

# Reuse of medical face masks in domestic and community settings without sacrificing safety: Ecological and economical lessons from the Covid-19 pandemic

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Reuse of medical face masks in domestic and community settings without 1 sacrificing safety: ecological and economical lessons from the Covid-19 2 pandemic 3 4 5 Jean-Pierre Alcaraz<sup>a</sup>, Laurence Le Cog<sup>b</sup>, Jérémie Pourchez<sup>c</sup>, Dominique Thomas<sup>d</sup>, Sandrine Chazelet<sup>e</sup>, 6 Isabelle Boudry<sup>f</sup>, Maud Barbado<sup>f</sup>, Sophie Silvent<sup>f</sup>, Claire Dessale<sup>g</sup>, Fabienne Antoine<sup>g</sup>, Catherine 7 Guimier-Pingault<sup>h</sup>, Laurent Cortella<sup>i</sup>, Sophie Rouif<sup>i</sup>, Nathalie Bardin-Monnier<sup>d</sup>, Augustin Charvet<sup>d</sup>, Olivier Dufaud<sup>d</sup>, Lara Leclerc<sup>c</sup>, Yoann Montigaud<sup>c</sup>, Coralie Laurent<sup>c</sup>, Paul Verhoeven<sup>k,I</sup>, Aurélie 8 9 Joubert<sup>b</sup>, Ala Bouhanguel<sup>b</sup>, Yves Andres<sup>b</sup>, Joël Gaffé<sup>a</sup>, Donald K Martin<sup>a</sup>, Christophe Huet<sup>h</sup>, Sandrine Boisset<sup>a,h</sup>, Max Maurin<sup>a,h</sup>, Pascal Rumeau<sup>m</sup>, Frédéric Charlot<sup>n</sup>, Emmanuel Richaud<sup>o</sup>, Alexandre Moreau-10 Gaudry<sup>a,f</sup>, Vincent Bonneterre<sup>a,h</sup>, Philippe Cinquin<sup>a,h</sup>, Caroline Landelle<sup>a,h</sup>. 11 12 13 a Univ. Grenoble Alpes, CNRS, Grenoble INP, TIMC-IMAG, 38000 Grenoble, France 14 b IMT Atlantique, GEPEA, CNRS UMR 6144, CS 20722, 44307, Nantes, France c Mines Saint-Etienne, Univ Lyon, Univ Jean Monnet, INSERM, U 1059 Sainbiose, Centre CIS, F-15 16 42023 Saint-Etienne, France 17 d Université de Lorraine, CNRS UMR 7274 LRGP, Nancy 54001, France e INRS, département Ingénierie des procédés 18 19 f Clinical Investigation Center-Technological Innovation 1406 (CIC-IT), Department of Public Health, Grenoble Alpes University Hospital, Grenoble, France 20 21 g CIC Inserm 1433 Innovation Technologiques, CHRU de Nancy, Université de Lorraine, 54000 22 Nancy, France 23 h Centre hospitalier Universitaire Grenoble Alpes, 38700 La Tronche, France. 24 i ARC-Nucleart, CEA Grenoble, 17, rue des Martyrs, 38054, Grenoble Cedex 9, France 25 j Ionisos SAS, 13 chemin du Pontet, 69380 Civrieux-d'Azergues, France

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## 43 Abstract:

