacy against all types of microorganisms (high-level disinfection), the requirement is that the tests must show antimicrobial efficacy specified in the standards against all the mandatory bacteria. See also: Requirements for high-level disinfection products.

Documentation for antimicrobial efficacy against fungi

For CEI to evaluate whether a product has antimicrobial efficacy against fungi, the requirement is that the following tests have to be conducted:

- Tests performed by EN 13624 must as a minimum show the antimicrobial efficacy specified in the standard against one or both mandatory fungi, depending on how the product is to be categorized (see below).
- If the product is intended to be applied to a surface without mechanical treatment (i.e. the disinfectant is sprayed or poured on the surface without the use of a cloth or a wipe), tests performed by EN 17387 must as a minimum show antimicrobial efficacy specified in the standard against one or both mandatory fungi, depending on how the product is to be categorized (see below).
- If the product is to be applied to a surface by mechanical treatment (e.g. by wiping with a pre-impregnated disinfection wipe or a wipe soaked with a disinfectant) tests performed by EN 16615, must as a minimum show antimicrobial efficacy specified in the standard against yeast (*Candida albicans*).
- The preliminary standard (prEN 16615) include mold (*Aspergillus brasiliensis*) as mandatory test organisms, but this standard has not yet been finalized. Therefore, it is not included as a mandatory requirement in CEI's evaluation until a final version is available, but it is recommended to test according to this standard.

For a product, which is to be categorized as a product with antimicrobial efficacy against certain types of microorganisms (low-level disinfection) the requirement is that tests performed by EN 13624 and in addition by EN 17387 or EN 16615 must show antimicrobial efficacy specified in the standard against yeast (*Candida albicans*).
For a product, which is to be categorized as a product with antimicrobial efficacy against certain types of microorganisms (intermediate-level disinfection) the requirement is that tests performed by EN 13624 and in addition by EN 17387 or EN 16615 must show antimicrobial efficacy specified in the standard against yeast (*Candida albicans*). In addition, tests performed by EN 13624 and in addition by EN 17387 or prEN 16615 must show "limited" antimicrobial efficacy against mold (*Aspergillus brasiliensis*). "Limited" efficacy can either be in the form of a lower log reduction (<4 log) or that the antimicrobial efficacy specified in the standard is achieved by a longer contact time (up to 15 minutes). As EN 16615 does not include mold (*Aspergillus brasiliensis*) as a mandatory test organism, CEI can only recommend that test could be performed against mold according to prEN 16615.
For products to be categorized as a product with antimicrobial efficacy against all types of microorganisms (high-level disinfection), the requirement is that the tests performed by EN 13624 and in addition by EN 17387 or EN 16615 and prEN 16616 must show antimicrobial efficacy specified in the standards against both mandatory fungi. As EN 16615 does not include mold (*Aspergillus brasiliensis*) as a mandatory test organism, CEI can only recommend that test could be performed against mold according to prEN 16615.
See also: Requirements for high-level disinfection products.

Documentation for antimicrobial efficacy against virus

For CEI to evaluate whether a product has antimicrobial efficacy against viruses, the requirement is that the following tests have to be conducted:

- Tests performed by EN 14476 must as a minimum show antimicrobial efficacy specified in the standard against the enveloped virus (vaccinia virus) or one or more of the mandatory non-enveloped viruses (murine norovirus, adenovirus and/or poliovirus) depending on how the product is to be categorized (see below) and how the virucidal efficacy of the product is claimed.
- If the product is intended to be applied to a surface without mechanical treatment (i.e. the disinfectant is sprayed or poured on the surface without the use of a cloth or a wipe), test performed by EN 16777 must as a minimum show antimicrobial efficacy specified in the standard against enveloped viruses (vaccinia virus) or one or more of the mandatory non-enveloped viruses (murine norovirus, adenovirus and/or poliovirus) depending on how the product is to be categorized (see below) and how the virucidal efficacy of the product is claimed.
- If the product is to be applied to a surface by mechanical treatment (e.g. by wiping with a pre-impregnated disinfection wipe or a wipe soaked with a disinfectant) CEI can only recommend that test could be performed by a modified EN 16615, which should as a minimum show antimicrobial efficacy specified in EN 16777 against enveloped viruses (vaccinia virus) or one or both of the mandatory non-enveloped viruses (murine norovirus, and/or adenovirus) depending on how the product is to be categorized (see below) and how the virucidal efficacy of the product is claimed.

