

CONFORMITY DECLARATION

We, VYRTYCH a.s. on base of tests provided by Accredited testing laboratory No 1206 for physical factors of State Health Institute hereby declare the conformity with norm

ČSN EN ISO 14644-1

Clean rooms and corresponded controlled areas – Classification of air cleanness according to particles concentration for

LUMINAIRES series :

HOUND4-MAG-LED, HOUND/3-MAG-LED, HOOVER4-LED, HOOVER/3-LED

meets the requirements for clean areas Class 5 and 6 (most cleanness superaseptic operation room) according to above mentioned norm

Supplement :

Accredited testing report No 1.6./ČP/21/11 – MEASUREMENT OF SOLID VAPOUR PARTICLES NUMBER


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IČO: 278 62 470, DIČ: CZ27862470

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Issued by
Petr Beneš
Head of technical department



Test Report No. 1.6/ČP/21/11

Measurement of the number of particles of determinate aerosol in air

Expertise No.: EX 210922, SZÚ/07955/2021
Costumer: VYRTYCH a. s., Židněves 116, 294 06 Březno
Date of measurement: 16. 7. 2021
Reason of measurement: **Verification of luminaires for clean rooms**
– Manufacturer VYRTYCH a.s.
Place of measurement: Operating room Klinika Dr. Pírka, Mladá Boleslav
Measurement performed by: Ing. Z. Mathauserová, NIPH

Test method and evaluation

The test method of measuring dustiness in clean rooms was used, i. e. determining of the number of solid aerosol particles with dimensions $\geq 0,5 \mu\text{m}$ and $\geq 5,0 \mu\text{m}$ accordance to Annex B of ČSN EN ISO 14644-1:2019 Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration and accordance to the document of the Laboratory for Physical Factors – SOP No.2/1.6 Determination of cleanliness classes defined cleanroom.

One measurement (one data reading on the measuring device) is a two-minute sampling of air at an air flow through a particle counter of $1\text{ft}^3 / \text{min}$ - the results are converted to a volume of 1m^3 of air according to the requirements of the standard

A clean room without installed luminaires was monitored, after verifying the cleanliness class of the operating room, luminaires HOUND4-MAG-LED – SQ-5300-4K, IP65, HOUND/3-MAG-LED-SQ-OP-6100-4K, IP65, HOOVER4-418-EP, 4x18W, IP65 were placed and turned on. After an hour of operation of the luminaires, repeated measurement of the number of particles of determinate aerosol in air was performed - the conclusion follows from the comparison of the obtained data.

Used equipment:

Particle counter - CI-200 model, serial No. 034316, CC No. 6014-KL-C0058-19, which determines and registers numbers of dust particles in 6 dimension intervals from 0,2 to $10 \mu\text{m}$.

Place of measurement was a clean room of the operating room with a verified cleanliness class 5 under the laminar air supply (except for the laminar cleanliness class 5/6) according to ČSN EN ISO 14644-1. The measurement took place "at rest", i.e. without no personnel present in the room.

Measurement results:

In Tab. 1 are the requirements for a clean room of cleanliness class 5 and 6 (i.e. parameters of the cleanest superaseptic operating room) according to ČSN EN ISO 14644, Tab. 2 shows the measured values of the number of particles of determinate aerosol.

Tab. 1: Requirements for cleanliness air according to Decree No. 84/2008 Coll.

Cleanliness classes of air (at rest)	Number of particles in 1m^3 of air	
	$\geq 0,5 \mu\text{m}$	$\geq 5,0 \mu\text{m}$
5	3 520	29
6	35 200	293





Tab. 2: Measured values of the number of solid aerosol particles in the operating field where the luminaires were placed.

Before installing the luminaire		After installing the luminaire	
Number of particles in 1ft ³ of size and larger		Number of particles in 1ft ³ of size and larger	
0,5 µm	5,0 µm	0,5 µm	5,0 µm
4	0	3	0
6	1	3	0
2	0	1	0
3	0	4	0
5	0	8	1
8	1	7	0
6	0	8	1
5	0	5	0
Number of particles in 1 m ³		Number of particles in 1 m ³	
171	10	171	10

Note: Due to the very low measured values and the nature of test, uncertainty of measurement was not determined.