44 The need for personal protective equipment increased exponentially in response to the Covid-19 45 pandemic. To cope with the mask shortage during springtime 2020, a French consortium was created 46 to find ways to reuse medical and respiratory masks in healthcare departments. The consortium 47 addressed the complex context of the balance between cleaning medical masks in a way that maintains their safety and functionality for reuse, with the environmental advantage to manage 48 49 medical disposable waste despite the current mask designation as single-use by the regulatory frameworks. We report a Workflow that provides a quantitative basis to determine the safety and 50 51 efficacy of a medical mask that is decontaminated for reuse. The type IIR polypropylene medical 52 masks can be washed up to 10 times, washed 5 times and autoclaved 5 times, or washed then sterilized with radiations or ethylene oxide, without any degradation of their filtration or 53 54 breathability properties. There is loss of the anti-projection properties. The Workflow rendered the medical masks to comply to the AFNOR S76-001 standard as "type 1 non-sanitory usage masks". This 55 56 qualification gives a legal status to the Workflow-treated masks and allows recommendation for the 57 reuse of washed medical masks by the general population, with the significant public health 58 advantage of providing better protection than cloth-tissue masks. Additionally, such a legal status 59 provides a basis to perform a clinical trial to test the masks in real conditions, with full compliance 60 with EN 14683 norm, for collective reuse. The rational reuse of medical mask and their end-of-life management is critical, particularly in pandemic periods when decisive turns can be taken. The reuse 61 62 of masks in the general population, in industries, or in hospitals (but not for surgery) has significant 63 advantages for the management of waste without degrading the safety of individuals wearing reused 64 masks.

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66 Keywords: mask, reuse, Covid-19, waste management, filtration, polypropylene

#### 1. Introduction

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2 The healthcare sector has a high utilisation of single-use disposables and thus generates a large amount of waste, albeit that 20 to 25% of which is recyclable plastic material (Campion 2015, Byeong 3 4 Kyu 2002, Kane 2018). Medical masks are medical-use disposables and have become essential for 5 usage by the general community due to the need to control the Covid-19 pandemic. Governments 6 around the world quickly mandated that wearing a mask was compulsory in public spaces. This 7 rapidly increased the demand for respiratory and surgical masks, leading to mask shortages that 8 forced authorities to change their policies and restrict initially the use of surgical masks to healthcare 9 workers (HCW). At the beginning of the pandemic, one or two mask per day per person were 10 distributed instead of following the normal practice of changing the mask for each person between 11 each medical procedure. The consequences for that pattern of usage led to a reduced breathability in 12 the masks and the possibility for germs to translocate. Indeed, sub-optimal recycling procedures 13 consisted of disinfection without any cleaning step (Liao, 2020, Ibáñez-Cervantes 2020, Cai 2020,

14 Cheng 2020, Bernard 2020).

15 Concurrent with the enhanced needs for HCW, the general community was mandated to have 16 face coverings to combat the spread of Covid-19. Since the use of medical masks was reserved 17 initially for HCW, cloth-tissue mask face coverings were developed as a last-resort interim solution 18 for the general community. However, their level of protection is at least 5 times less than medical 19 masks, simply due to the structure and material used for manufacturing and the light-touch 20 regulatory environment (SI-0).

The Covid-19 pandemic is caused by the community transmission of the SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) virus. The 60-140 nm virus (Zhu 2020) travels in micron-size water droplets (Tang 2021, Wei 2021) and can also be infectious in the form of aerosols. However, the larger amount of virus is found in large particles (Wei 2021).

The Type IIR medical masks are disposable medical devices following standards: NF EN 14683:2019 in Europe, ASTM F2100-19 level 1,2,3 in USA, and YY/T 0969-2013 and YY 0469-2011 in

27 China (SI-0). Type IIR medical masks are made from at least 3 layers of non-woven polypropylene, 28 with 2 layers (inward-facing and outward-facing) spun bond (S) polypropylene, between which a melt 29 blown (M) higher filtration layer of polypropylene is disposed. Those 3 "SMS" layers provide an 30 efficient network for filtration. They are certified to prevent the projection of secretions from the 31 airways of the wearer as they filter more than 98% of 3µm droplets from inside to outside. They are 32 certified to protect others from the wearer's respiratory emissions. Nevertheless, they are used to 33 protect the wearer from the respiratory emissions of others.

