Istituto Nazionale di Fisica Nucleare
Laboratori Nazionali del Sud

BRIT
Bio-nanotech Research and Innovation Tower

UNIVERSITÀ degli STUDI di CATANIA

Test Mascherine Chirugiche

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UNI EN 14683

NORMA
EUROPEA

Maschere facciali ad uso medico - Requisiti e metodi di prova

UNI EN 14683

OTTOBRE 2019

Medical face masks - Requirements and test methods

La norma specifica i requisiti di fabbricazione, progettazione e prestazione e i metodi di prova per le maschere facciali ad uso medico destinate a limitare la trasmissione di agenti infettivi tra pazienti e personale clinico durante gli interventi chirurgici e altri contesti medici con requisiti simili.

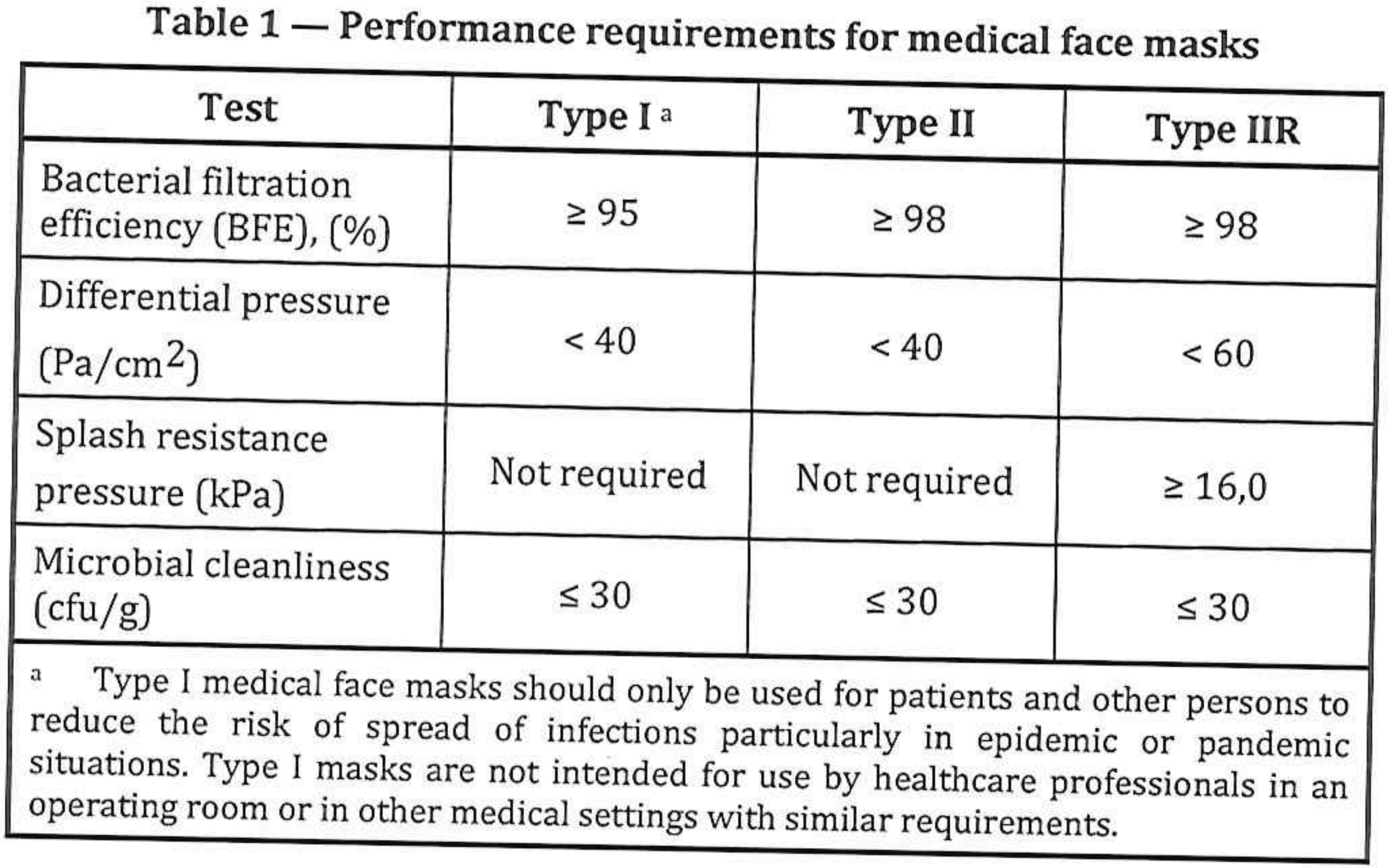


Table 1 — Performance requirements for medical face masks

Test	Type I [a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm^2)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

[a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

B.7.1 Assemble the test apparatus in accordance with the flow chart shown in Figure B.1 or Figure B.3.

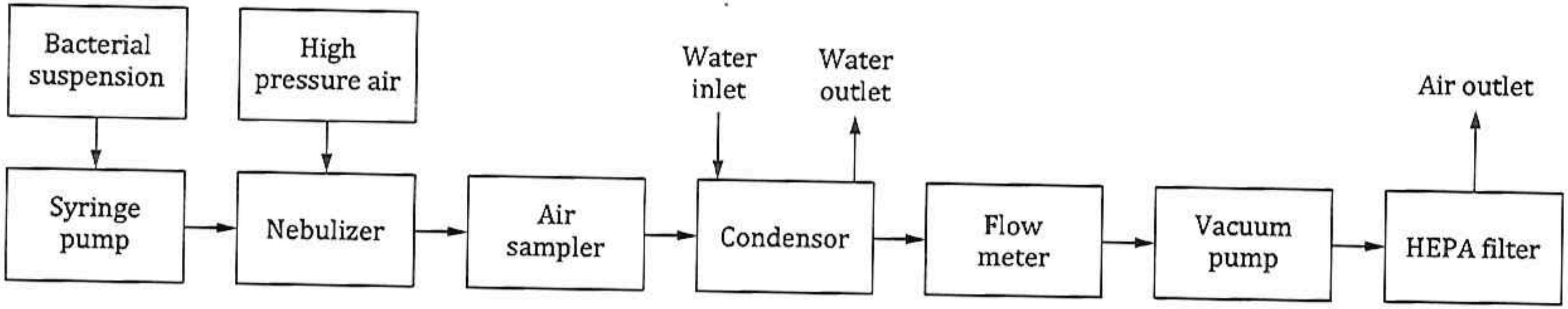
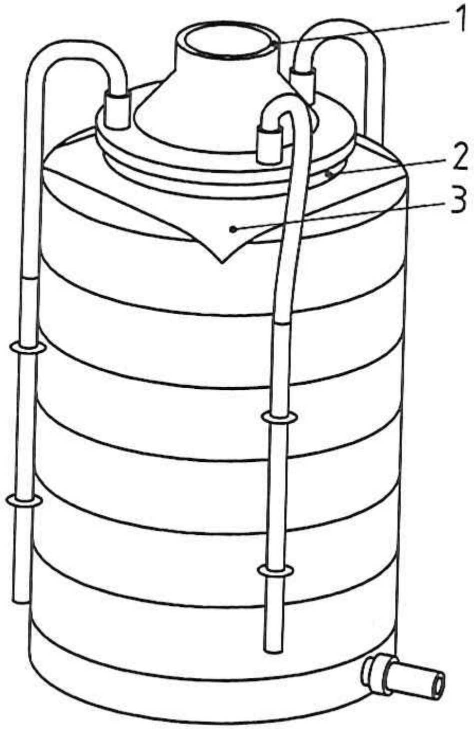

Bacterial suspension
High pressure air
Water inlet
Water outlet
Air outlet
Syringe pump
Nebulizer
Air sampler
Condensor
Flow meter
Vacuum pump
HEPA filter

Figure B.1 — Principle of BFE test apparatus

B.7.3. AC⟩ The test area shall be minimum 49 cm² ⟨AC. Alternative means to position the sample may be appropriate, but, if deviated from the procedure, this shall be documented in the test report.