For a product, which is to be categorized as a product with antimicrobial efficacy against certain types of microorganisms (low-level disinfection) the requirement is that tests performed by EN 14476 and in addition by EN 16777 or a modified EN 16615 must show antimicrobial efficacy specified in the standards against enveloped virus (vaccinia virus). As EN 16615 does not include viruses as mandatory test organisms, CEI can only recommend testing with virus in a modified test performed by EN 16615.
For a product, which is to be categorized as a product with antimicrobial efficacy against certain types of microorganisms (intermediate-level disinfection) the requirement is that tests performed by EN 14476 and in addition by EN 16777 or a modified EN 16615 must show antimicrobial efficacy specified in the standards against enveloped viruses (vaccinia virus) or one or more of the non-enveloped viruses (murine norovirus and/or adenovirus). As poliovirus does not tolerate dehydration it is not a mandatory virus in EN 16777 or in a modified EN 16615. As EN 16615 does not include viruses as mandatory test organisms, CEI can only recommend testing with viruses in a modified test performed by EN 16615.
For a product, which is to be categorized as a product with antimicrobial efficacy against all types of microorganisms (high-level disinfection) the requirement is that tests performed by EN 14476 and in addition by EN 16777 or a modified EN 16615 must show antimicrobial efficacy specified in the standards against all the mandatory non-enveloped viruses (adenovirus, murine norovirus and poliovirus). As poliovirus does not tolerate dehydration it is not a mandatory virus in EN 16777 or in a modified EN 16615. As EN 16615 does not include viruses as mandatory test organisms, CEI can only recommend testing with viruses in a modified test performed by EN 16615.
See also: Requirements for high-level disinfection products.

Documentation for antimicrobial efficacy against mycobacteria

For CEI to evaluate whether a product has antimicrobial efficacy against mycobacteria, the requirement is that the following tests have to be conducted:

- Tests performed by EN 14348 must as a minimum show the required mycobactericidal efficacy against all mandatory bacteria depending on how the product is to be categorized (see below).
- If the product is to be applied to a surface by mechanical treatment (e.g. by wiping with a pre-impregnated disinfection wipe or a wipe soaked with a disinfectant) CEI can only recommend that tests could be performed by the preliminary standard prEN 16615. As EN 16615 does not include mycobacteria as mandatory test organisms, CEI can only recommend that test could be performed against mycobacteria according to prEN 16615 depending on how the product is to be categorized (see below).

For a product, which is to be categorized as a product with antimicrobial efficacy against certain types of microorganisms (low-level disinfection) there is no requirement for tests performed by EN 14348 or prEN 16615.
For a product, which is to be categorized as a product with antimicrobial efficacy against certain types of microorganisms (intermediate-level disinfection) or a product with antimicrobial efficacy against all types of microorganisms (high-level disinfection) the requirement is that tests performed by EN 14348 must show antimicrobial efficacy specified in the standard against all mandatory mycobacteria. As EN 16615 does not yet include mycobacteria as mandatory test organisms, CEI can only recommend testing against mycobacteria performed by prEN 16615.
See also: Requirements for high-level disinfection products.

