STATENS SERUM INSTITUT

EVALUATION OF PRODUCTS FOR DISINFECTION IN DANISH HEALTHCARE

A guidance document on the evaluation procedure, requirements for documentation and legislation
(February 2018)

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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 summerizasion 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 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 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 and classified 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, CEI's guidance document has to be used in a word formate. On request CEI will mail the guidance document in word formate and the applicant will fill-in the document (page 17 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

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 EU and Danish legislation

- the Biocidal Products Regulation

and/or

- the Medical Devices Directory

and other 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 1084 of 19/09/2017 from the Danish Ministry of Employment.
- 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 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 classified 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 from ECHA.

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).

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 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

In the evaluation CEI also include other factors, which is considered relevant for the use of a product for disinfection.
This include a user instruction for the product and/or a product description in Danish.

NB! CEI recommends that the manufacturer/the marketing company of a product follow ECHA's guidance in legislation on biocidal products.

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 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 odors 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/chemicals.
- Possible requerements for use of protective equipment when using the product.

NB! CEI emphasizes, that in general, disinfection products containing fragrance or perfume will NOT be recommended for use in Danish healthcare. Disinfection products containing chemicals wich are seriosly damgerous to humans (mutagenic, teratogenic, carcinogenic, endocrine disrupting) will generally NOT be recommended for use in Danish healthcare. However, exceptions can be made.
Additionally, disinfection products containing ingredients suspected of causing an allergic skin reaction will NOT be recommended for hand and skin disinfection in Danish healthcare.
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). See requirements for documentation of antimicrobial efficacy.

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.

NB! The detailed list of ingredients in the product that CEI requires for the evaluation (see later) will be treated confidentially, but as CEI some times request advice from the Region's Chemical Cooperation (REKS) on toxicological and occupational aspects, REKS 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 summerized in the evaluation.

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 standards). EN 14885 provides an overview of the EN standards 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 standards, 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 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, perfumes, 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").

Requirements for contact times in Tests by relevant EN standards

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 2-5 minutes.

When testing products intended for 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 (according to EN 14885). Testing with shorter contact times can be conducted and claimed. In certain cases (i.e. when testing for antimicrobial efficacy against *Aspergillus brasiliensis* and bacteria spores) a contact time of 10-15 minutes may be necessary. 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". It does not mean that the surface have to be visibly wet during this period, as the added disinfectant may evaporate. The contact time should be the time used for surface disinfection and should be stated/claimed in the user instruction for the product and/or the product description.

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 claimed 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.

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 % (requirements for hand disinfection products as a gel is under revision and might be changed). The recommendations 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.

Table 1. Tests by relevant EN standards for testing the antimicrobial efficacy of disinfection products to be used in healthcare according to EN 14885

Krav ifm. kategorise-ring	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 13727:2015		EN 13727:2015		EN 13727:2015
		2,2	EN 1500:2013	EN 12791:2017	EN 13697:2015 **c)**	EN 16615:2015 **d)**	EN 14561:2006
Low-level **a)** Intermediate-level **a)** High-level	Yeasticidal	2,1	EN 13624:2013		EN 13624:2013		EN 13624:2013
		2,2	***		EN 13697:2015 **c)**	EN 16615:2015 **d)**	EN 14562:2006
Low-level **a)** Intermediate-level **a)** High-level	Fungicidal	2,1	***		EN 13624:2013		EN 13624:2013
		2,2	***		EN 13697:2015 **c)**	**modificeret EN 16615 **d)**	EN 14562
Intermediate-level **b)** High-level	Virucidal (non-envel-oped)	2,1	EN 14476:2015	***	EN 14476:2015		EN 14476:2015
		2,2	*	**	EN 16777		*prEN 17111 **e)**
Intermediate-level High-level	Mycobacteri-cidal	2,1	EN 14348:2005		EN 14348:2005		EN 14348:2005
		2,2	***		**	**modificeret EN 16615 **d)**	EN 14563:2008
High-level	Sporicidal	2,1	***		EN 13704:2002 **c)** *prEN 17126 **e)**		EN 13704:2002 **c)** *prEN 17126 **e)**
		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 14476:2015 must show the required antimicrobial efficacy against one or more of the mandatory organisms (poliovirus, adenovirus eller murin norovirus).
c) The standards are intended for use in the food industry, by consumers and institutions (not the medical area). Accordingly, CEI will evaluate individually whether a disinfection product for surface disinfection is likely to have a sufficient efficacy.
d) EN 16615 has been published and implemented. EN 16615 can be used in modified form to test antimicrobial efficacy against other non-mandatory test organ-isms, including mold (*Aspergillus brasiliensis*) and mycobacteria, but not spores from bacteria.
e) prEN 17111 and prEN 17126 are preliminary, i.e. available as drafts, which has not yet been finalized. These are therefore not included as mandatory require-ments for CEI's evaluation until a final version is available.