Key

1 inlet cone

2 o'ring inlet cone

3 cloth / mask

Figure B.2 — Placement of test specimen on the cascade impactor

[redacted]

Stage number	1	2	3	4	5	6
Size of particle	P1	P2	P3	P4	P5	P6
Viable "particle" plate count	C1	C2	C3	C4	C5	C6

where

P1 = 7,00 µm

P2 = 4,70 µm

P3 = 3,30 µm

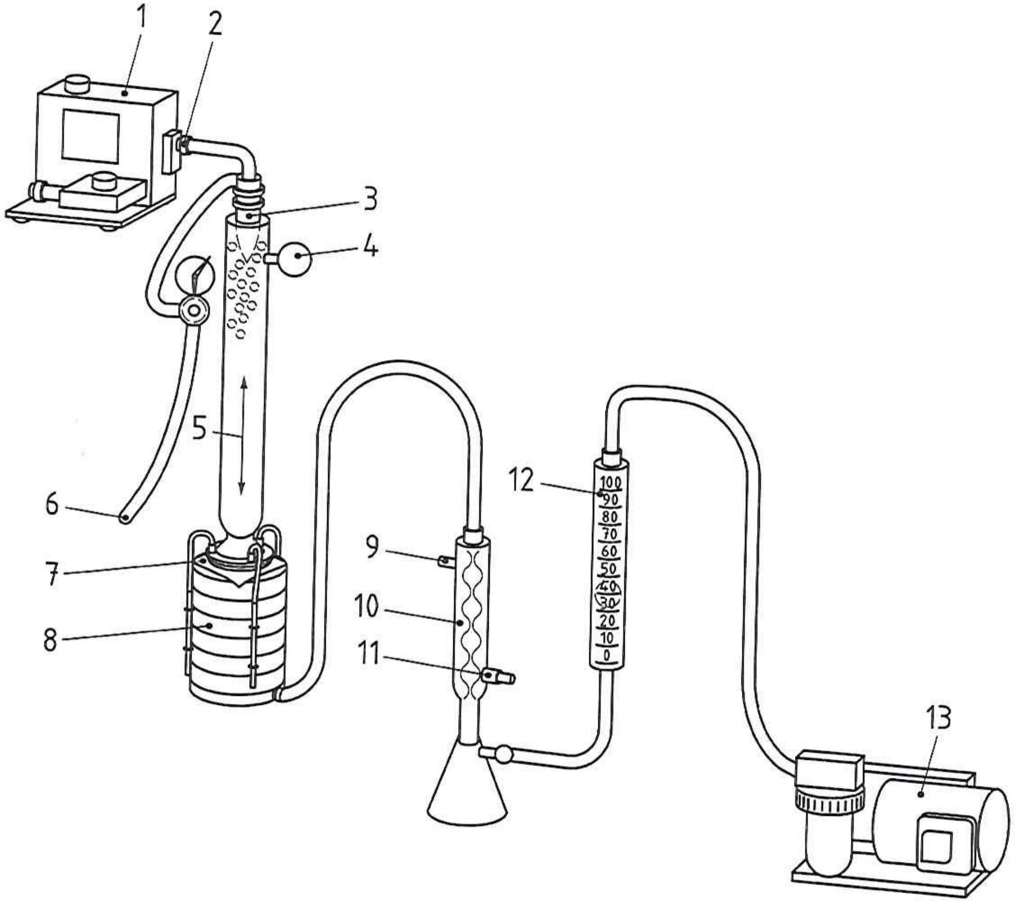
P4 = 2,10 µm

P5 = 1,10 µm

P6 = 0,65 µm

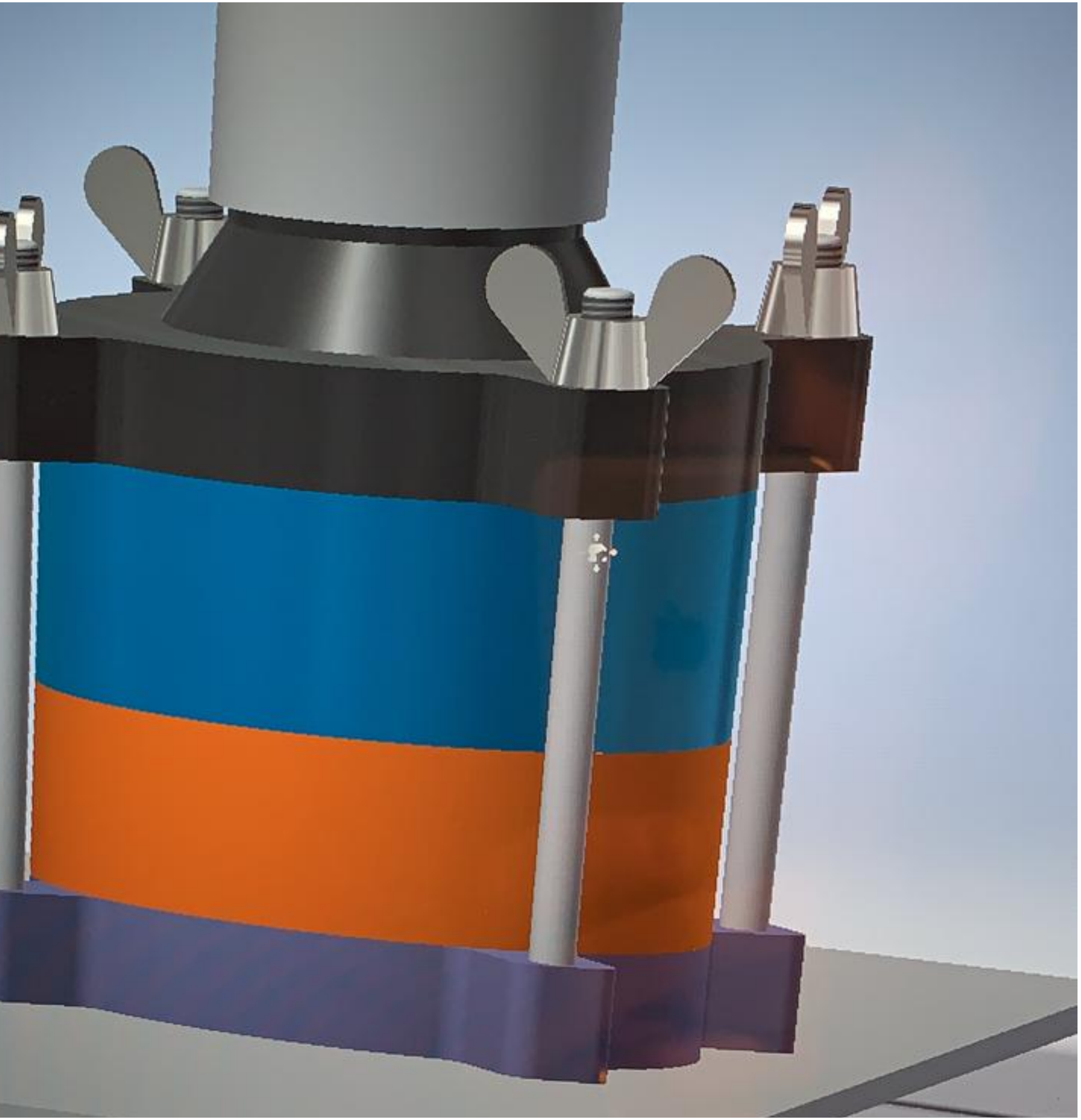
$$MPS = \frac{(P1 \times C1) + (P2 \times C2) + (P3 \times C3) + (P4 \times C4) + (P5 \times C5) + (P6 \times C6)}{C1 + C2 + C3 + C4 + C5 + C6} \qquad \text{(B.1}$$

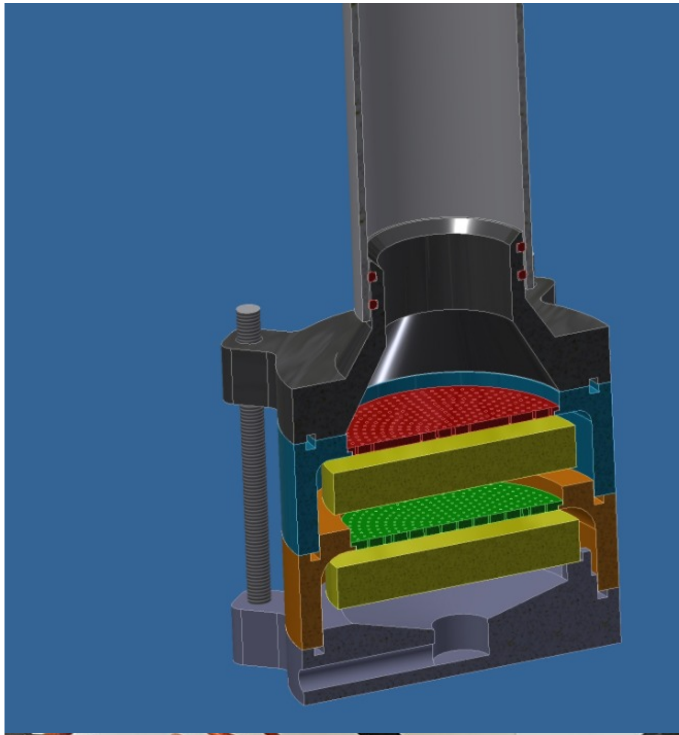
[redacted]

