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 manyyears 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.
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.
- 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 Danish Environmental Protection Agency is a national authority in Denmark and they will evaluate and approve disinfection products, which falls within jurisdiction of the Biocidal Products Regulation (product type 1-5), when all active substances have been evaluated and authorised on the European level.
If a manufacturer/marketing company of a disinfection product specifies that the product is specifically intended for disinfection of medical devices, the product is considered to be a medical device and therefore the product must comply with the requirements of the Medical Devices Directive which is under the jurisdiction of the Danish Medicines Agency. The product must be CE marked according to the Medical Devices Directive. A new EU regulation has been adopted and will come into force in 2020. More information on the Danish Medicines Agency website.
A disinfection product may be subjected to both the Biocidal Products Regulation and the Medical Device Directive, depending on the disinfection task(s) to which the product is intended. In this case, the requirements of both legislations must be fulfilled.

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, this document has to be used and completed (page 17 onwards) and mailed 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

Several aspects, which have an influence on whether CEI finds a disinfection product suitable for disinfection in Danish healthcare or not, are included in the evaluation.

Legislation

The product has to be legal according to both tEU legislation

- the Biocidal Products Regulation

and/or

- the Medical Devices Directory

and Danish legislation

- Danish Chemicals Act no 115 of 26/01/2017 from the Danish Ministry of Environment.
- Act concerning medical devices no 139 of 15/02/2016 from the Danish Ministry of Health.
- The Danish Product Safety Act No. 1262 of 16/12/2009 from the Danish Ministry of Health.
- The Working Environment Act No 1072 of 7 September 2010 from the Danish Ministry of Employment.
- LBK Consolidated Act on a pesticides' duty, Consolidation Act no 232 of 26/02/2015 from the Danish Ministry of Taxation.

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

In this context, the company has to ensure that the active substance(s) in a disinfection product that falls within the Biocidal Product Regulation has to be listed on the European Chemicals Agency's (ECHA) list of approved active substances for the relevant product type (e.g. PT 1 and/or PT 2) or on the list of active substances under evaluation for these product types. For more information see the Danish Environmental Protection Agency's website.

A disinfection product specifically intended for disinfection of medical devices may be defined as an accessory of medical devices, and the product will fall within the Medical Devices Directive. The product should be CE marked and categorized within the Medical Devices Directive and registered at 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.

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)
- On the environment (e.g. issues on waste removal)
- On bacteria (e.g. selection (resistance/tolerance/cross resistance to antibiotics), formation of biofilm).

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 Club 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.

Other factors included in the evaluation

CEI includes other information that is relevant for the use of a disinfection product.

- The user instruction for the product and/or the product description.
- Information on possible corrosive effects or other kind of impact on materials.
- Possible interaction of the product with organic materials or with other materials.
- The ease of use of the product (e.g. a ready-to-use product vs. a product, which has to be mixed).
- Possible odours from the product.
- Shelf life/durability of the product before and after it has been opened.

NB! CEI emphasizes, that in general, disinfection products containing fragrance or perfume will NOT be recommended for use in Danish healthcare. However, exceptions can be made. Additionally, in general, disinfection products containing ingredients suspected of causing an allergic skin reaction will NOT be recommended for hand and skin disinfection in Danish healthcare. Again, exceptions can be made.
In addition, CEI wishes to limit the use of active substances suspected of selecting for resistance or cross-resistance to antibiotics, as stated in the consensus statement on the principles for the use of disinfection in Danish healthcare.

Documentation of antimicrobial efficacy

CEI requires relevant documentation for the antimicrobial efficacy of the disinfection product for an evaluation. This documentation should primarily be based on harmonized European standards for testing the antimicrobial efficacy of disinfection products in the medical area, developed by the European standards organization CEN (Le Comité Européen de Normalisation).

Information included in CEI's evaluation is usually obtained by consulting relevant third parties, by searching relevant chemical and toxicological databases and peer-reviewed journals in biological, chemical, toxicological and medical literature databases.