Documentation for antimicrobial efficacy against bacteria spores

For CEI to evaluate whether a product has antimicrobial efficacy against bacteria spores, the requirement is that the following tests have to be conducted:

- Tests performed by EN 17126 must as a minimum show the required sporicidal efficacy against all mandatory bacteria spores depending on how the product is to be categorized (see below).
- If the product is to be applied to a surface by mechanical treatment (e.g. by wiping with a pre-impregnated disinfection wipe or a wipe soaked with a disinfectant) tests performed by EN 17846 must as a minimum show the required sporicidal efficacy against all mandatory bacteria spores depending on how the product is to be categorized (see below).

For a product, which is to be categorized as a product with antimicrobial efficacy against certain types of microorganisms (low-level disinfection) or (intermediate-level disinfection) there is no requirement for tests performed by EN 17126 or EN 17846.
For a product, which is to be categorized as a product with antimicrobial efficacy against all types of microorganisms (high-level disinfection) the requirement is that tests performed by EN 17126 must show antimicrobial efficacy specified in the standard against mandatory bacteria spores.
For a product to be applied to a surface by mechanical treatment (e.g. by wiping with a pre-impregnated disinfection wipe or a wipe soaked with a disinfectant), which is to be categorized as a product with antimicrobial efficacy against all types of microorganisms (high-level disinfection) the requirement is that tests performed by EN 17846 must show antimicrobial efficacy specified in the standard against mandatory bacteria spores.
See also: Requirements for high-level disinfection products.

Requirements for contact times in tests for products for surface disinfection

See under: Requirements for contact times in tests by relevant EN standards.

Requirements for pre-impregnated disinfection wipe or disinfectant which is applied with at wipe

If surface disinfection is carried out by wiping with a pre-impregnated disinfection wipe the efficacy should as a minimum be tested according to EN 16615 and the fluid in the wipe should be tested according to other relevant suspension tests. If a product is to be categorized as a product with antimicrobial efficacy against all types of microorganisms (high-level disinfection) the requirement is that tests performed by EN 17846 must show antimicrobial efficacy specified in the standard against mandatory bacteria spores (see Table 1). According to EN 16615 and EN 17846, the efficacy is tested on the basis of the wiping (once forward and once back) over a contaminated test field and 3 non-contaminated test fields. Mandatory for the test protocol is that the contact time must not exceed 5 minutes, but shorter contact times can be used. Mandatory for the test protocol for EN 17846 is that the contact time must not exceed 30 minutes, but shorter contact times can be used. For both standards this does not mean that the surface is visibly wet during the contact time, as the supplied disinfectant liquid may have evaporated.
As active substances may bind to and/or be inactivated by substances in a wipe or a tissue, this may influence the concentration of active substances in the liquid coming out of the wipe/tissue and have an effect on the antimicrobial efficacy of the product. For documentation of antimicrobial efficacy of a disinfection wipe, the relevant suspension tests (see Table 1) (not EN 16615 and EN 17846) should be conducted using the wring out liquid from the wipes. Alternatively, it must be

documented that the wring out liquid is absolutely identical to the liquid being added to the wipes. If a disinfection wipe meets the requirements of EN 16615 or EN 16615 and EN 17846, as well as the relevant suspension tests, there is sufficient evidence of efficacy against the tested spectrum of microorganisms.
prEN 16615 can be used for tests against mold (*Aspergillus brasiliensis*) and mycobacteria and a modified form of EN 16615 can be used for tests against viruses. Tests according to preliminary or modified standards are not included as a mandatory requirement in CEI's evaluations until final versions are available, but it is recommended that test according to these standards, if the product is claimed to have antimicrobial efficacy against these microorganisms.
For documentation of sporicidal efficacy see: Requirements for high-level disinfection products.

Requirements for products for disinfection by submersion

After cleaning, semi-critical and non-critical instruments/medical devices can be disinfected by submersion. CEI recommend that a product to be categorised as having maximum antimicrobial efficacy ("high-level" disinfection) must be used for disinfection by submersion. Critical instruments/medical devices must additionally be sterilised.