34 Despite the health-care value of Type IIR masks, such disposable masks create an environmental 35 hazard since the complete biodegradation of polypropylene is a very slow process that requires hundreds of years (Fotopoulou 2017, Dharmarai 2021). Moreover, the term "disposable", or indeed 36 37 descriptions such as "paper masks", reinforces the accumulation of these masks as litter in the 38 environment. Such inappropriate community disposal of contaminated masks raises health 39 questions, not the least of which is the high cost due to environmental damage. Indeed, if good-40 practices for waste management or recycling have not been established then the disposal of the 41 increased number of polypropylene masks becomes a major, and increasing, environmental 42 pollutant. Recent publications on the subject reveal an overload of the plastic waste used during the pandemic, as occurred in Wuhan's hospital, producing 200 tonnes of medical waste in one day, 43 which has to be incinerated by mobile treatment facilities (Saadat 2020, Silva 2020, Singh 2020, 44 45 Ardusso 2020). The number of medical masks is roughly estimated between 1 and 1.3 billion per 46 month in Italy and UK, corresponding to 66,000 tonnes/year of waste (Allison 2020, Prata 2020). 47 Furthermore, during the first pandemic episode in Europe, the price of medical masks was multiplied 48 by at least a factor 10, including the price increase of the raw material and the transport cost.

Here we take a systematic and experimental approach to the question of whether Type IIR masks can be reused. There is a complex context for this question that includes the balance between cleaning medical masks in a way that maintains their safety and functionality for reuse, with the environmental advantage to manage medical disposable waste despite the current mask designation

53 as single-use by the regulatory frameworks. Our approach is to design a Workflow for cleaning masks 54 that is based on elements from existing Standards to ensure the safety and function of reused 55 medical masks. Our Workflow provides data upon which to base a possible revision of the regulatory 56 framework for Type IIR masks. Such an evidence-based Workflow, designed to maintain the efficacy 57 of medical masks, then provides a rational basis to respond to the needs for community protection 58 and prevention in the face of the emergence of highly transmissible SARS-CoV-2 mutants or indeed the next virus pandemic. It also provides the basis for a possible revision of the regulations for the 59 60 reuse of medical masks to address the significant broader issue of improving the sustainability of 61 medical disposables.

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# 63 2. Materials and Methods

We designed a 8-stage Workflow to assure the safety and functionality of medical masks for reuse derived from existing Standards publications. The Workflow was applied to both unused (new) masks taken directly from the original packaging, and used masks collected from hospitals in Grenoble and Nancy. We anticipated the outcomes from this Workflow can provide quantifiable ways to determine and trace the reusability of medical masks.

# 69 2.1. Unused (new) masks

All the new masks used in this study are type II medical face masks following the European standard "*EN 14683+AC august 2019 Medical face masks - Requirements and test methods*", corresponding to ASTM F2100-19 (USA) and YY/T 0969-2013 (China). The properties of type IIR masks as defined by *EN 14683+AC august 2019* are as follows:

74 (i) the microbial cleanliness should be less than 30CFU/g of mask.

- (ii) the label "II" refers to class II masks featuring a 98% bacterial filtration efficiency (BFE) with
   3±0.3µm mean particle size. This FE is measured in the direction of its normal usage, i.e. from
   the wearer to the environment,
- 78 (iii) the breathability refers to the differential pressure and should be lower than 40Pa/cm<sup>2</sup>,

(iv) the label "R" refers to a splash resistance layer protection (≥ 16kPa) against body fluid spills.
The new unused 3 ply IIR-type masks (ref. CA 1960) were provided by CA diffusion to Grenoble
and Nancy hospitals for all the 7 stages of the workflow (Figure 1). The masks comprise non-woven
fabric SMS (Spunbond, Meltblown, Spunbond). They contain a low amount of phenolic antioxidant
(butylated hydroxytoluene, Irganox 1076). The mask fits snugly with the help of a nasal bar (pliable
nose piece) and with ear loop elastic bands (containing elastane + polypropylene) or with 2 flat
polypropylene ties.





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Figure 1: Description of the type IIR new mask used in this study: a) Outside face of the mask b) Nasal bar out of the mask and its non-covered metallic extremity c) The 3 layers of a polypropylene mask.