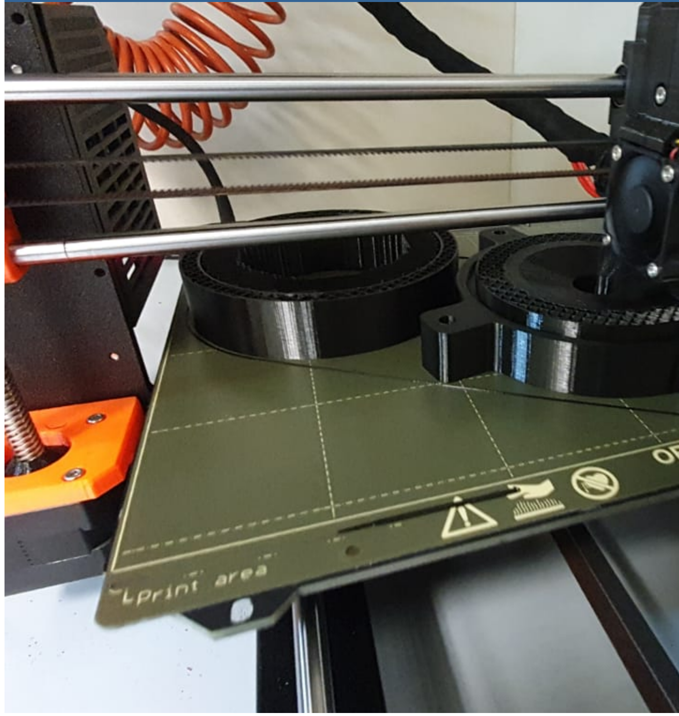

1
2
3
4
5
6
7
8
9
10
11
12
13
100
90
80
70
60
50
40
30
20
10
0

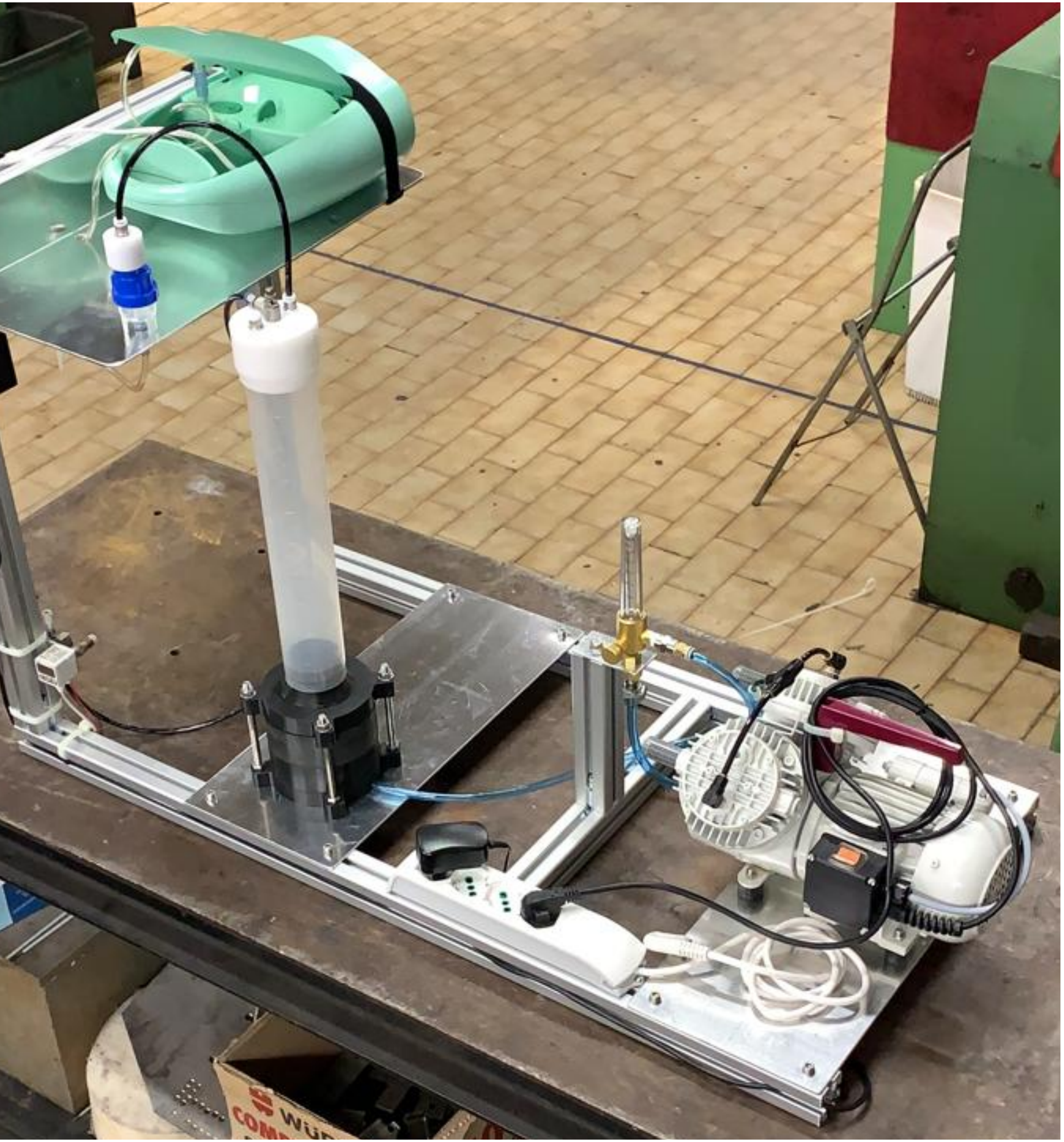
Key

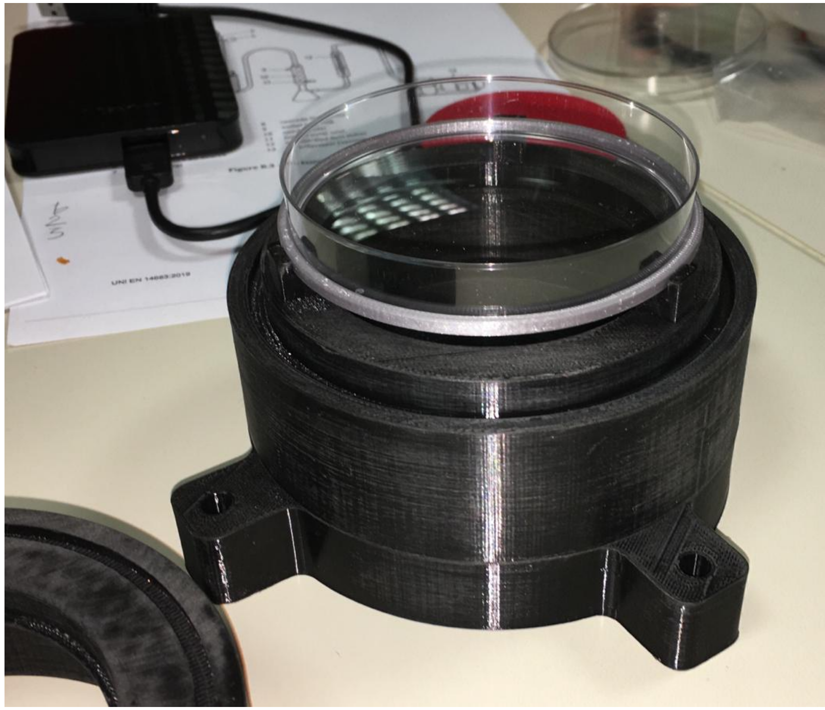
1	drive mechanism
2	bacterial suspension
3	nebulizer
4	filter
5	aerosol chamber
6	high pressure air source
7	test material
8	cascade impactor
9	outlet to sink
10	condenser
11	cold water inlet
12	calibrated flow meter
13	compressor (vacuum pump)