Documentation for antimicrobial efficacy against vegetative bacteria

For CEI to evaluate whether a product has antimicrobial efficacy against vegetative bacteria, the requirement is that the following tests have to be conducted:

- Tests performed by EN 13727 must as a minimum show the required bactericidal efficacy specified in the standard against all the mandatory bacteria.
- Tests performed by EN 14561 must as a minimum show the required bactericidal efficacy specified in the standard against all the mandatory bacteria.

See also: Requirements for high-level disinfection products.

Documentation for antimicrobial efficacy against fungi

For CEI to evaluate whether a product has antimicrobial efficacy against fungi, the requirement is that the following tests have to be conducted:

- Tests performed by EN 13624 must as a minimum show the required fungicidal efficacy specified in the standard against all the mandatory fungi.
- Tests performed by EN 14562 must as a minimum show the required fungicidal efficacy specified in the standard against all the mandatory fungi.

See also: Requirements for high-level disinfection products.

Documentation for antimicrobial efficacy against virus

For CEI to evaluate whether a product has antimicrobial efficacy against viruses, the requirement is that the following tests have to be conducted:

- Tests performed by EN 14476 must as a minimum show antimicrobial efficacy specified in the standard all of the mandatory non-enveloped viruses (murine norovirus, adenovirus and poliovirus).
- Tests performed by EN 17111 must as a minimum show antimicrobial efficacy specified in the standard all of the mandatory non-enveloped viruses (murine norovirus, adenovirus and poliovirus).

See also: Requirements for high-level disinfection products.

Documentation for antimicrobial efficacy against mycobacteria

For CEI to evaluate whether a product has antimicrobial efficacy against mycobacteria, the requirement is that the following tests have to be conducted:

- Tests performed by EN 14348 must as a minimum show the required mycobactericidal efficacy against all mandatory mycobacteria.
- Tests performed by EN 14563 must as a minimum show the required mycobactericidal efficacy against all mandatory mycobacteria.

See also: Requirements for high-level disinfection products.

Documentation for antimicrobial efficacy against bacteria spores

For CEI to evaluate whether a product has antimicrobial efficacy against bacteria spores, the requirement is that the following tests have to be conducted:

- Tests performed by EN 17126 must as a minimum show the required sporicidal efficacy against all mandatory bacteria spores.

See also: Requirements for high-level disinfection products.

Requirements for contact times in tests for products for surface disinfection

See under: Requirements for contact times in tests by relevant EN standards.

Requirements for products for room disinfection

CEI recommend that a product to be categorised as having maximum antimicrobial efficacy (high-level disinfection) must be used for room disinfection.
For CEI to evaluate whether a product has antimicrobial efficacy against vegetative bacteria, fungi, viruses, mycobacteria and bacteria spores the requirement is that the following tests have to be conducted:

- Tests performed by EN 17272 must as a minimum show the required antimicrobial efficacy against all mandatory bacteria, fungi, virus, mycobacteria and bacteria spores.

The evaluation procedure

Upon request by the applicant company (i.e. a manufacturer or a marketing company) CEI will mail this guidance document on the evaluation procedure in a Word-format, which **MUST** be used in the submission of the required documentation (page 16 and forward).
The applicant must submit a formal request to CEI in a digitized format through e-mail. Mail address: CEImail@ssi.dk or csj@ssi.dk.

NB! It is important that the request contains the following information for each disinfection product to be evaluated:

