

## STERISAFE PRO

The company Sterisafe ApS has requested an evaluation from National Center for Infection Control (CEI) of the product STERISAFE PRO. Sterisafe ApS wants CEI's evaluation of whether STERISAFE PRO can be used for disinfection of non-critical equipment in a dedicated room setting.

STERISAFE PRO is a mobile, automated room disinfection unit/robot that - in a disinfection process - uses water to increase air humidity and electricity to create the active substance ozone from the surrounding air. Ozone concentration to be used in the disinfection process is up to 350 ppm.

Documentation for antimicrobial efficacy has been submitted by tests in accordance with the EN standard for room disinfection (EN 17272), which shows that STERISAFE PRO meets the antimicrobial efficacy required by the standard when tested in a 33.12 m<sup>3</sup> room under clean conditions against:

- Bacteria at a concentration of 135 ppm for 240 min. with 85% relative humidity (RH)
- Fungi at a concentration of 320 ppm for 360 min. with 85% RH
- Virus at a concentration of 160 ppm for 240 min. with 86% RH
- Mycobacteria at a concentration of 350 ppm for 720 min. with 85% RH
- Bacterial spores at a concentration of 350 ppm for 720 min. with 85% RH.

### Issues to be addressed before the use of ozone for disinfection in the health care sector

- Material compatibility.  
There are several types of material, which are more or less incompatible with ozone. In the submitted user manual, it is stated, that a number of different metals will corrode, and that iron, natural rubber and nitrile are incompatible with ozone.
- Generation of potentially toxic by-products.  
A report prepared by Teknologisk Institut has been submitted, where a set-up based on a 30 min. exposure time with an ozone concentration of approx. 80 ppm. This generates a formaldehyde concentration, which is stated to be around 20% of the limit value for formaldehyde. From the submitted documentation according to EN 17272, it appears that it requires higher ozone concentrations and longer exposure time to achieve the required antimicrobial efficacy defined in the standard. No data have been submitted for generated concentrations of formaldehyde, volatile organic compounds (VOCs) and other potential toxic chemicals, which are formed by using higher ozone concentrations and longer exposure time.

### Conclusion

- It is documented that STERISAFE PRO has the required antimicrobial efficacy on clean surfaces in a 33.12 m<sup>3</sup> room against bacteria, fungi, virus, mycobacteria and bacteria spores under clean conditions at an ozone concentration of 350 ppm for 720 min. with 85-86% RH.
- CEI finds, that STERISAFE PRO can be used for the disinfection of surfaces on non-critical equipment in the health care sector, provided that the issues listed above are taken into account and addressed. Additionally, it needs to be ensured that people are not exposed to concentrations of ozone and formaldehyde, which are higher than the limit values set by the Working Environment Authority.

**Note.** CEI's recommendation is that, in the most cases, non-critical equipment should only be cleaned with soap and water. Only in the presence of special microorganisms, in the event of an outbreak or in the event of spillage of human biological material should cleaning be supplemented with disinfection in accordance to the national Danish guidelines for infection prevention and control, see [NIR om supplerende forholdsregler ved infektioner og bærertilstand i sundhedssektoren](#) and [NIR for desinfektion i sundhedssektoren](#).