89 In addition, ten different unused brands of masks have been tested in Nancy Hospital as a control

90 for the washing cycles: CA diffusion 1931 (II), 2015-30 Medicom (IIR), MPB-CH1 Paul Boyé (IIR),

91 PLM.01R Aerokyn (IIR), Earloop LyncMed 302089 (II), Sunrise Nursing (not known), TD Professional

- 92 45455 (II), The Lite One Kimberly Clark (IIR), LiangYa DGTMYY (I), Saudel 85002 (II).
- 93 2.2. <u>Used masks</u>

A protocol was established in different departments of Grenoble Alpes University Hospital (CHUGA) for collection of masks between 03/17/2020 and 06/04/2020, and for collection in different departments of Nancy University Hospital between 04/24/2020 and 08/06/2020.

The protocol required that containers and bags dedicated to collection were placed in the 97 98 different departments where HCW left their used masks at the end of their working day. The used 99 masks were collected within specifically labelled double packaging, transported and stored in an 100 appropriate place. Particular attention was paid to the protection conditions of the collection 101 personnel (wearing of gowns, masks and strict hand hygiene). A wide range of brands was used in 102 the hospital during this period and up to 9 different references of type IIR medical masks have been 103 collected and tested, comprising the trademarks CA diffusion, Kolmi, Valmy, Euronda, Medicom, LCH 104 Medical product, LyncMed and Paul Boyé. Masks with ties have been excluded.

# 105 2.3. Workflow Stage 1: Sorting and washing of the used masks

After collection, the reusable masks have been rapidly selected under a laminar flow cabinet. When the guidelines were properly applied, this step was no more necessary and the masks were then transferred directly to the Hospital's laundry and washed according to the recommendations of the cleaning product manufacturer. The washing step followed the existing classical closed-circuit of the hospital. The 2 procedures are summarized in the washing step procedure in SI-1 section and consist in a 60°C washing with detergents and disinfectants solutions.

112 2.4. Workflow Stage 2: Sterilization

113 (a) by autoclave

The Sterility Assurance Level (SAL) of 10<sup>-6</sup> is the probability of 1-in-1-million to find a remaining living bacteria. It is frequently used for the last step of sterilization of implantable devices. Steam sterilization is the reference method for sterilizing items at the hospital and in all biology science departments. It follows the European regulation ISO 17665-1.

Before autoclaving, the masks were unfolded, bundled in lots of 10 masks, and packed in peelable
 see-through pouches with steam and EtO indicators BOP<sup>®</sup>. After sealing, the pouches were placed in

120 the autoclave Advantage class B or for a treatment at 121°C during 20min. The pouches were dried at

121 70°C during 20min after this treatment to remove the condensed water inside the pouches.

#### 122 (b) <u>by cold sterilizations</u>

123 Three types of cold sterilizations were conducted. The first two were beta and gamma irradiations 124 from 20kGy to 40kGy. The third one was an EO treatment consisting in an exposition of the masks to 125 850mg/L EO gas during 12h at 40°C and 65% relative humidity (SI-2a and -2b).

# 126 2.5. Workflow Stage 3: Analysis of microbial cleanliness

127 The microbial cleanliness was verified according appendix D of EN 14683+AC august 2019 and 128 described in SI-3a. Briefly, 5 washed masks per batch were tested. Each mask was weighed, incubated in a 300mL volume extraction buffer (0,1% peptone, 0,2% Tween 20, 0,5% NaCl) for 5min 129 130 at 25°C with stirring at 250rpm. Then a volume of 100mL of the extraction buffer was filtered on a 131 0.45µm filter fitted into a filtration apparatus. Rinsing of the filtration apparatus was performed with 132 an additional 5mL of sterile extraction buffer. Then, the 0.45µm filter was removed and placed on 133 trypticase soja agar plate. Bacterial colony counting was performed after 3 days of incubation at 134 30°C. The operation was repeated with another 100mL of the extraction buffer for yeast and fungus 135 counting. The new filter from this second filtration was placed on Sabouraud + chloramphenicol (BD 136 France) plates that were incubated for 7 days at room temperature before counting.