1. Overview of submitted documents indicating the document title and a short description of its content (Table 2).
2. Information regarding the product:
   a. Name of disinfection product (or several (former) names, if there are more names in the submitted documentation).
   b. The applying company's name and the contact's details. If more companies are involved names of these companies and names of additional contacts indicating affiliation and status of access to confidential information (see paragraph c) to avoid accidental transmission of confidential information (Table 3).
   c. Complete list of ALL ingredients with exact concentration and a declaration of purpose, e.g. active substance, excipient, preservative, skin care product, detergent, surfactant, perfume, etc. (Table 4).
   NB! The list must contain the CAS and/or EC numbers for all ingredients, exact concentrations indicated in vol/vol % or weight/weight % and a statement of purpose for why each ingredient is added to the product. **This information is treated confidentially**.
   d. Description of disinfection task(s) in healthcare.
   e. Information and documentation on the durability of the product and/or shelf life.
   f. Safety Data Sheet for the product.
   g. Danish instructions for the product and/or a product description.
   h. Information on possible corrosive effect or any other impact on materials.
3. Information on whether the product's active substance(s) are included in Biocidal Products Regulation's "positive" list or are on the list of active substances under evaluation.
4. Information about whether the product is to be considered an accessory to medical devices and therefore falls within the Medical Devices Directive. In which case the product should be CE marked and categorised within the Medical Devices Directive.
5. Documentation of the registration of the product in the Product Registry administered by the Danish Working Environment Authority.
6. Documentation of antimicrobial efficacy (see overview in Table 1)
   NB! The documentation must be submitted as EN-test reports in the full form including test data.
   - For disinfection products for hand disinfection and/or surgical hand disinfection - use Table 6.
   - For disinfection products for surface disinfection - use Table 7.
   - For disinfection products for instrument disinfection by submersion - use Table 8.
   - For disinfection products for room disinfection – use Table 9.

NB! Deviations from the protocols of the performed Tests by relevant EN standards must be described in details under "Deviations from the Tests by relevant EN standards".

7. Possible performed phase 3 tests ("in field-test").
8. Possible performed test on toxicity, allergy, etc.
9. Any relevant publications in peer-reviewed journals.
10. Any other relevant documentation (e.g. brochures, sales literature, reference to a website, etc.).

Steps for the evaluation procedure

1. Request for the evaluation by the applicant.
2. CEI mails the guidance document in Word-format, which MUST be used and filled in when submitting the required documentation.
3. The required documents are submitted by the applicant in a digitized format. Should there be a lack in documentation, CEI will request additional documentation or testing of the product.
4. CEI will only start the evaluation when all required material has been received.
5. If necessary, CEI reserves the right to obtain additional information or comments on chemical substances in the product from the Region's Chemical Cooperation (REKS) or other relevant parties (e.g. the Danish Working Environment Authority, The Danish Environmental Protection Agency, etc.).
6. A draft of an evaluation is sent to the applicant, who may comment the evaluation. CEI will prepare the final evaluation, containing a confidential part and a part for publication.
7. The applicant will receives a digital copy of the final assessment.
8. The evaluation is published on CEI's website.

Publication of the evaluation

CEI will issue a written evaluation in dialogue with the applicant. CEI reserves the right to formulate the final wording. The part of the evaluation not containing confidential information will be published on CEI's website.

NB! Test results according to relevant EN standards are not considered confidential information and will be presented in a summarized form in the evaluation.

The published evaluation may only be used in its full form unless otherwise agreed (in writing) with CEI.

Notes regarding marketing, etc.

If CEI observes or is informed about irregularities or errors in the registration, the labelling, the documentation of antimicrobial efficacy and/or undocumented claims of a product (which is not in accordance with the evaluation from CEI), CEI will act on this, informing the relevant authorities.

Documents to be completed and submitted

1. Overview of submitted documents

Fill in the form with a list of submitted documents indicating the document title and a short description of content. Document numbers from the list should be used in the later reference.

Table 2. Submitted documents.

Doc. N0.	Document title	Description of document content
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		
16.		
17.		
18.		
19.		
20.		

2. Information regarding the product

a. Name of disinfection product (or several (former) names, if there are more names in the submitted documentation).

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b. The applying company's name and the contact's details. If more companies are involved names of these companies and names of additional contacts indicating affiliation and status of access to confidential information (see paragraph c) to avoid accidental transmission of confidential information).

Table 3. The applicant's company name, contact information and confidential information.