Print area

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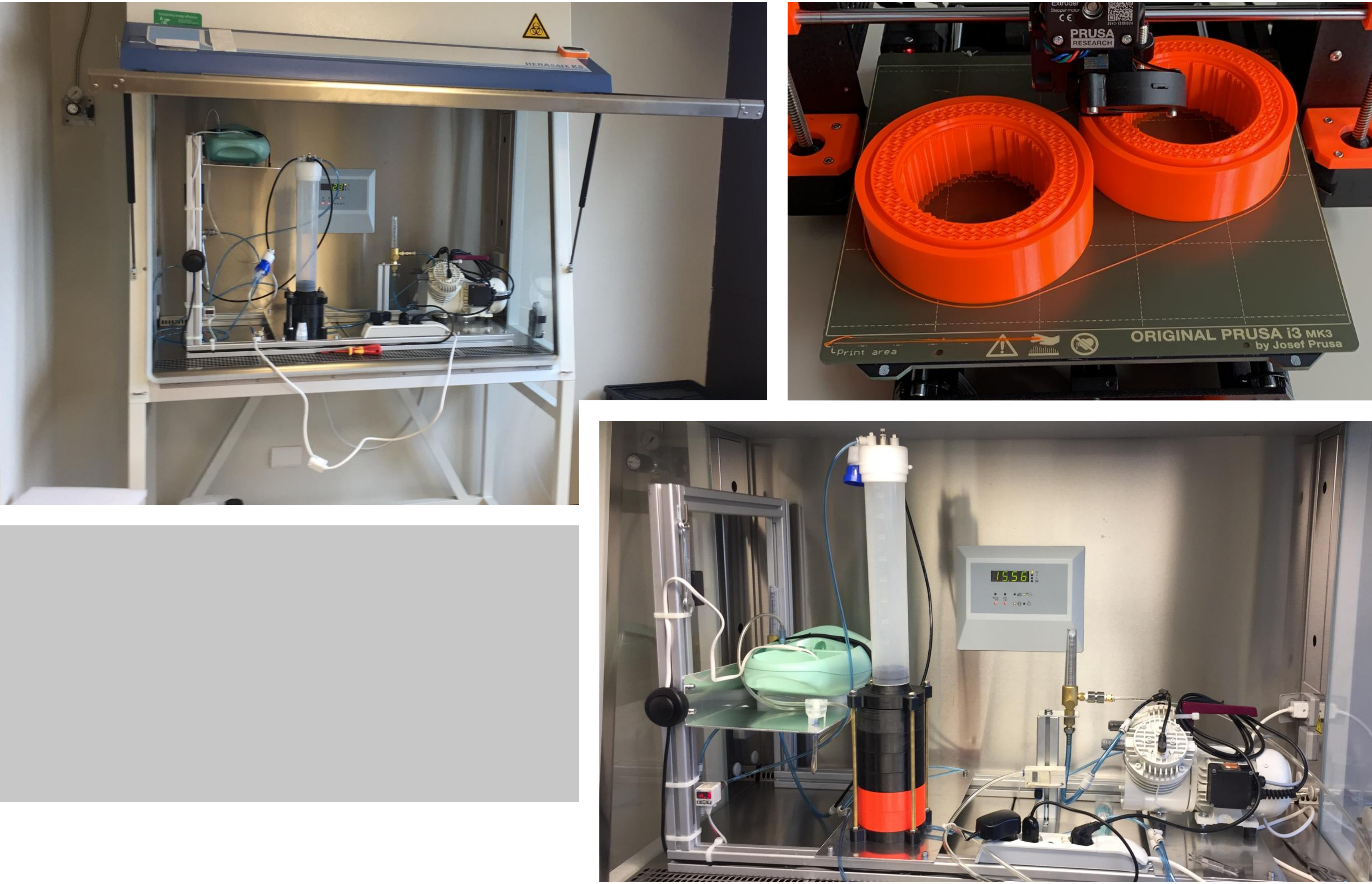
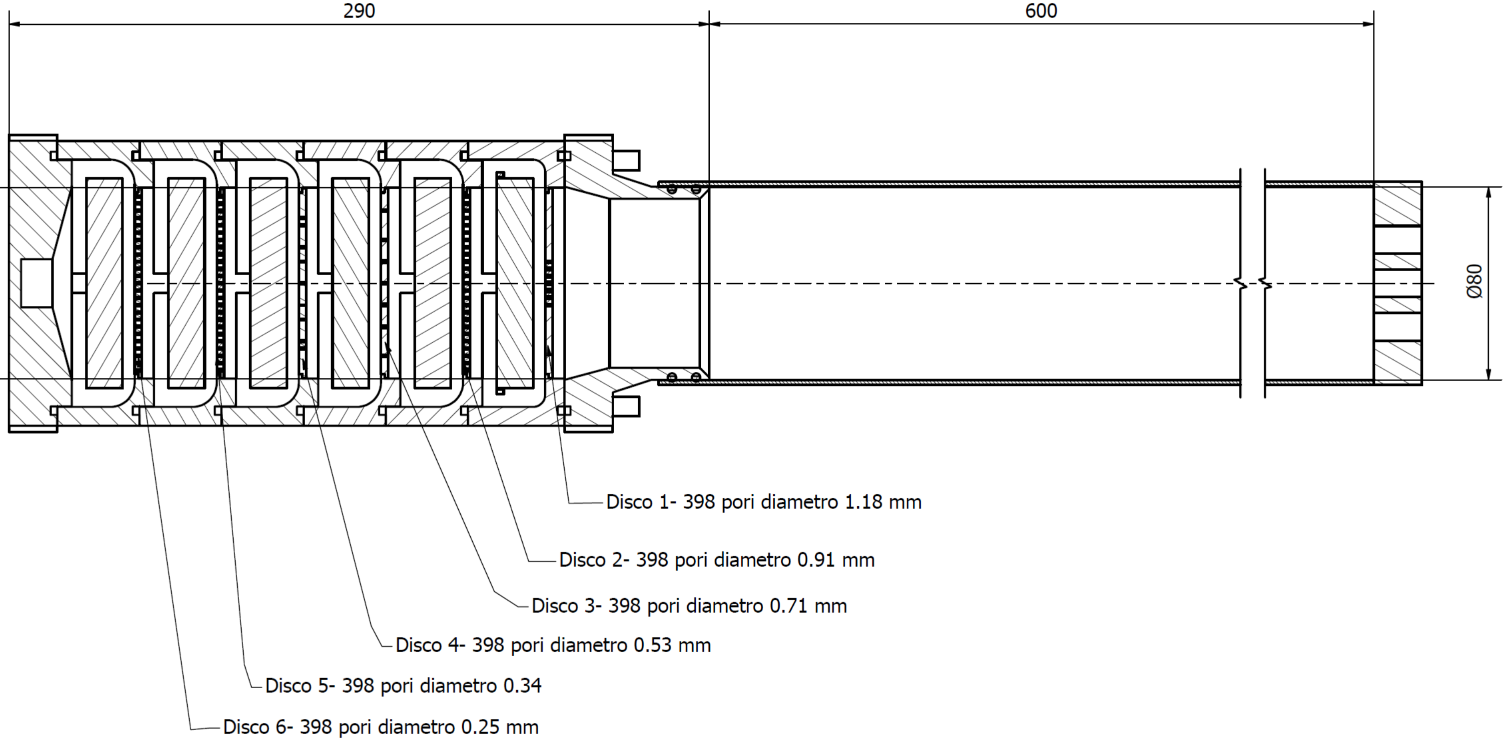