REQUIREMENTS FOR DOCUMENTATION

Requirements for documentation of antimicrobial efficacy

According to the consensus statement, disinfection products are categorized according to their antimicrobial efficacy.
The evaluation of a product's antimicrobial efficacy is primarily based on harmonized European standards for testing of disinfection products (EN-tests). EN 14885 provides an overview of EN-tests in the area. 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-tests, according to the intended task of disinfection for a product (hand disinfection and surgical hand disinfection, surface disinfection, or disinfection by submersion) and how the disinfection product will be categorized.

Important considerations regarding EN-tests

When designing EN-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, perfumes, etc. (see also below on requirements for alcohol-based disinfection products and disinfection wipes).
Any deviations from the protocol for an EN-test 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").

Requirements for contact times in EN-tests

When testing products for hand disinfection the contact time in the tests (EN 1500) should be maximum 30 seconds and rubbing for 30 seconds should achieve dryness of the hands, wrists and forearms.
When testing products for surgical hand disinfection, the contact time when rubbing in the tests (EN 12791) should be 2 minutes.
When testing water-based products intended for surface disinfection of surfaces that are likely to come into contact with patients or staff close to the patient and “multitouch” contact points, the contact time in the tests should be maximum 5 minutes. The purpose of this is to reflect the actual contact time between the product and microorganisms on a surface during surface disinfection under practical conditions. This contact time must be stated in the instructions for the product. Testing with shorter contact times can be conducted, but in certain cases (when testing for antimicrobial efficacy against *Aspergillus brasiliensis* and bacteria spores) a contact time of 10-15 minutes may be necessary.
For alcohol-based products for surface disinfection the contact time used in the tests should reflect the time the product under practical conditions will be in contact with microorganisms on the surface before it evaporate from the surface. CEI’s recommendation is that this contact time must be no longer than 1 minute. The relation between the used contact time and the evaporation of the product should be documented.
When testing products for disinfection by submersion the contact time in the tests should be maximum 60 minutes. Testing with shorter contact times can be conducted and these contact times can be indicated in the instruction for the product.

Requirements for test concentrations of the product

The same concentration of the product as indicated in the instruction for the product should be used in all tests. The same concentration should be used when tested on the various types of microorganisms, as the antimicrobial efficacy against a given microorganism can be dependent on concentration.

Table 1. EN-tests for testing the antimicrobial efficacy of disinfection products to be used in healthcare according to EN 14885

Level of efficacy	Antimicrobial efficacy	Phase, step	Hand disinfection	Surgical hand disinfection	Surface disinfection		Disinfection by submersion
					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 13697 **c)**	EN 16615 **d)**	EN 14561
Low-level Intermediate-level High-level	Yeasticidal	2,1	EN 13624		EN 13624		EN 13624
		2,2			EN 13697 **c)**	EN 16615 **d)**	EN 14562
Intermediate-level **a)** High-level	Fungicidal	2,1			EN 13624		EN 13624
		2,2			EN 13697 **c)**	EN 16615 **d)**	EN 14562
Intermediate-level **b)** High-level	Virucidal (non-enveloped)	2,1	EN 14476		EN 14476		EN 14476
		2,2					
Intermediate-level High-level	Mycobactericidal	2,1	EN 14348		EN 14348		EN 14348
		2,2				EN 16615 **d)**	EN 14563
High-level	Sporicidal	2,1			EN 13704 **c)**		EN 13704 **c)**
		2,2					

a) For products to be categorized as having minimal or medium antimicrobial efficacy ("low-level" and "intermediate-level" disinfection), the tests should show "limited" antimicrobial efficacy against the mandatory organism *Aspergillus brasiliensis*. The "limited" efficacy may either be in the form of a lower log reduction or that the antimicrobial efficacy is achieved after a longer contact time (up to 15 minutes).
b) For products to be categorized as having medium antimicrobial efficacy ("intermediate-level" disinfection) the requirement is that tests according to EN 14476 must show the required antimicrobial efficacy against one or more of the mandatory organisms.
c) The standards are intended for use in the food industry, by consumers and institutions (not the medical area), but they are part of CEI's evaluation for the medical area.
d) EN 16615 has been published and implemented, and will be added to EN 14885 at the next revision. EN 16615 can be used in modified form to test antimicrobial efficacy against other non-mandatory test organisms, including mycobacteria and mold (*Aspergillus brasiliensis*).