	Names	Insight into confidential information (yes / no)
The applicant's company name: Contact:		
Name of the market leader: Contact:		
Name of the producer: Contact:		
Importing company name: Contact:		
Distributor company name: Contact:		
Supplier company name: Contact:		
Sub-contractor company name: Contact:		

c. Complete list of ALL ingredients with exact concentration and a declaration of purpose, e.g. **active substance, excipient, preservative, skin care product, detergent, surfactant, perfume,** etc.

NB! The detailed list of product ingredients is treated confidentially, but when seeking advice from the Regions' Chemical Cooperation (REKS) regarding toxicological and working environment aspects, REKS will be presented with the list of ingredients as well as any relevant documentation regarding working environment and/or environmental aspects.

Table 4. Complete list of ingredients.

Ingredients	CAS no. or EC no.	EXACT concentration in v/v% or w/w%	Purpose of ingredient*

*Enter the purpose of each ingredient, e.g. active substance, excipient, preservative, skin care product, perfume or other.

d. Description of disinfection task(s) in healthcare
Write here or refer to the document number and title.

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e. Information on the durability of the product and/or shelf life
Write here or refer to the document number and title.).

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f. Safety Data Sheet for the product
Refer to the document number and title.

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g. Danish instructions for the product and/or a product description
Write here or refer to the document number and title.

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h. Information on possible corrosive effect or any other impact on materials
Write here or refer to the document number and title

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3. Information on the status within the Biocidal Products Regulation

Fill in the form with information on whether all active substances (substances that are stated to have biocidal/antimicrobial efficacy) in the product are included in the Biocidal Products Regulation's positive list, negative list, in the list of active substances under evaluation or that the

active substance is not reviewed (see more on the Danish Environmental Protection Agency's website under "Biocides").

Table 5. Information on status according to the Biocidal Products Regulation (see more on ECHA's webpage under "Approval of active substances" and "Biocidal Active Substances").

Biocides (active substances)	CAS no.	EC no.	Status according to the Biocidal Products Regulation			
			Positive-list (product type)	Negative-list (product type)	Under evaluation	Not reviewed

4. Information on the status within the Medical Devices Directive

Specify whether the product is considered an accessory to medical devises and if it is, is it categorized and CE-marked.
Write here or refer to the document number and title.

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5. Documentation of the registration of the product in the Product Registry

Write here or refer to the document number and title.

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6. Documentation of tests for antimicrobial efficacy

- Fill in Table 6 for disinfection products for hand disinfection and/or surgical hand disinfection.
- Fill in Table 7 for disinfection products for surface disinfection.
- Fill in Table 8 for disinfection products for instrument disinfection by submersion.
- Fill in Table 8 for disinfection products for room disinfection

NB! The documentation must be submitted as relevant EN-test rapports in the full form including test data. Test results are not considered as confidentially. Deviations from the protocol of the performed Tests by relevant EN standards must be described in detail under "Deviations from the Tests by relevant EN standards".

NB! Products for disinfection must be in accordance with the Danish national guidelines: ”Nationale Infektionshygiejniske Retningslinjer (NIR) for desinfektion i sundhedssektoren”. and ”NIR om håndhygiejne”.

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7. Documentation if phase 3 tests ("in field-test") have been conducted

Write here or refer to the document number and title.

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8. Documentation if tests for toxicity/allergy have been conducted

Write here or refer to the document number and title.

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9. Relevant publications in peer-reviewed journals

Write here or refer to the document number and title.

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10. Any other relevant documentation

(E.g. brochures, sales material, reference to a website, etc.)
Write here or refer to the document(s) number and title.

Table 6. Tests by relevant EN standards of disinfection products for hand disinfection and surgical hand disinfection

Fill in the form and refer to doc.no in the overview list.