HERASAFE KS
PRUSA RESEARCH
ORIGINAL PRUSA i3 MK3
by Josef Prusa
Print area
15.56



Disco 1- 398 pori diametro 1.18 mm

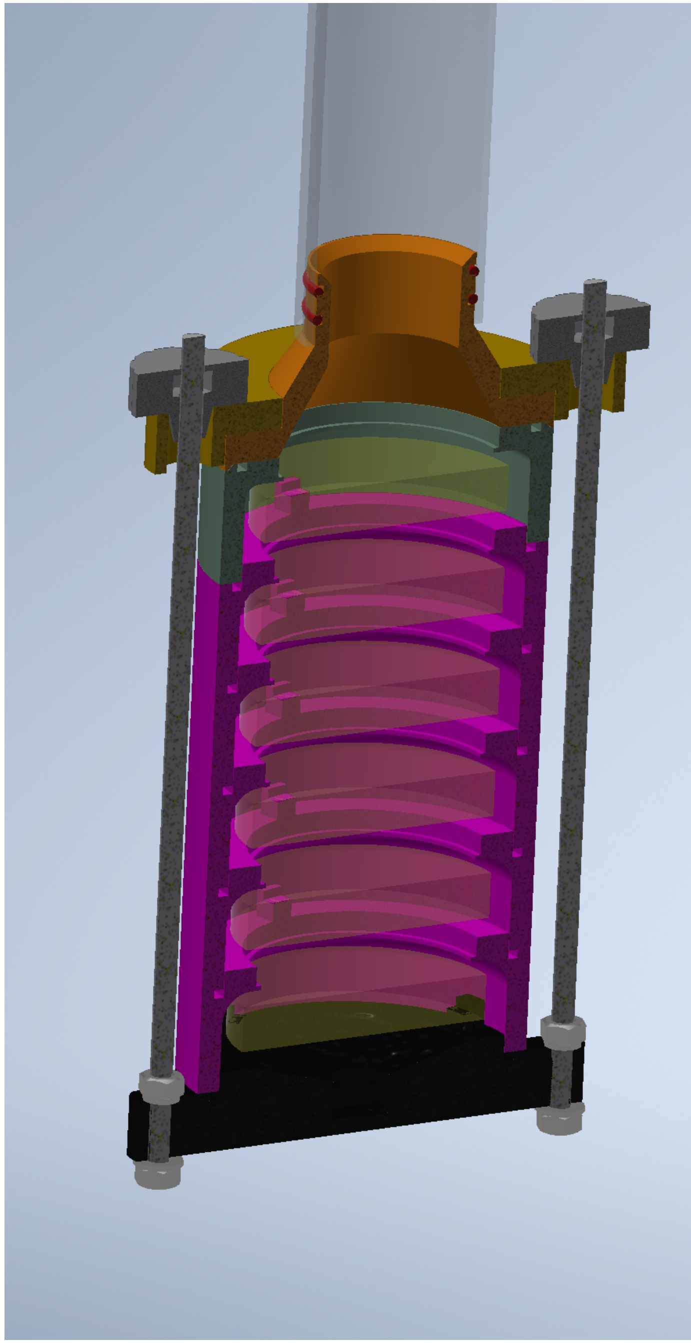
Disco 2- 398 pori diametro 0.91 mm

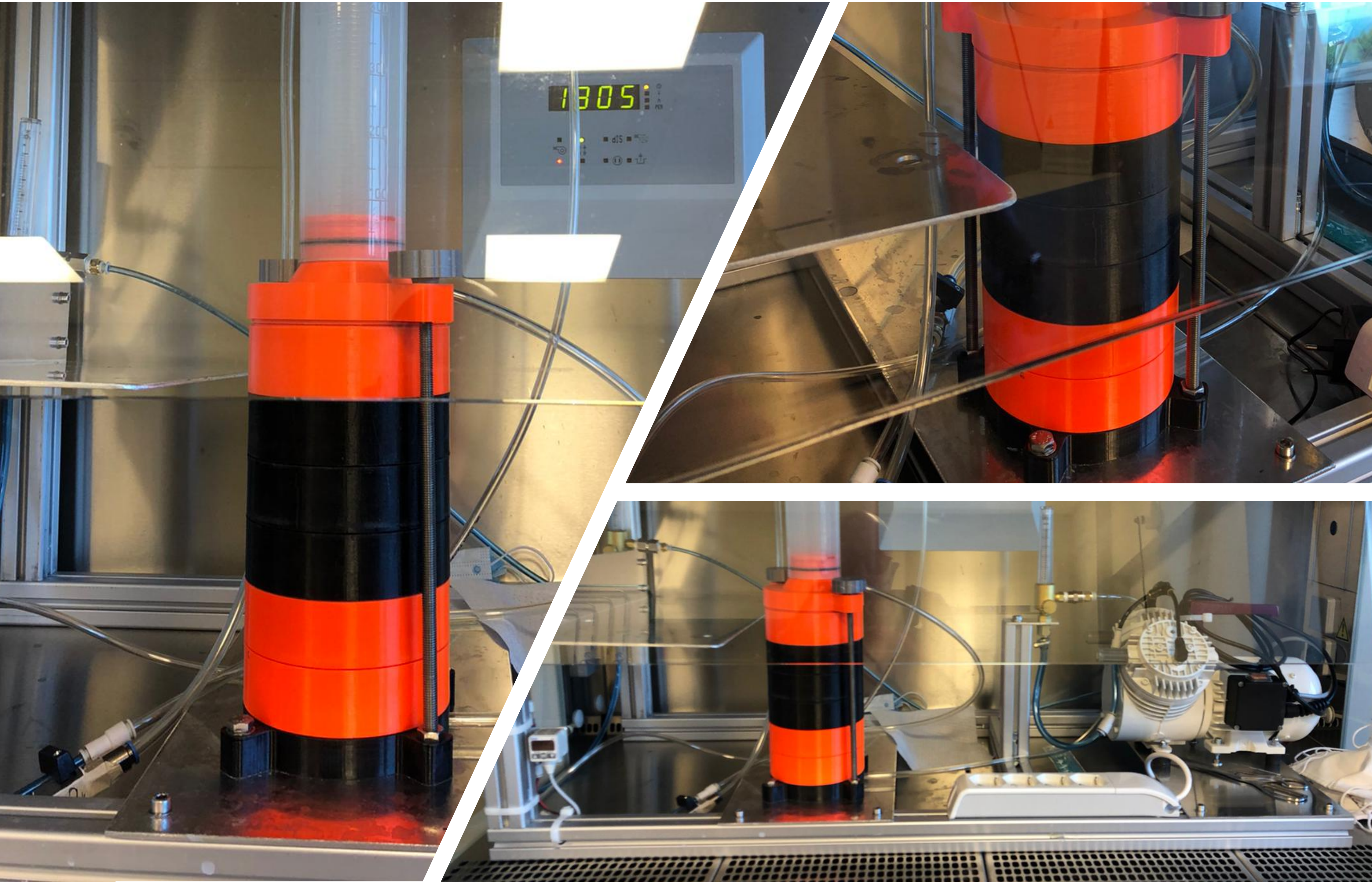
Disco 3- 398 pori diametro 0.71 mm

Disco 4- 398 pori diametro 0.53 mm

Disco 5- 398 pori diametro 0.34