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 requirement for alcohol-based disinfection products for hand disinfection as a gel is 80-85 vol/vol %, corresponding to approx. 74-80 weight/weight %. This is based partly on the existing literature on the antimicrobial efficacy of alcohol, partly on requirements from the Danish fire authorities. To achieve a sufficient hand disinfection the recommendation is that the hands should be rubbed for 30 seconds until dryness.

According to “The Substitution Principle” from the Working Environment Authority in Denmark and Region’s Chemical Cooperation (REKS) 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 for 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 the Regions Chemical Cooperation (REKS) propan-1-ol (n-propanol/1-propanol) should be marked: "Prolonged or repeated skin contact and/or inhalation of fumes, even in small amounts can cause damage to the central nervous system, liver and kidneys" and therefore it should be replaced by a less hazardous or harmful substance according to “The Substitution Principle". Therefore, disinfection products containing propane-1-ol (n-propanol/1-propanol) are not recommended for disinfection in Danish healthcare.

In summary

For an alcohol-based product to be recommended for disinfection in Danish healthcare, the product must meet the following requirements:

- The total concentration of alcohol in a liquid product must be 70-85 vol/vol %, corresponding to approx. 63-80 weight/weight %.
- The total concentration of alcohol in a gel product must be 80-85 vol/vol %, corresponding to approx. 74-80 weight/weight %.
- The product must be based on ethanol.
- 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).
- Hand rubs must contain skin care ingredients.
- Hand rubs must not contain allergens.
- An antimicrobial efficacy must be documented at a contact time of a maximum of 1 minute or 30 seconds (see relevant requirements for hand disinfection and surface disinfection).

Requirements for “high-level” disinfection products

In addition to having the previously mentioned documentation of antimicrobial efficacy, the requirement to be categorised as a high-level disinfection product for a chlorine-based product is a documentation of the *in situ* concentration of free chlorine (the sum of chlorine, hypochlorite and hypochloric acid in the solution to be used), as well as active chlorine (concentration of active hypochloric acid in the solution to be used) in ppm and pH in the in-use product. The requirement for a product based on hydrogen peroxide/peracetic acid is an additional documentation of the *in situ* generated active substances in ppm and pH in the in-use product.

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 have medium antimicrobial efficacy ("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 no allergens and that a product for surgical hand disinfection must contain chlorhexidine.

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 against all mandatory bacteria.
- In addition, for a product intended for hand disinfection, tests performed by EN 1500 must as a minimum show the required antimicrobial efficacy against the mandatory bacteria.
- In addition, for a product intended for surgical hand disinfection, tests performed by EN 12791 must as a minimum show the required antimicrobial efficacy against the mandatory bacteria.

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 against *Candida albicans*.

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

Antimicrobial efficacy against virus

There are no tests that demonstrate antimicrobial efficacy against enveloped viruses, but a product with documented antimicrobial efficacy against vegetative bacteria will also have antimicrobial efficacy against enveloped virus.

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

- Tests performed by EN 14476 must as a minimum show the required virucidal efficacy against one or more mandatory viruses.

For a product to be categorised as having medium antimicrobial efficacy ("intermediate-level" disinfection) with limited virucidal efficacy, the product must as a minimum show antimicrobial efficacy against one or more mandatory viruses (poliovirus, adenovirus and murine norovirus).
For a product to be categorised as having medium antimicrobial efficacy ("intermediate-level" disinfection) with full virucidal efficacy, the product must as a minimum show antimicrobial efficacy against all mandatory viruses (poliovirus, adenovirus and murine norovirus).
For surgical hand disinfection products documentation for virucidal efficacy is considered not relevant.

Antimicrobial efficacy against mycobacteria

For CEI to evaluate whether a product has mycobactericidal efficacy, 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 both mandatory bacteria.

Requirements for contact times in EN-tests of products for hand disinfection and surgical hand disinfection

When testing products for hand disinfection according to EN 1500, the contact time when rubbing in the tests should be maximum 30 seconds and rubbing for 30 seconds should achieve dryness of the hands, wrists and forearms.
When testing products for surgical hand disinfection according to EN 12791, the contact time when rubbing in the tests should be 2 minutes.

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 should be categorised.