EN-Standard	Phase, step	Organic load	Efficacy	Test organisms	Performed yes / no. If yes: doc. No.
EN 13727	2,1	Clean conditions	Bactericidal	*Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* NCTC 10538 *Enterococcus hirae* ATCC 10541	
EN 1500	2,2	Clean conditions	Bactericidal	*Escherichia coli* NCTC 10538	
EN 12791 (surgical hand disinfection)	2,2	Clean conditions	Bactericidal	Test persons normal skin flora	
EN 13624	2,1	Clean conditions	Fungicidal	*Candida albicans* ATCC 10231	
EN 14476	2,1	Clean conditions	Virucidal	Poliovirus type 1, LSc-2ab Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine norovirus, strain S99 Berlin Vacciniavirus, strain Ankara (MVA), ATCC VR-1508 eller strain Elstree, ATCC VR-1549	
EN 17430	2,2	Clean conditions	Virucidal	Murine norovirus, strain S99 Berlin	
EN 14348	2,1	Clean conditions	Mykobactericidal	*Mycobacterium avium* ATCC 15769 *Mycobacterium terrae* ATCC 15755	

NB! The documentation must be submitted as EN-test rapports in the full form including test data.

Deviations from the Tests by relevant EN standards

Deviations from the protocol of the performed Tests by relevant EN standards must be described in detail.

Table 7. Tests by relevant EN standards of disinfection products for surface disinfection.

Fill in the form and refer to doc. no. in the overview list.

EN-Standard	Phase, step	Organic load	Efficacy	Test organisms	Performed yes / no. If yes: doc. No.
EN 13727	2,1	Clean and dirty conditions	Bactericidal	*Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* NCTC 10538 *Enterococcus hirae* ATCC 10541	
EN 17387	2,2	Clean and dirty conditions	Bactericidal	*Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* NCTC 10538 *Enterococcus hirae* ATCC 10541	
EN 16615	2,2	Clean and dirty conditions	Bactericidal	*Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Enterococcus hirae* ATCC 10541	
EN 13624	2,1	Clean and dirty conditions	Fungicidal	*Candida albicans* ATCC 10231 *Aspergillus brasiliensis* ATCC 16404	
EN 17387	2,2	Clean and dirty conditions	Fungicidal	*Candida albicans* ATCC 10231 *Aspergillus brasiliensis* ATCC 16404	
EN 16615	2,2	Clean and dirty conditions	Fungicidal	*Candida albicans* ATCC 10231	
*prEN 16615	2,2	Clean and dirty conditions	Fungicidal	*Aspergillus brasiliensis* ATCC 16404	
EN 14476	2,1	Clean and dirty conditions	Virucidal	Poliovirus type 1, LSc-2ab Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine norovirus, strain S99 Berlin Vacciniavirus, strain Ankara (MVA), ATCC VR-1508 eller strain Elstree, ATCC VR-1549	
EN 16777	2,2	Clean and dirty conditions	Virucidal	Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine norovirus, strain S99 Berlin Vacciniavirus, strain Ankara (MVA), ATCC VR-1508 eller strain Elstree, ATCC VR-1549	
**Modified EN 16615	2,2	Clean and dirty conditions	Virucidal	Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine norovirus, strain S99 Berlin Vacciniavirus, strain Ankara (MVA), ATCC VR-1508 eller strain Elstree, ATCC VR-1549	

EN 14348	2,1	Clean and dirty conditions	Mycobactericidal	*Mycobacterium avium* ATCC 15769 *Mycobacterium terrae* ATCC 15755	
*prEN 16615	2,2	Clean and dirty conditions	Mykobaktericidal	*Mycobacterium avium* ATCC 15769 *Mycobacterium terrae* ATCC 15755	
EN 17126	2,1	Clean and dirty conditions	Sporicidal	*Bacillus subtilis* sporer ATCC 6633 *Bacillus cereus* sporer CIP 105151 *Clostridium difficile* sporer NCTC 13366	
EN 17846	2,2	Clean and dirty conditions	Sporicidal	*Clostridium difficile* sporer NCTC 13366	

*prEN 16615 is a preliminary standard, i.e. it is a draft not finalised. Therefore, this standard is not mandatory for an evaluation until it is finalised, but it is recommended to test according to this standard.
**Tests according to a modified EN 16615 using test organisms according to EN 16777 can be used to document surface disinfection against viruses. Tests according to modified EN 16615 are not a mandatory requirement for an evaluation, but it is recommended to test according to a modified EN 16615 standard.