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

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 % (this is under revision and might be changed).
- 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.

Requirements for “high-level” disinfection products

For a product to be kategorised as a “high-level” disinfection products the requirement is that the product has been tested on all obligatory testsorganisms according to relevant EN standards for bactericidal, yeasticidal, fungicidal, virucidal and mycobactericidal efficacy.
Currently, there is only one EN standard for testing sporicidal efficacy (EN 13704), which is a suspension test not directed to the medical area. Therefore, there should be increased awareness of whether a disinfection product for surface disinfection is likely to have sufficient sporicidal efficacy.
In addition to having the previously mentioned documentation of antimicrobial efficacy, the requirement for a product to be categorised as a high-level disinfection product is, that all the *in situ* generated active substances with excact concentration in the product should be documented.
The requirement for a product based on chlorine (where the active substances are hypochlorite/hypochloric acid) is an additional documentation of the *in situ* generated active substances of either **free** chlorine (the sum of chlorine, hypochlorite and hypochloric acid in the solution to be used) or **active** chlorine (concentration of active hypochloric acid in the solution to be used) in ppm and the pH-value 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 the pH-value 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. In addition, the requirement for a product for surgical hand disinfection the product must contain chlorhexidine (this requirement is under revision and might be changed).

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 (*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 (an addition to EN 14476 is curremtly in progress), 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 Tests by relevant EN standards 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 2-5 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 yesticidal efficacy. EN 16615 can in a modified form be used to show fungicidal efficacy (*Aspergillus brasiliensis*).

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.

A draft of a preliminary standard (prEN 16777) is available, but is not yet finalized. Therefore it is not included as mandatory requirement for CEI's evaluation until a final version is available.

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.

A draft of a preliminary standard (prEN 17126) is available, but is not yet finalized. Therefore it is not included as mandatory requirement for CEI's evaluation until a final version is available.
EN 16615 cannot be used to show sporicidal efficacy.

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 tests by relevant EN standards of products for 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 “multitouch” 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, but in certain cases (i.e. when testing for antimicrobial efficacy against *Aspergillus brasiliensis* and bacteria spores) a contact time of 10-15 minutes may

be necessary. 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". It does not mean that the surface have to be visibly wet during this period, as the added disinfectant may evaporate. The contact time should be the time used for surface disinfection and should be stated/claimed in the user instruction for the product and/or the product description.
If surface disinfection is carried out by wiping (either with a preimpregnated disinfection wipe or by adding a disinfectionfluid to a wipe) the efficacy should be tested according to EN 16615 and the fluid in or added to the wipe should be tested according to other relevant suspension tests (see Table 1). EN 16615 can be modified to show efficacy against mold (*Aspergillus brasiliisisis*) and mycobactericidal and tuberculosidal efficacy but currently, it cannot be used to show sporicidal efficacy.
If a disinfection wipe or the wiping with a wipe added a disinfectant meets the requirements of EN 16615, as well as the relevant suspension tests, there is sufficient evidence of efficacy against the tested spectrum of microorganisms.
Currently, there is only one EN test standard for testing sporicidal efficacy (EN 13704), which is a suspension test not directed to the medical area. Therefore, there should be increased awareness of whether a given disinfection product for surface disinfection is likely to have a sufficient sporicidal efficacy.
For this reason, CEI recommend, that to obtain a sufficient sporicidal efficacy for surface disinfection one should when using chlorine-based products (where the active substances will be hypochloric acid / hypochlorite):

- apply a concentration of at least 1000 ppm **active** chlorine (typically products with pH <8, where the active substance primarily will be in the form of hypocloric acid) or
- apply a concentration of at least 5000 ppm **free** chlorine (typically products with pH> 8, where the active substance primarily will be in the form of hypochlorite.

In both situations it is recommended to use a contact time where the surface is visibly wet for at least 10 minutes.

Specific requirements for disinfection wipes

If surface disinfection is carried out by wiping with a preimpregnated disinfection wipe the efficacy should be tested according to EN 16615 and the fluid in the wipe should be tested according to other relevant suspension tests (see Table 1). EN 16615 can be modified to show efficacy against mold (*Aspergillus brasiliisisis*) and mycobactericidal and tuberculosidal efficacy but currently, it cannot be used to show sporicidal efficacy.
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) 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, as well as the relevant suspension tests, there is sufficient evidence of efficacy against the tested spectrum of microorganisms. As described previously this do not include sporicidal efficacy.

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 Tests by relevant EN standards 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 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 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.

---

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

---

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

---

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 Tests by relevant EN standards must be described in detail under "Deviations from the Tests by relevant EN standards".

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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. 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, 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 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	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 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	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 Tests by relevant EN standards

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