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 against all mandatory bacteria.
- In addition to the testing by EN 13727, for a product intended for surface disinfection without mechanical treatment (e.g. by spraying), tests performed by EN 13697 must as a minimum show the required antimicrobial efficacy against all mandatory bacteria.
- In addition to the testing by EN 13727, for a product intended for surface disinfection with mechanical treatment (e.g. by wiping), tests performed by EN 16615 must as a minimum show the required antimicrobial efficacy against all mandatory bacteria.

For products to be categorized within all categories of disinfection products: minimal antimicrobial efficacy ("low-level" disinfection), medium antimicrobial efficacy ("intermediate-level" disinfection)

and maximum antimicrobial efficacy ("high-level" disinfection), the requirement is that the tests must as a minimum show antimicrobial efficacy according to the standards against all mandatory bacteria.

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 against *Candida albicans*.
- In addition to the testing by EN 13624, for a product intended for surface disinfection without mechanical treatment (e.g. by spraying), tests performed by EN 13697 depending on how the product should be categorised (see below), must as a minimum show the required antimicrobial efficacy against one or both test fungi.
- In addition to the testing by EN 13624, for a product intended for surface disinfection with mechanical treatment (e.g. by wiping), tests performed by EN 16615 depending on how the product should be categorised (see below), must as a minimum show the required antimicrobial efficacy against one or both fungi.

For products to be categorized within all categories of disinfection products: minimal antimicrobial efficacy ("low-level" disinfection), medium antimicrobial efficacy ("intermediate-level" disinfection) and maximum antimicrobial efficacy ("high-level" disinfection), the requirement is that the tests must as a minimum show the antimicrobial efficacy against yeast (*Candida albicans*) in the standards.
For a product to be categorised as having medium antimicrobial efficacy ("intermediate-level" disinfection), the requirement is that the tests must as a minimum show "limited" antimicrobial activity against mold (*Aspergillus brasiliensis*). The "limited" efficacy can either be in the form of a lower log reduction or that the standard antimicrobial efficacy has been obtained after a longer contact time (see requirements for contact time).
For a product to be categorised as having maximum antimicrobial efficacy ("high-level" disinfection), the requirement is that the tests must as a minimum show fungicidal efficacy against both types of fungi.

Antimicrobial efficacy against virus

There are no tests that demonstrate antimicrobial efficacy against enveloped viruses, but a product with documented antimicrobial efficacy against vegetative bacteria will also have antimicrobial efficacy against enveloped virus.

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

- Tests performed by EN 14476 depending on how the product should be categorised (see below), must as a minimum show the required virucidal efficacy against one or more mandatory viruses.

For a product to be categorised as having minimal antimicrobial effect ("low-level" disinfection), the product is not required to be tested by EN 14476.

For a product to be categorised as having medium antimicrobial efficacy ("intermediate-level" disinfection) with limited virucidal efficacy, the product must as a minimum show antimicrobial efficacy against one or more mandatory viruses (poliovirus, adenovirus and murine norovirus).
For a product to be categorised as having medium antimicrobial efficacy ("intermediate-level" disinfection) with full virucidal efficacy, the product must as a minimum show antimicrobial efficacy against all mandatory viruses (poliovirus, adenovirus and murine norovirus).
For a product to be categorised as having maximum antimicrobial effect ("high-level" disinfection), the product must as a minimum show antimicrobial efficacy against all mandatory viruses (poliovirus, adenovirus and murine norovirus).

Antimicrobial efficacy against mycobacteria

For CEI to evaluate whether a product has mycobactericidal efficacy, 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 both mandatory bacteria.

As EN 16615 at the moment do not include mycobacteria as mandatory test organisms, CEI can only recommend that the following tests should been performed:

- For a product intended for surface disinfection with mechanical treatment (e.g. by wiping), modified tests using EN 16615, depending on how the product should be categorized (see later), should show antimicrobial effect against the EN 14348 required mandatory bacteria.

For a product to be categorised as having minimal antimicrobial effect ("low-level" disinfection), the product is not required to be tested by EN 14348 or EN 16615.
For a product to be categorised as having medium or maximum antimicrobial efficacy ("intermediate-level" or "high-level" disinfection), the product must as a minimum show antimicrobial efficacy against both mandatory bacteria.
As EN 16615 at the moment do not include mycobacteria as mandatory test organisms, CEI can only recommend that a product intended for surface disinfection with mechanical treatment (e.g. by wiping), should be tested according to a modified EN 16615 and show antimicrobial effect against the EN 14348 required mandatory bacteria.