### 137

# 2.6. Workflow Stage 4: Sporicidal claim check after washing and autoclave treatment

138 10<sup>6</sup> Geobacillus stearothermophilus spores were inoculated on masks under dirty soiling 139 conditions (SI-4a) according to norms NF T72-230/231, NF EN 14347 and NF EN 13704. The spot of 140 inoculation was marked using a permanent marker. The masks were left on the bench for 24h00 and 141 then washed according to the Workflow Stage 1 protocol, and autoclaved (212°C-20min) using the 142 Workflow Stage 2 protocol. Colony counting was carried out after treatment (washing or washing/autoclaving) versus untreated samples. The marked spot was cut out (3 to 4cm<sup>2</sup>) then 143 transferred to a 15mL tube containing 5mL of 2M NaCl. The tubes were placed under vigorous 144 145 stirring (250rpm) for 5min at 25°C before being filtered through a 0.45µm filter placed on a filtration

apparatus. Rinsing of the device was performed with an additional 5mL of sterile water. The
membrane was then transferred to a trypticase soja plate and incubated at 65°C for 24h before
colony counting.

# 149 2.7. Workflow Stage 5: Particle filtration efficiency (PFE)

150 BFE is the existing standard method to evaluate the resistance of a face mask to the penetration 151 of a bioaerosol of Staphylococcus aureus. However, we have chosen to confirm and supplement the 152 BFE measurements with spectral PFE measurements for an inert di-ethyl-hexyl-sebacate (DEHS) 153 liquid aerosol. The BFE and PFE techniques are comparable since the respective particle sizes are 154 around 3µm and their capture by a filter is the result of physical mechanisms that depend mainly in 155 inertial impact (Brosseau 1994, Wake 1997, Gonzales 2016). The main difference is that BFE test was 156 expressed from the number of 1µm viable bacteria contained in 3µm droplets passing through the medical face mask, whereas the PFE test was calculated from the fractional number concentration of 157 158 3µm vectors measured upstream and downstream of the mask. However, the PFE provides a more 159 robust quantification of the spectral efficiency of the filter in capturing the inert DEHS particles since 160 it based on optical or aerodynamic particle sizer techniques to count particles both upstream and 161 downstream of the filter. The PFE measurements provide more reliable quantification of spectral 162 efficiency of the filtering capability of the masks compared with microbial particle counting using 163 culture-based methods (BFE).

# 164 (a) <u>according to NF EN 14683</u>

The assessment of BFE was performed according to the EN 14683:2019 standard for the performance of medical masks and using a published procedure (Pourchez 2021). Test specimens with a minimum size of 100mm by 100mm were cut from complete masks so that the test specimen included all layers of the mask. The test specimen of the mask material was clamped between a sixstage viable Andersen cascade impactor and an aerosol chamber (glass, 445mm long and 60mm in external diameter). Each test specimen was conditioned in air at 21±5°C and 85±5% relative humidity for a period of at least 4h to allow equilibration with that atmosphere prior to testing. An aerosol of

172 3.0±0.3µm droplets was formed from a suspension of 3mL at 2,000CFU/mL of S. aureus (ATCC 6538) using an E-Flow<sup>®</sup> mesh nebulizer (Pari GmbH, Starnberg, Germany) to maintain a bacterial challenge 173 174 2,200±500CFU per test with a 1min nebulization. The aerosol of S. aureus was introduced into the 175 aerosol chamber and drawn through the mask material and the impactor under vacuum. The testing 176 was performed with the inside of the medical face mask in contact with the airborne bacterial 177 challenge. The FE of the mask is given by the number of colony forming units (CFU) passing through 178 the medical face mask material expressed as a percentage of the number of CFU present in the 179 challenge aerosol. The positive control reference was obtained by omitting the test specimen from 180 the measurement chamber. Then, the BFE score for the mask, as a percentage, was calculated using 181 the following formula:  $BFE=(C-T)/C \times 100$ , where C is the mean of the total plate counts for the two 182 positive control runs, and T is the total plate count for the test specimen. The testing procedure was 183 repeated for at least 5 specimens of the mask.