Disco 6- 398 pori diametro 0.25 mm

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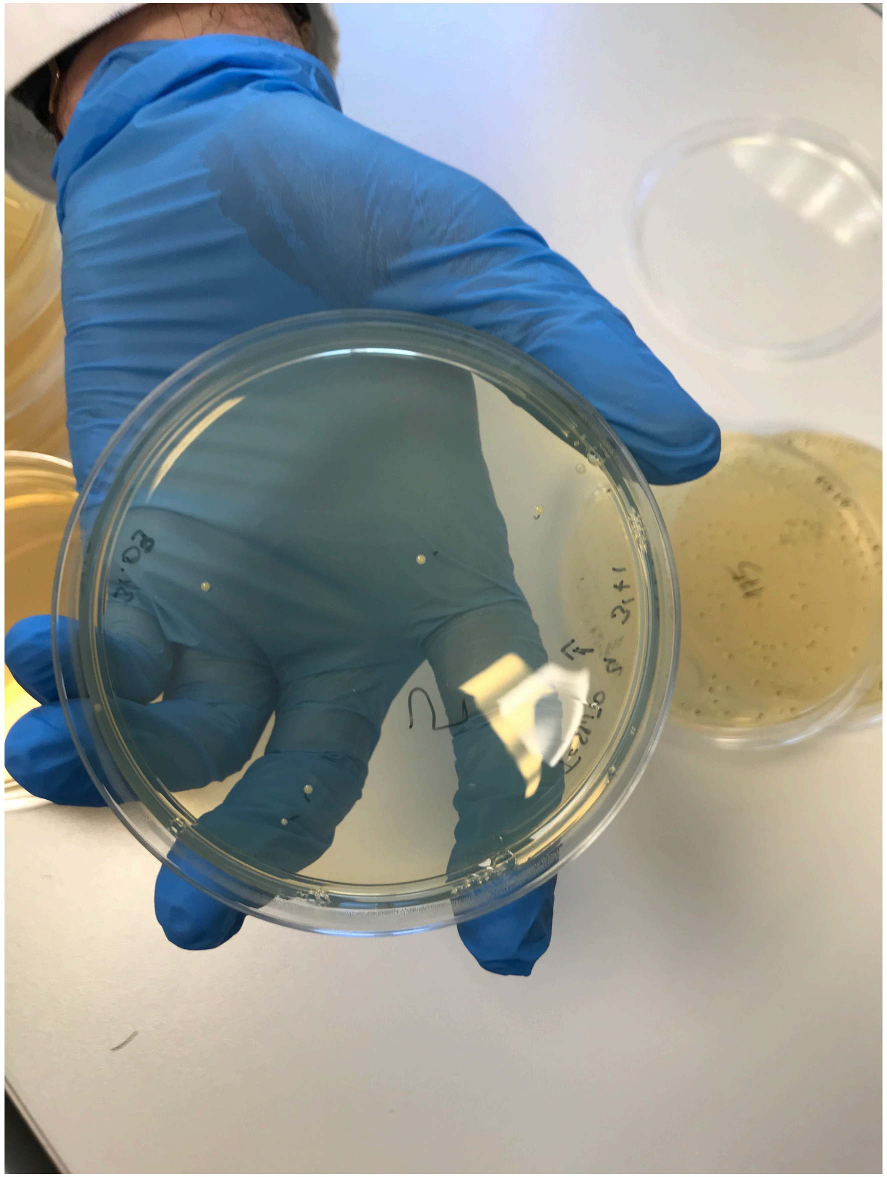
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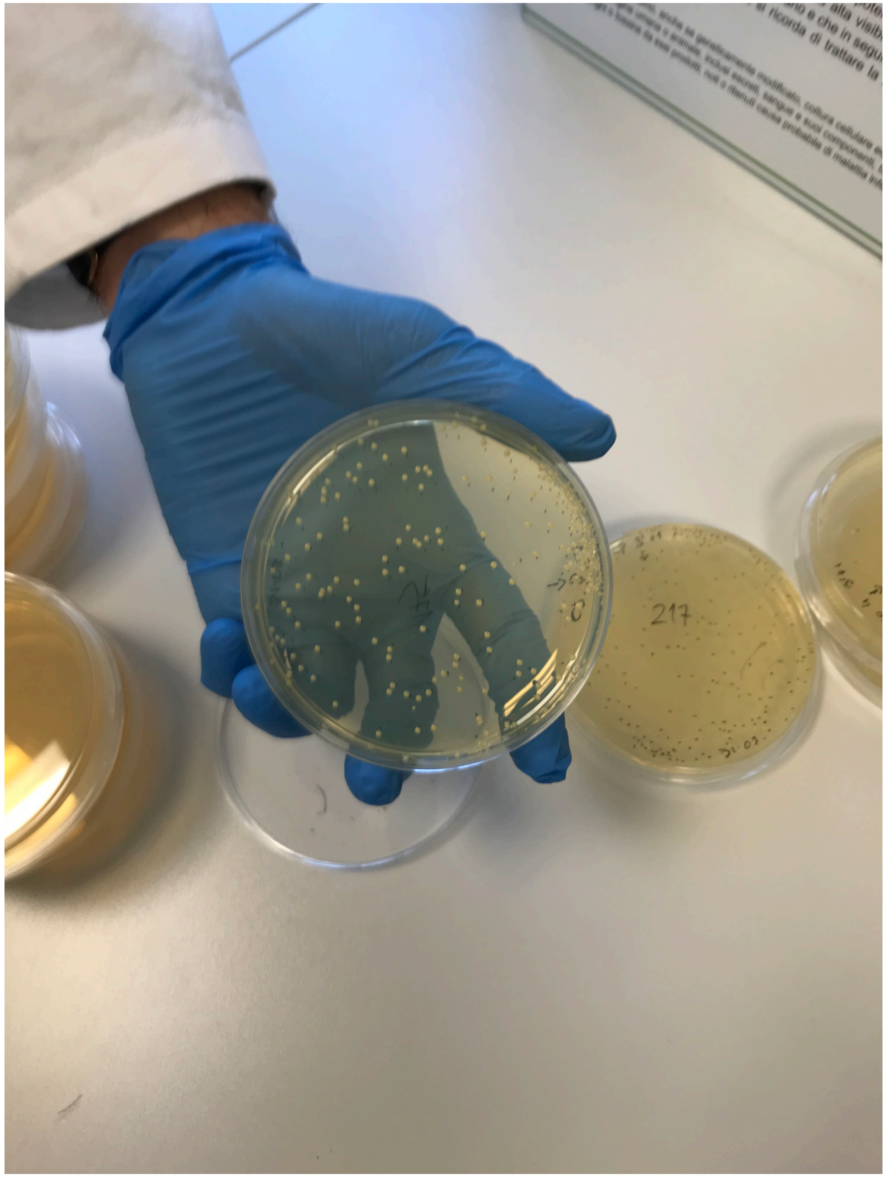
2
115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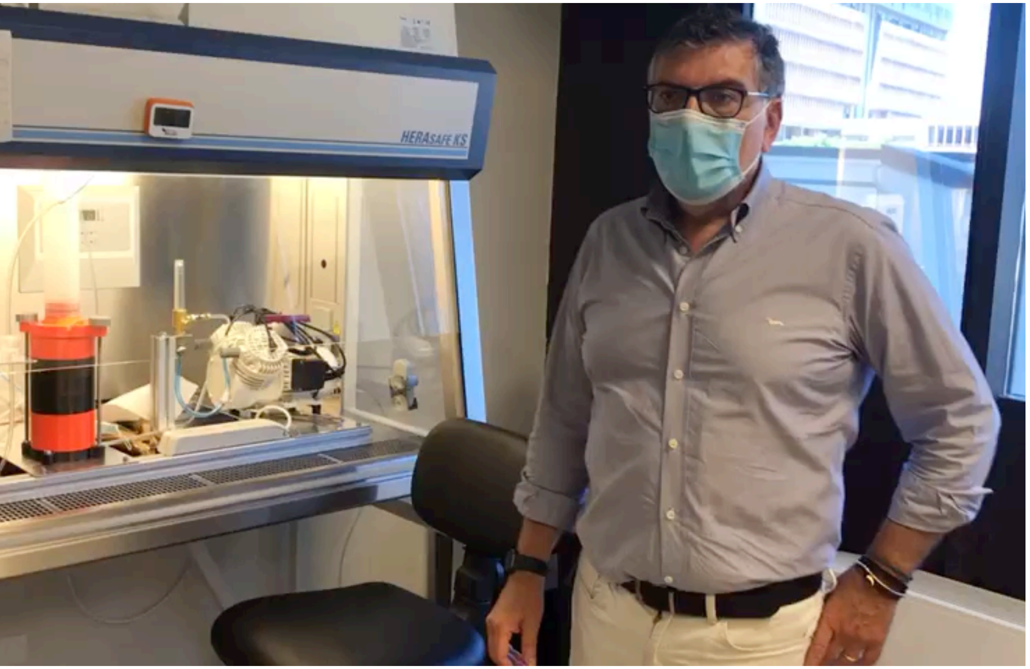
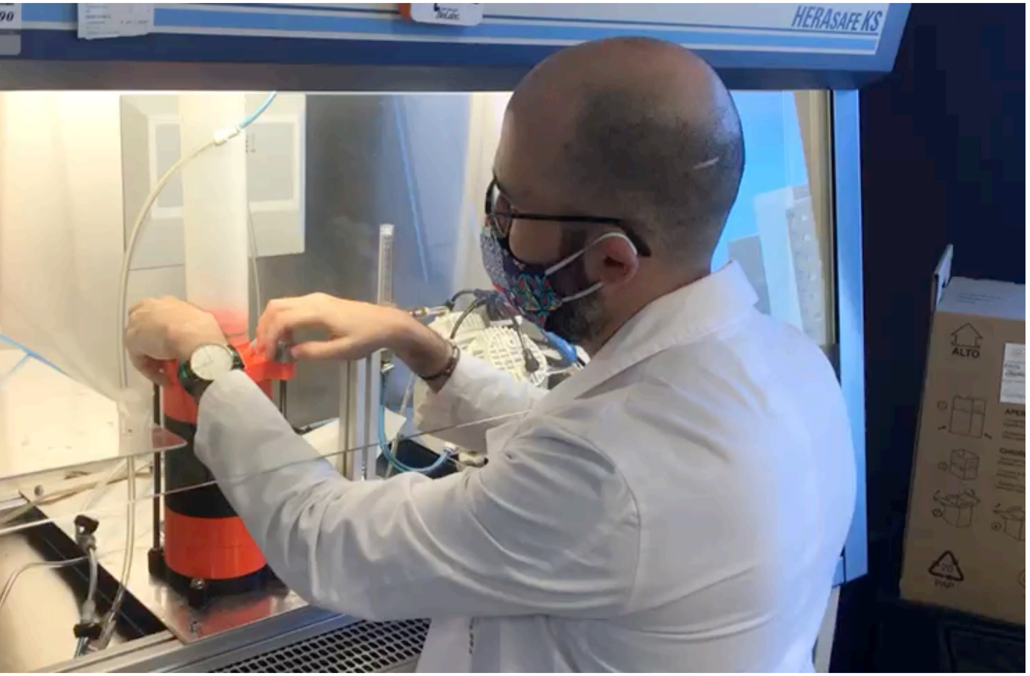