Antimicrobial efficacy against bacteria spores

The current standard for testing of sporicidal efficacy, EN 13704, does not at the moment cover the medical area.

For CEI to evaluate whether a product has sporicidal efficacy, CEI can only recommend that the following tests should to be conducted:

- Tests using EN 13704 should show the standard antimicrobial efficacy against the mandatory bacterial spores.

For a product to be categorised as having minimal or medium antimicrobial effect ("low-level" or “intermediate-level" disinfection), the product is not required to be tested by EN 13704.
For a product to be categorised as having maximum antimicrobial efficacy ("high-level" disinfection), CEI can only recommend that the product should be tested according to EN 13704 and show sporicidal efficacy against the mandatory bacterial spores.

Requirements for contact times in EN-tests of products for surface disinfection

When testing water-based products for surface disinfection of surfaces that are likely to come into contact with patients or staff close to the patient and “multitouch” contact points, the tests must be performed at a contact time of a maximum of 5 minutes.
In certain cases (when testing for antimicrobial efficacy against *Aspergillus brasiliensis* and bacteria spores) when products are to be categorised as having minimal or medium antimicrobial effect ("low-level" or “intermediate-level" disinfection),a contact time of 10-15 minutes may be used.

When testing alcohol-based products for surface disinfection, the contact time used in the standards should reflect the time that the given product in a practical situation will be in contact with microorganisms, before it evaporates from the surface. CEI’s recommendation is that this contact time must be no longer than 1 minute. This contact time must be stated in the instructions for the product and/or a product description. Use of longer contact times, must be referred to in instructions for the product and/or the product description.

Specific requirements for disinfection wipes

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 tests described above (not EN 16615) should be conducted using the wring out liquid from wipes. Alternatively, it must be documented that the wring out liquid is absolutely identical to the liquid being added to the wipes.

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.

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 antimicrobial efficacy against all mandatory bacteria.
- Tests performed by EN 14561 must as a minimum show the required antimicrobial efficacy against all mandatory bacteria.

Antimicrobial efficacy against fung

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 antimicrobial efficacy against both mandatory fungi.
- Tests performed by EN 14562 must as a minimum show the required antimicrobial efficacy against both mandatory fungi.

Antimicrobial efficacy against virus

There are no tests that demonstrate antimicrobial efficacy against enveloped viruses, but a product with documented antimicrobial efficacy against vegetative bacteria will also have antimicrobial efficacy against enveloped virus.

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

- Tests performed by EN 14476 must as a minimum show the required antimicrobial efficacy against all mandatory viruses.

Antimicrobial efficacy against mycobacteria

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

- Tests performed by EN 14348 must as a minimum show the required antimicrobial efficacy against both mandatory bacteria.
- Tests performed by EN 14563 must as a minimum show the required antimicrobial efficacy against both mandatory bacteria.

Antimicrobial efficacy against bacteria spores

The current standard for testing of sporicidal efficacy, EN 13704, does not at the moment cover the medical area.

For CEI to evaluate whether a product has sporicidal efficacy, CEI can only recommend that the following tests should to be conducted:

- Tests using EN 13704 should as a minimum show the standard antimicrobial efficacy against the mandatory bacterial spores.

For a product to be categorised as having maximum antimicrobial efficacy ("high-level" disinfection), CEI can only recommend that the product should be tested according to EN 13704 and show sporicidal efficacy against the mandatory bacterial spores.

Requirements for contact times in EN-tests of products for disinfection by submersion

CEI's general recommendation is a contact time of 60 minutes to ensure optimal instrument disinfection by submersion. In some cases (e.g. if the instruments/medical devices are less tolerant to disinfection products), contact time may be shorter if this is documented for the product.

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.

   NB! Deviations from the protocols of the performed EN-tests must be described in details under "Deviations from the EN-tests".
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 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. 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. no.	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:		
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 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 with confidentially.

