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2023-04-03

Microbiocidal activity (bactericidal, fungicidal and mycobactericidal claim) of a plasma disinfection process in a “PlasmaEgg®” device

Expert Opinion

In September 2021, December 2022 and February 2023, tests on the activity of a plasma disinfection process using a “PlasmaEgg®” device were performed at the accredited test lab for medical devices and disinfectants HygCen Germany GmbH (test reports 2021-2891_SN32538, dated 2021-09-10, 2022-3220_SN 35808, dated 2022-12-28 and 2023-0394_SN 36115, dated 2023-02-10). The activity tests were performed against several bacterial, fungal and mycobacterial strains in order to claim bactericidal, fungicidal and mycobactericidal activity according to the required reduction factors in the medical area defined in EN 14885.

The following strains have been used:

Bacteria: *Enterococcus faecium*; *Pseudomonas aeruginosa*; *Staphylococcus aureus*; *Escherichia coli* and *Proteus mirabilis*

Yeast: *Candida albicans*

Fungi: *Aspergillus brasiliensis*

Mycobacteria: *Mycobacterium terrae*; *Mycobacterium avium*

The tests were performed on different carrier materials (plastic, silicone and textiles). No interfering substance was added to the test setup. Different holding times of the process were applied (20, 60, 90 and 120min).

Activity on nonporous surfaces (silicone and plastic) can be confirmed for the parameters shown in table 1 and 2 (only the parameters that passed the requirements are listed).

Tab.1: Activity on nonporous surfaces (silicone)

Test strain	Holding time	Required reduction	Reached reduction
<i>Staphylococcus aureus</i> (bactericidal claim)	20min	≥5 lg	>5.51 lgR
<i>Candida albicans</i> (yeastocidal claim)	20min	≥4 lg	>6.08 lgR
<i>Aspergillus brasiliensis</i> (fungicidal claim)	60min	≥4 lg	≥6.66 lgR

Tab.2: Activity on nonporous surfaces (plastic)

Test strain	Holding time	Required reduction	Reached reduction
<i>Staphylococcus aureus</i> (bactericidal claim)	20min	≥5 lg	>5.82 lgR
<i>Candida albicans</i> (yeasticidal claim)	20min	≥4 lg	>5.75 lgR
<i>Aspergillus brasiliensis</i> (fungicidal claim)	60min	≥4 lg	≥6.72 lgR

Activity on porous surfaces (textiles) can be confirmed for the parameters shown in tab. 3 (only the parameters that passed the requirements are listed).

Tab.3: Activity on porous surfaces (textile)

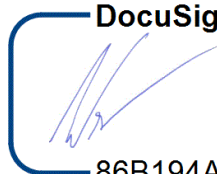
Test strain	Holding time	Required reduction	Reached reduction
<i>Enterococcus faecium</i> (bactericidal claim)	20min	≥5 lg	5.39 lgR
<i>Pseudomonas aeruginosa</i> (bactericidal claim)	20min	≥5 lg	≥6.32 lgR
<i>Staphylococcus aureus</i> (bactericidal claim)	20min	≥5 lg	>5.92 lgR
<i>Escherichia coli</i> (bactericidal claim)	20min	≥5 lg	≥5.60 lgR
<i>Proteus mirabilis</i> (bactericidal claim)	20min	≥5 lg	≥6.20 lgR
<i>Candida albicans</i> (yeasticidal claim)	20min	≥4 lg	>5.00 lgR
<i>Aspergillus brasiliensis</i> (fungicidal claim)	90min	≥4 lg	≥6.04 lgR
<i>Mycobacterium terrae</i> (mycobactericidal claim)	20min	≥4 lg	≥6.08 lgR
<i>Mycobacterium avium</i> (mycobactericidal claim)	20min	≥4 lg	≥6.08 lgR

Summary and evaluation

After 20 minutes contact time, bactericidal and yeasticidal activity could be demonstrated on nonporous surfaces (silicone and plastic). Fungicidal activity can be confirmed for a contact time of 60 minutes. The tests were carried out without interfering substances.

On porous surfaces (textiles), bactericidal, yeasticidal and mycobactericidal activity could be demonstrated after 20 minutes of contact time. Fungicidal activity can be confirmed for a contact time of 90 minutes. The tests were carried out without interfering substances.

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