#### 184 (b)

## (b) Inert particle filtration using PFE

185 The spectral PFE of the tested masks was evaluated using separate devices from two different 186 French laboratories, the GEPEA Lab in Nantes (Génie des Procédés Environnement – Agroalimentaire, 187 UMR 6144) and the LRGP Lab in Nancy (Laboratoire Réactions et Génie des Procédés, UMR 7274). Depending on the device that was utilised, the sample of medical face mask was placed in a filter 188 holder with a filtration surface area of either 168cm<sup>2</sup> (GEPEA Lab) or 28.3cm<sup>2</sup> (LRGP Lab). A 189 190 polydisperse DEHS aerosol was produced with a MAG300 Palas® generator diluted with filtered air 191 for the device with the surface are of section 168cm<sup>2</sup>, and with an AGK 2000 Palas<sup>®</sup> generator diluted 192 with compressed air for the device of section 28.3cm<sup>2</sup>. The polydispersed liquid aerosol of DEHS 193 generated in both experimental devices produced droplets between 1µm and 3µm to provide a 194 comparison with the 3.0µm droplets generated by the aerosol chamber of the BFE tests. Filtration 195 velocity was adjusted at 9.6cm/s corresponding to the one used in the NF EN 14683+AC. After 196 dilution, the fractional number concentration was measured upstream and downstream of the mask

with respectively an optical counter (Welas Palas<sup>®</sup>) and an Aerodynamic Particle Sizer (Model 3321
TSI<sup>®</sup>).

199 The fractional efficiency, efficiency for a given particle size, is calculated as follows:

200 
$$E_N(d_p) = 1 - \frac{C_{N,down}(d_P)}{C_{N,up}(d_P)}$$

where  $C_{N,up}$  and  $C_{N,down}$  are respectively the particle number concentration upstream and downstream of the filter for a given DEHS droplet size ( $d_p$ ).

The efficiency measurement was achieved from a series of 7 counts conducted successively upstream and downstream of the filter. Before each measurement, a sampling of 30 seconds is performed in order to purge and stabilize the concentration of particles in the sampling lines. These 7 counts give three efficiency results for the same mask sample (repeatability test). Efficiency measurements are conducted on three or four samples cut in one or two medical face masks (reproducibility test).

# 209 2.8. Workflow Stage 6: Breathability

In accordance with the Standard <u>NF EN 14683</u>, the pressure drop of the mask was determined at a filtration velocity of 27.2cm/s. This differential pressure should be divided by the standard filtration area of 4.9cm<sup>2</sup> before being compared with the normative values of <40Pa/cm<sup>2</sup> for type I and II, and <60Pa/cm<sup>2</sup> for type IIR.

# 214 2.9. Workflow Stage 7: Projection resistance

For these measurement the masks, the experimental set-ups proposed by ISO 22609:2004 standard were adapted to the materials and equipment available in the labs. The experimental devices were validated by monitoring the corresponding injection pressure and injection duration with reference to those given by the ISO norm table. The projection resistance tests were performed under the conditions described by the ISO Standard, at a blood ejection rate of 550cm/s corresponding to a blood pressure of 16kPa. The tests were repeated once for each type of mask under the same conditions. To be fully compliant with ISO 22609, nearly 30 tests should be

222 performed for each type of mask, which is obviously not possible in the current context (SI-5a and -

223 5b).

# 224 2.10. Workflow Stage 8: Chemical and structural characterizations

Fourier Transform Infrared (FTIR) spectroscopy and Scanning Electron Microscopy (SEM)
 experiments were conducted to complete the workflow. Each protocol is described in SI-8a and -8b.

227

# 228 3. Results

## 229 3.1. <u>Cleanliness after Workflow: Macroscopic inspection of the washed masks</u>

For this stage of the Workflow an initial mask sorting step was performed before the washing step. Some masks were excluded from the washing because they were too dirty, mostly due to makeup smears (around 3-4% of the total collection). Masks with low quantity of makeup were well cleaned. We've noticed during this study, that around 1% of the collected masks were repaired with a staple, which highlighted the shortage of masks during the collection periods. Up to 10 washing/drying cycles did not modify the appearance of the mask.