HERASAFE KS


HERASAFE KS
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Test Respirabilità

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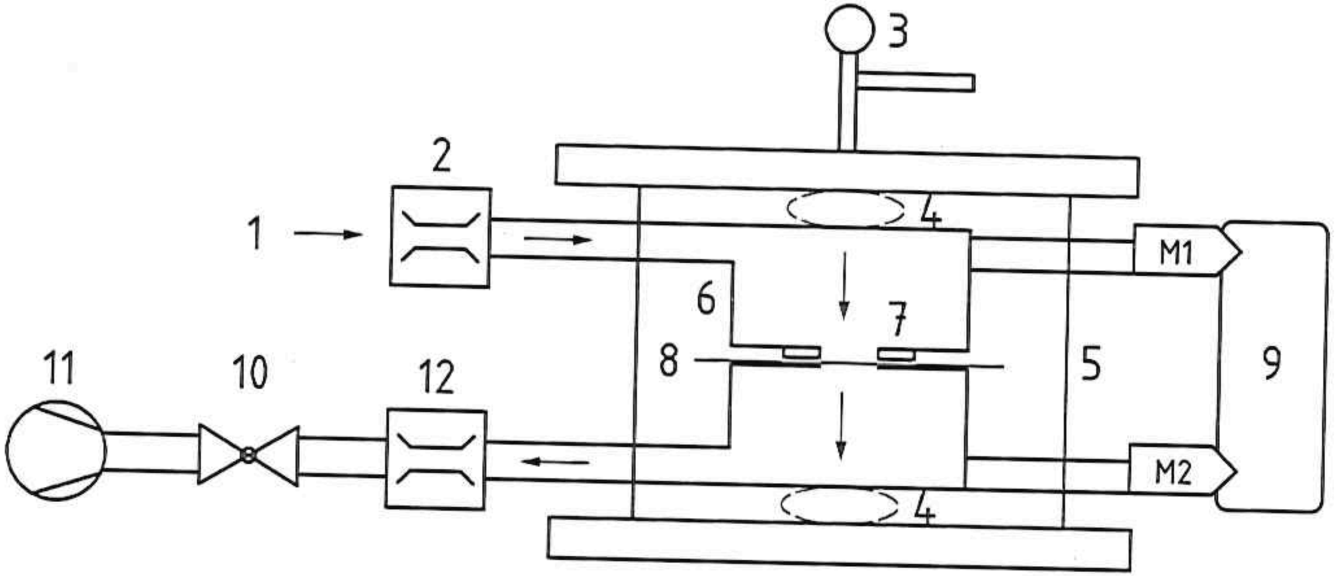
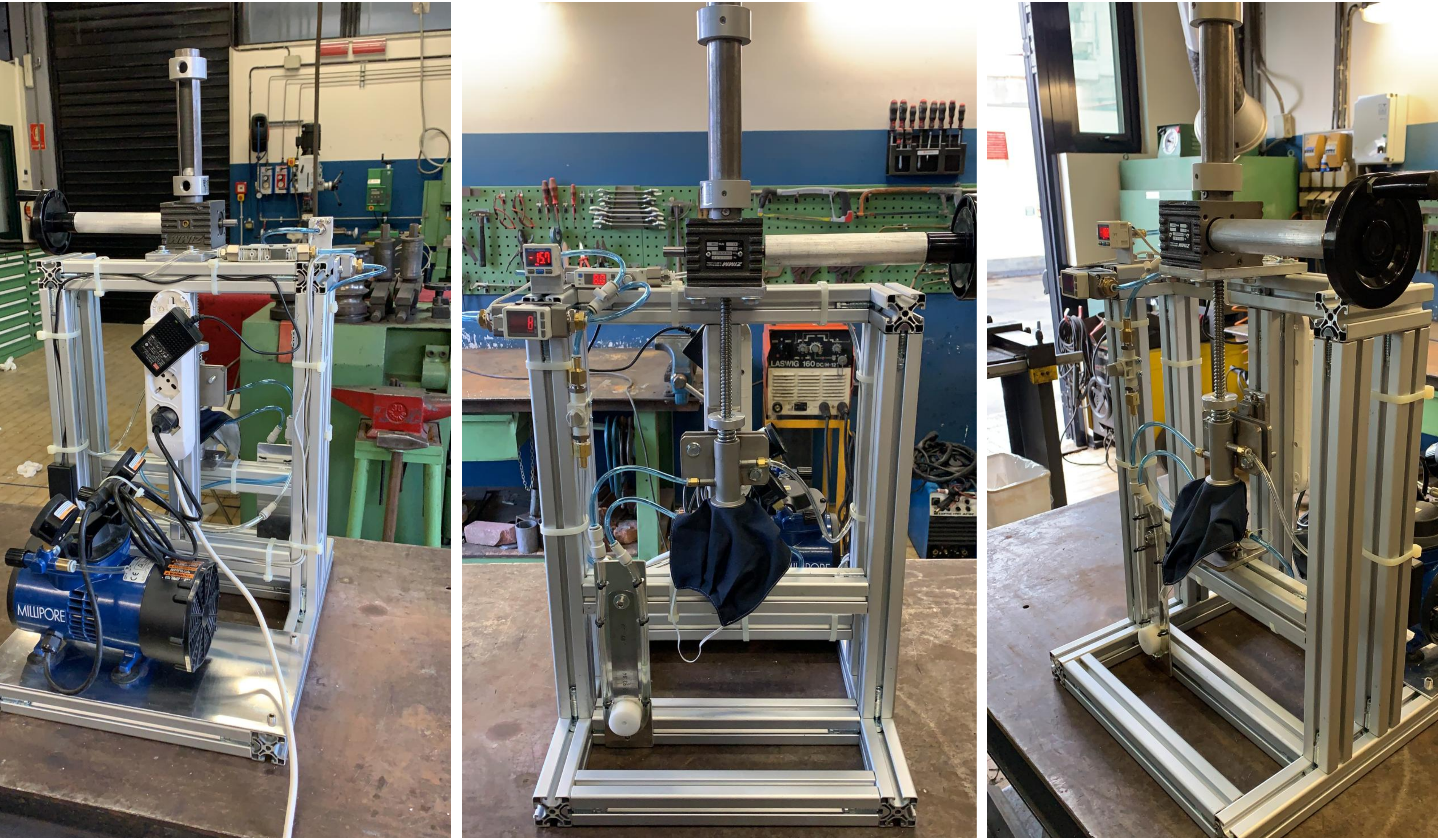
A device which measures the differential pressure required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material, as shown in Figure C.1. A water-filled (or digital) differential manometer is used to measure the differential pressure. A mass flow meter is used for measurement of the airflow. An electric vacuum pump draws air through the test apparatus and a needle valve is used to adjust the airflow rate.