The Laboratory declares that all results apply to the given measurements only. This report shall not be reproduced, except in full, without the written approval of the technical head of laboratory.

Date: 20. 7. 2021

Prepared by and approved: Ing. Z. Mathauserová
Technical head of Laboratory

END OF TEST REPORT



Statement on the Test Report No. 1.6/MKL/21/11

Measurement of the number of particles of determinate aerosol in air for the purpose of verification of
luminaires manufactured by VYRTYCH a.s. for clean rooms

Expertise No.: EX 210922, SZÚ/07955/2021

CONCLUSION

Installed luminaires HOUND4-MAG-LED-SQ-5300-4K, IP65, HOUND/3-MAG-LED-SQ-OP-6100-4K, IP65, HOOVER4-418-EP, 4x18W, IP65 were not a source of pollution of clean room, during their operation did not release any solid aerosol particles into the clean room air. Due to its identical construction, used materials and the installation procedure into the ceiling of the clean room are recessed luminaires of the entire product type series HOOVER/3-LED, HOOVER2-LED, HOOVER3-LED, HOOVER4-LED, HOOVER5-LED, HOOVER6-LED, HOUND / 3- LED, HOUND2-LED, HOUND4-LED, HOUND5-LED, HOUND6-LED, HOUND/3-MAG-LED, HOUND4-MAG-LED, CORGI-LED, HOOVER, HOOVER2, HOOVER3, HOOVER4, HOOVER5, HOOVER6, HOUND, HOUND2, HOUND3, HOUND4, HOUND5, HOUND6, HOUND-MAG, HOOVER-MAG, CORGI suitable for use in all types of clean rooms.



Picture 1, 2

Measurement of the number of particles of determinate aerosol in air in the operating room during operation of VYRTYCH luminaires

16/07/2021	ID= U	COUNT/CF	SAMPLE VOL= 1.0 CF						
TIME	> 0.2	> 0.3	> 0.5	> 1.0	> 5.0	> 10.0	RH	TEMP	FLOW
18:24:31	76	16	3	2	0	0	64.0	24.3	1.00

16/07/2021	ID= U	COUNT/CF	SAMPLE VOL= 1.0 CF						
TIME	> 0.2	> 0.3	> 0.5	> 1.0	> 5.0	> 10.0	RH	TEMP	FLOW
18:23:31	46	12	3	2	0	0	64.0	24.3	0.99

16/07/2021	ID= U	COUNT/CF	SAMPLE VOL= 1.0 CF						
TIME	> 0.2	> 0.3	> 0.5	> 1.0	> 5.0	> 10.0	RH	TEMP	FLOW
18:22:31	62	11	1	0	0	0	63.2	24.3	1.00

16/07/2021	ID= U	COUNT/CF	SAMPLE VOL= 1.0 CF						
TIME	> 0.2	> 0.3	> 0.5	> 1.0	> 5.0	> 10.0	RH	TEMP	FLOW
18:21:31	54	10	4	2	0	0	63.2	24.3	1.00

16/07/2021	ID= U	COUNT/CF	SAMPLE VOL= 1.0 CF						
TIME	> 0.2	> 0.3	> 0.5	> 1.0	> 5.0	> 10.0	RH	TEMP	FLOW
18:20:31	59	13	8	5	1	0	63.2	24.3	1.00

16/07/2021	ID= U	COUNT/CF	SAMPLE VOL= 1.0 CF						
TIME	> 0.2	> 0.3	> 0.5	> 1.0	> 5.0	> 10.0	RH	TEMP	FLOW
18:19:31	44	11	7	5	0	0	62.4	24.3	1.00

16/07/2021	ID= U	COUNT/CF	SAMPLE VOL= 1.0 CF						
TIME	> 0.2	> 0.3	> 0.5	> 1.0	> 5.0	> 10.0	RH	TEMP	FLOW
18:18:31	66	16	8	4	1	0	62.4	24.3	0.99

Picture 3

Sample of measured values of the number of particles of determinate aerosol in air after one hour of operation of luminaires

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