EVALUATION OF BIOCIDAL ACTIVITY OF « DUST FREE AIRKNIGHT» PROCESS ACCORDING TO A METHOD BASED ON EN 17272

(20°C ± 2°C – CLEAN CONDITIONS)

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INDEX OF REVISIONS

Each revision of the test report cancels/supersedes the previous one.
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Amendment history		
Report N°	Amended paragraph(s)	Purpose of the amendment
3194.KLI.21.17272 – V1	-	Creating the report

CONTENT

I. DESCRIPTION OF THE STUDY:

Title:	Evaluation of biocidal activity of « Dust Free Airknight » process according to a method based on EN 17272 (20°c ± 2°C – Clean conditions)
Internal reference:	Study N° : 3194.KIL.20
Sponsor:	KLIMA RODACLIM 255 Avenue De La Roche Fourcade ZI St Mitre 13400 AUBAGNE Contact : Jean-Baptiste SALGI
Test period:	From : 02/03/2020 to 02/06/2020
Study manager:	Suzy BULOT
Test done by:	Andréa COL
Test laboratory :	Laboratoire EUROFINS BIOTECH – GERMANDE Parc Scientifique de Luminy 163 avenue de Luminy – Case 927 13288 Marseille Cedex 9

II. OBJECTIVE OF THE STUDY:

Evaluate, according to the test conditions described in EN 17272, the capacity of « Dust Free Airknight » process to reduce, in presence of specific interfering substances (clean conditions), in 2 and 6 hours, of at least 10^5 the number of viable cells of *Staphylococcus aureus* dried on stainless steel disk.

III. TESTED PROCESS:

Name:.....	Dust Free Airknight (cf. figure n°1)
Serial number*:.....	07020
Manufacturer:.....	KLIMA RODACLIM
Disinfectant used *:.....	N.A.

*Data provided by the customer, do not engage the laboratory responsibility.

Figure n°1: Dust Free Airknight ▶

IV. METHOD:

a) Tested strain:

Staphylococcus aureus CIP 4.83

The conditions of preservation and control of the microbial strains used for the determination of the bactericidal activity are those described in the European standard NF EN 12353 (internal protocol: T-DM-S-WO37879).

b) Interfering substances:

Bovine albumine:.....	0,03g
Tryptone-salt:.....	q.S.p. 100ml
Bovine albumine concentration:.....	0,3g/l
Internal reference:.....	03022021

Sterilized by membrane filtration.

c) Neutralizing solution:

Composition of the neutralizing solution:

Tween 80:.....	10% (v /v)
Lecithin:.....	2%
Sodium thiosulfate:.....	2%
L-Histidin:.....	2%
Saponin:.....	1%
Tryptone soya broth:.....	q.s.p. 100ml

Steam sterilized (121°C, 21 minutes).

Internal reference: E339.1.1/E330.2.1

d) Growth and counting conditions:

Trypticase soya agar.

Steam sterilized (121°C, 21 minutes).

Internal reference : E338.2.2/E338.2.3

e) Carriers:

Stainless steel disk according to the paragraph 5.2.3.2 of the standard.

f) Conditions of use of the device:

The method used for the test is described in the standard EN 17272 (Fig. 1).

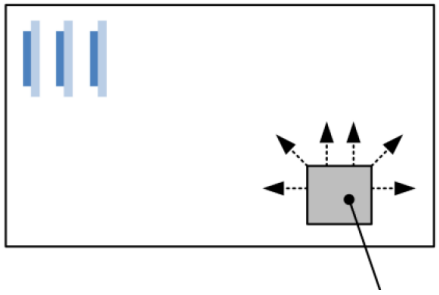

Figure 1. Arrangement of the equipment during the test. The carriers are placed opposite side to the disinfectant process according to the specification of the standard.

Areas:.....	80m^3
Tested temperature:.....	20°C ± 2°C
Incubation temperature:.....	37°C ± 1°C
Aspect of the product:.....	Incolore/inodore
Relative humidity:.....	Between 51.2% and 58.3%

V. RESULTS:

Contact time	Microbial test suspension (N) (Nb. CFU/ml)	Preliminary tests			Positive control (T) (Nb. CFU/carrier)	Test		
		n_1/N_1	n_2/N_2	n_3/N_1		n'1+n'2	Log_{10} reduction - mean	Red %
2 hours	$1,4.10^9$	122/136 127/136	98/115 103/115	118/136 137/136	$T_{2h}=1,3.10^7$	d1: $4,8.10^6$ d2: $4,3.10^6$ d3: $6,7.10^6$	R1: 6,7 R2: 6,6 R3: 6,8 **Rmean =0,4**	**60%**
6 hours					$T_{6h}=1,0.10^7$	d1: $4,8.10^5$ d2: $3,7.10^6$ d3: $2,5.10^6$	R1: 1,3 R2: 0,4 R3: 0,6 **Rmean =0,8**	**78%**
24 hours					$T_{24h}=2,1.10^6$	d1: $1,8.10^5$ d2: $1,3.10^5$ d3: $1,1.10^5$	R1: 1,1 R2: 1,2 R3: 1,3 **Rmean =1,2**	**93%**

Table 1: Results. Evaluation of biocide activity of « Dust Free FC Unit » process according to EN 17272 against *Staphylococcus aureus* CIP 4.83. T: number of microorganisms on control disks. N1: counting of test suspension for dilution/inclusion – N2: counting of test suspension by filtration. n1: search of inhibitor effect in the agar medium. – n2: Search of inhibitor effect in membrane. n'1: number of surviving test organism in 100 ml of recovery liquid – n'2: number of colonies obtained directly by inclusion of the carrier. n'1+n'2: number of microorganisms on the test carrier. d1: disk n°1/d2: disk n°2/d3: disk n°3.

Hydrogen peroxide concentration measuring:

Device used: Dräger Polytron 7000

Detected concentration (device off): 0 ppm

Detected concentration (during testing): 0 ppm

Ozone concentration measuring:

Device used: AOM3000 O3 OZONE GAS MONITOR*

Detected concentration (device off): between 4 and 6 ppb

Detected concentration (during testing): between 4 and 6 ppb

*Customer-supplied device, do not engage the laboratory responsibility.

VI. CONCLUSIONS:

In the test conditions described, the process DUST FREE Airknight induces a reduction of the number of viable cells of *Staphylococcus aureus* CIP 4.83 spread on stainless steel carrier of 1,1 to 1,3 log_{10} (i.e. 92% to 95% of the initial load) after a contact time of 24 hours at 20°C.

VII. REFERENCES:

1-NF EN 17272 : April 2020. Chemical disinfectants and antiseptics – Method of airborne room disinfection by automated process – Determination of bactericidal, mycobactericidal, sporicidal, fungicidal, yeasticidal, virucidal and phagocidal activities.

2- Guide to good practice for disinfection of medical devices. Conseil Supérieur d'Hygiène Publique de France. https://www.vie-publique.fr/rapport/24373-guide-de-bonnes-pratiques-de-desinfection-des-dispositifs-medicaux

VIII. STATEMENT GOOD LABORATORY PRACTICE:

The study was conducted according to NF EN ISO/IEC 17025 (2017) General requirements for the competence of testing and calibration laboratories. Applicable Standard Operating Procedures and Good Laboratory Practice were followed in this study.

The original records of this report, the notebooks, protocol, and final study report are stored in the archives of Eurofins Biotech-Germande 3194.KLI.21.

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Le 2/15/2021