NB! The documentation must be submitted as EN-test rapports in the full form including test data.

Deviations from the Tests by relevant EN standards

Deviations from the protocol of the performed Tests by relevant EN standards must be described in detail.

Table 8. Tests by relevant EN standards of disinfection products for instrument disinfection by submersion

Fill in the form and refer to doc. no. in the overview list.

EN-Standard	Phase, step	Organic load	Efficacy	Test organisms	Performed yes / no. If yes: doc. No.
EN 13727	2,1	Clean and dirty conditions	Bactericidal	*Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* NCTC 10538 *Enterococcus hirae* ATCC 10541	
EN 14561	2,2	Clean and dirty conditions	Bactericidal	*Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Enterococcus hirae* ATCC 10541	
EN 13624	2,1	Clean and dirty conditions	Fungicidal	*Candida albicans* ATCC 10231 *Aspergillus brasiliensis* ATCC 16404	
EN 14562	2,2	Clean and dirty conditions	Fungicidal	*Candida albicans* ATCC 10231 *Aspergillus brasiliensis* ATCC 16404	
EN 14476	2,1	Clean and dirty conditions	Virucidal	Poliovirus type 1, LSc-2ab Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine norovirus, strain S99 Berlin	
EN 17111	2,2	Clean and dirty conditions	Virucidal	Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine norovirus, strain S99 Berlin Vacciniavirus, strain Ankara (MVA), ATCC VR-1508 eller strain Elstree, ATCC VR-1549	
EN 14348	2,1	Clean and dirty conditions	Mycobactericidal	*Mycobacterium avium* ATCC 15769 *Mycobacterium terrae* ATCC 15755	
EN 14563	2,2	Clean and dirty conditions	Mycobactericidal	*Mycobacterium avium* ATCC 15769 *Mycobacterium terrae* ATCC 15755	
EN 17126	2,1	Clean and dirty conditions	Sporicidal	*Bacillus subtilis* sporer ATCC 6633 *Bacillus cereus* sporer CIP 105151 *Clostridium difficile* sporer NCTC 13366	

NB! The documentation must be submitted as EN-test rapports in the full form including test data.

Deviations from the Tests by relevant EN standards

Deviations from the protocol of the performed Tests by relevant EN standards must be described in detail.

Table 9. Test by relevant EN standards of disinfection products for room disinfection.

Fill in the form and refer to doc. no. in the overview list.

EN-Standard	Phase, step	Organic load	Efficacy	Test organisms	Performed yes / no. If yes: doc. No.
EN 17272	2,2	Clean and dirty conditions	Bactericidal	*Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* NCTC 10536 *Enterococcus hirae* ATCC 10541 *Acinetobacter baumanii* ATCC 19606 *Proteus hauseri* ATCC 13315	
EN 17272	2,2	Clean and dirty conditions	Fungicidal	*Candida albicans* ATCC 10231 *Aspergillus brasiliensis* ATCC 16404	
EN 17272	2,2	Clean and dirty conditions	Virucidal	Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine norovirus, strain S99 Berlin Porcine Parvovirus strain NADL2	
EN 17272	2,2	Clean and dirty conditions	Mycobactericidal	*Mycobacterium avium* ATCC 15769 *Mycobacterium terrae* ATCC 15755	
EN 17272	2,2	Clean and dirty conditions	Sporicidal	*Bacillus subtilis* sporer ATCC 6633	

NB! The documentation must be submitted as EN-test rapports in the full form including test data.

Deviations from the Tests by relevant EN standards

Deviations from the protocol of the performed Tests by relevant EN standards must be described in detail.