Table 4. Complete list of ingredients

Ingredients	**CAS no. or EC no.**	**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 about all active substances.

Table 5. Information on status according to the Biocidal Products Regulation

ACTIVE BIOCIDER (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.

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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

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

- 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.

NB! Deviations from the protocol of the performed EN-tests must be described in detail under "Deviations from the EN-tests".

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7. Documentation of phase 3 tests ("in field-test")

Write here or refer to the document number and title.

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8. Documentation of tests for toxicity/allergy

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. EN-tests 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, steps	Organic load	Effect	Test Strains	Performed yes / no. If yes: doc. No.
EN 13727	2,1	Clean conditions	Bactericidal	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541	
EN 1500	2,2		Bactericidal	*Escherichia coli* K12 NCTC 10538; CIP 54.117; NCIMB 10083	
EN 12791 (surgical hand disinfection)	2,2		Bactericidal		
EN 13624	2,1	Clean conditions	Fungicidal	*Candida albicans* ATCC 10231	
EN 14476	2,1	Clean conditions	Virucidal	Poliovirus type 1, LSc-2ab[a] Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine norovirus, strain S99 Berlin, Friedrich Löffler-Institut	
EN 14348	2,1	Clean conditions	Mycobacte-ricidal	*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 EN-tests

Deviations from the protocol of the performed EN-tests must be described in detail.

Table 7. EN-tests 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	Effect	Test Strains	Performed yes/no. If yes: doc. no.
EN 13727	2,1	Clean and dirty conditions	Bactericidal	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541	
EN 13697	2,2	Clean and dirty conditions	Bactericidal	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Escherichia coli* ATCC 10 536.	
EN 16615	2,2	Clean and dirty con-ditions	Bactericidal	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541	
EN 13624	2,1	Clean and dirty conditions	Fungicidal	*Candida albicans* ATCC 10231 *Aspergillus brasiliensis* ATCC 16404	
EN 13697	2,2	Clean and dirty conditions	Fungicidal	*Candida albicans* ATCC 10231 *Aspergillus brasiliensis* ATCC 16404	
EN 16615	2,2	Clean and dirty con-ditions	Fungicidal	*Candida albicans* ATCC 10231	
(EN 16615)	2,2	Clean and dirty con-ditions	Fungicidal	*Aspergillus brasiliensis* ATCC 16404	
EN 14476	2,1	Clean and dirty conditions	Virucidal	Poliovirus type 1, LSc-2ab[a] Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine Norovirus, strain S99 Berlin, Friedrich Löffler-Institut	
EN 14348	2,1	Clean and dirty conditions	Mycobacte-ricidal	*Mycobacterium avium* ATCC 15769 *Mycobacterium terrae* ATCC 15755	
(EN 16615)	2,2	Clean and dirty con-ditions	Mycobacte-ricidal	*Mycobacterium avium* ATCC 15769 *Mycobacterium terrae* ATCC 15755	
(EN 13704)	2,1	Clean conditions	Sporicidal	*Bacillus subtilis* ATCC 6633 *Bacillus cereus* ATCC 12826 *Clostridium sporogenes* CIP 7939	

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

Deviations from the EN-tests

Deviations from the protocol of the performed EN-tests must be described in detail.

Table 8. EN-tests 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	Effect	Test Strains	Performed yes/no. If yes: doc. no.
EN 13727	2,1	Clean and dirty conditions	Bactericidal	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541	
EN 14561	2,2	Clean and dirty conditions	Bactericidal	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538 *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[a] Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine Norovirus, strain S99 Berlin, Friedrich Löffler-Institut	
EN 14348	2,1	Clean and dirty conditions	Mycobacte-ricidal	*Mycobacterium avium* ATCC 15769 *Mycobacterium terrae* ATCC 15755	
EN 14563	2,2	Clean and dirty conditions	Mycobacte-ricidal	*Mycobacterium avium* ATCC 15769 *Mycobacterium terrae* ATCC 15755	
(EN 13704)	2,1	Clean conditions	Sporicidal	*Bacillus subtilis* ATCC 6633 *Bacillus cereus* ATCC 12826 *Clostridium sporogenes* CIP 7939	

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

Deviations from the EN-tests

Deviations from the protocol of the performed EN-tests must be described in detail.