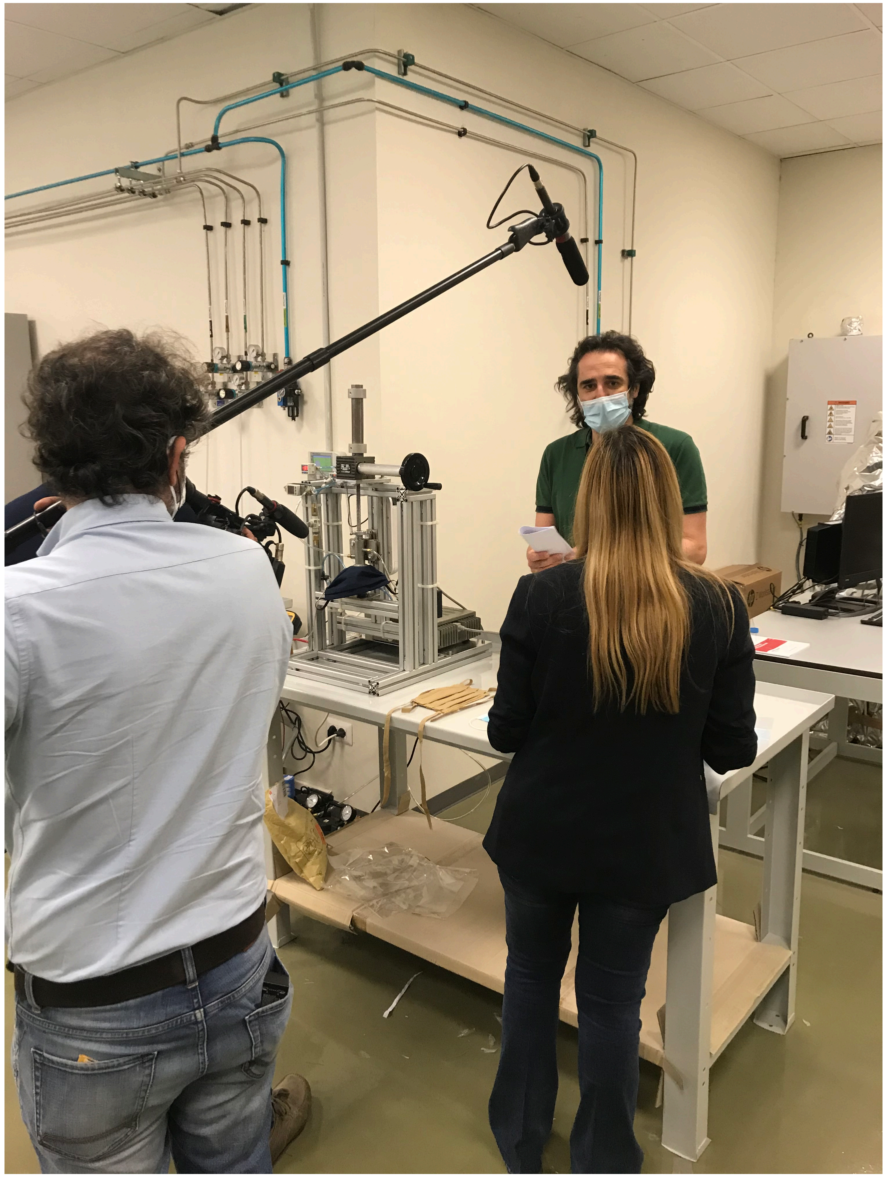


Key

1 air inlet
2 mass flow meter
3 lever for mechanical clamping
4 system for final adjustment of the pressure (either at the top or the bottom)
5 system ensuring optimal alignment of the 2 parts of the sample holder
6 sample holder with a metal sealing mechanism
7 metallic ring (3 mm thick)
8 filter material
9 differential manometer or M1 and M2 manometers
10 valve
11 vacuum pump including a pressure buffer tank
12 mass flow meter for checking leaks (optional)

Figure C.1 — Test apparatus for measuring differential pressure


MILLIPORE
ZIMM
-15.7
8.0
8
LASWIG 160 DC H-13

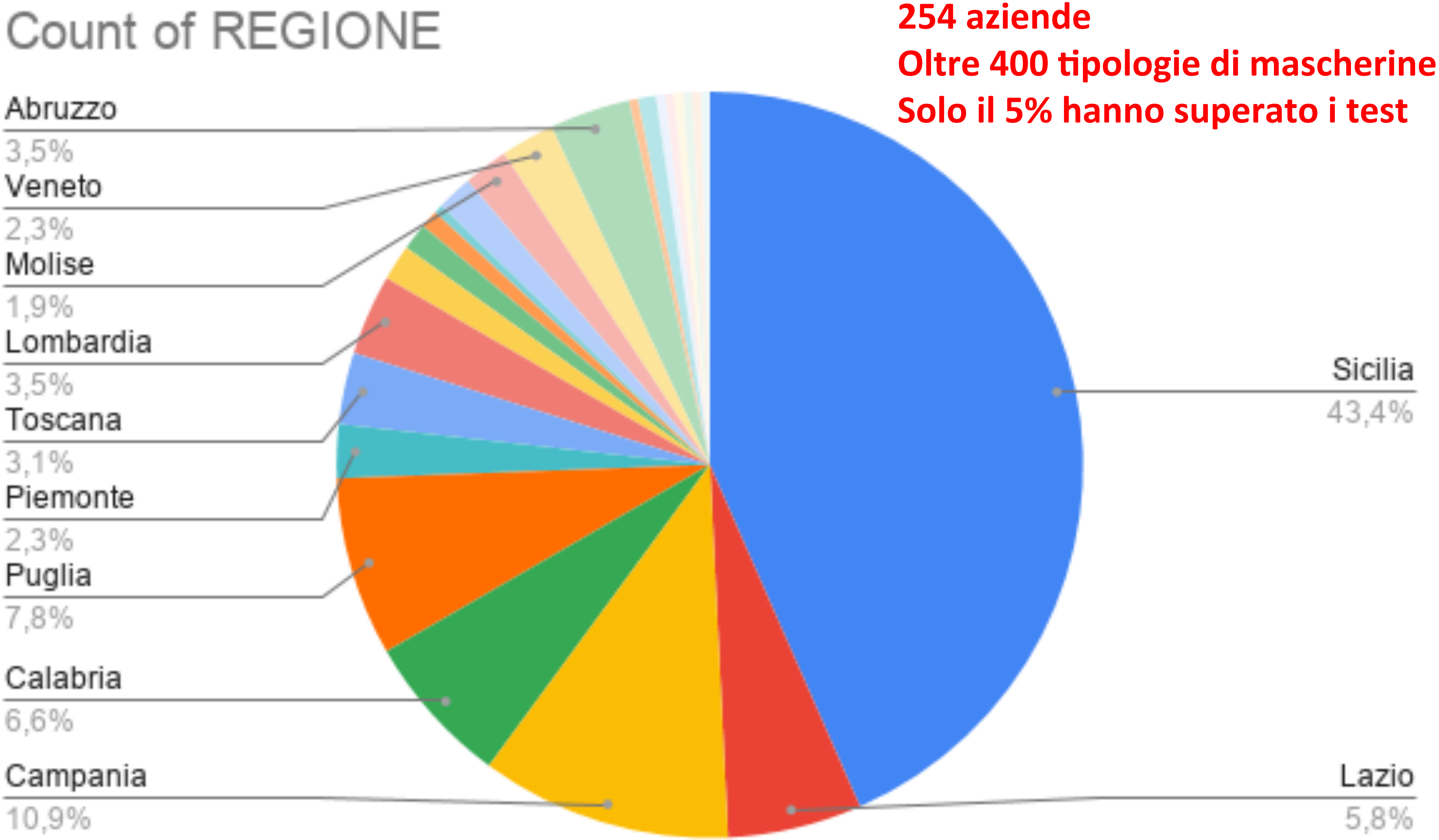


Alcuni Numeri

- 254 aziende
- Oltre 400 tipologie di mascherine testate
- Solo il 5% hanno superato i test

254 aziende

Oltre 400 tipologie di mascherine testat

Solo il 5% hanno superato i test