The visual inspection of the new CA diffusion 1960 masks after washing did not show any significant structural defect, apart from broken elastic ear-loops (5-7% of the masks) that always at the welding spot between the mask and the elastic band. Minor rust spots are appearing on 25% of the mask at the two ends of the nasal bar after 2 washing cycles. Those rust spots do not have any adverse effect on the face mask fitting.

Similar results were found with the 9 used collected different brands in Grenoble and 10 different brands in Nancy. All the masks look clean, without any dimensional change, 5% of the mask had a broken elastic ear-loop, rust spots were observed on 1/3 of the masks (Figure 2a). We have noted that for 50% of the Euronda masks the nasal bar was able to dislodge from the sheath on the mask.

245 3.2. <u>Cleanliness after Workflow: Microbial inspection of used masks</u>

We applied to our washed masks the same tests applied for new fabricated masks in accordance with NF EN 14683. For this, we extracted randomly 5 masks from 4 different washing batches and

measured the number of bacterial and fungal CFU present on each mask. The results (SI-3b) met expectations as the total measured CFU is 5 times less than the limit described in the norm ( $\leq$ 30CFU/g). Nonetheless, the variability from one mask to another is large (Figure 2c) with 1/3 of the mask containing between 6 and 9CFU/g and 1 mask containing 29CFU, which corresponds to the maximum allowed by the norm.

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#### 3.3. <u>Cleanliness after Workflow: Masks washed in dirty conditions</u>

Washing tests performed with 40 new masks in the dirty conditions recommended by the norms (SI-4a). Each new mask was soiled with 100µL inoculum of the "dirty suspension" and then dried before the treatment (Figure 2b). The blood stain was completely cleaned by the washing step. It may be noted that the permanent marker used to mark the spot is still present. Thus, the permanent marking of a used mask ensures easily a good traceability during all processes, and particularly during the tread life of a recycled mask.

We have also conducted an experiment to consider the worst possible case of spotting 10<sup>6</sup> spores of *G. stearothermophilus* in dirty conditions onto 5 new masks. A 4 log<sub>10</sub>-fold reduction of spores was observed after washing. Spores are considered as the most resistant living organisms and are a good standard for a quality control. The SAL of 10<sup>-6</sup> was largely achieved with a following sterilization step, for example by autoclaving the masks 20min at 121°C (Figure 2d and SI-4b).



Figure 2: a) Rust spots at the extremity of the nasal bar of a mask b) Mask (before/after) washed in dirty conditions c) Microbial distribution after a washing step d) *Geobacillus stearothermophilus* count after treatment in dirty conditions

## 267 3.4. FE after Workflow

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268 The results of BFE (mean and spectral) and spectral PFE are presented in Table 1 and SI-6a,b,c for 269 the treatments of new masks "CA diffusion 1960". Several batches comprising at least 5 masks were 270 first treated, in particular washing cycles, washing cycles followed by autoclaving cycles and washing/alternative sterilizing cycles. The first line of the table (L201, L203, L204, and L327) 271 272 corresponds to the untreated masks. Regardless of the treatment used, the filtration properties were 273 preserved as quantified by the mean BFE greater than  $99,6\%\pm0.3$  according to the NF EN 14683 274 standard (SI-0). These results indicate that those treated face masks passed the standard thresholds 275 for filtration efficiencies, despite the possibility that the 3 layers of the masks could have separated 276 during washing.

277 The spectral filtration efficiencies obtained by CFU counting for the BFE and by optical counting for PFE (Table 1) comply with the approved standards for particle size greater than  $1\mu m$ . For  $3\mu m$ 278 279 particles, spectral BFE and PFE are always higher than 99.0% (%<sub>CFU</sub> or %<sub>OPTICAL</sub>) indicating that the 280 different treatment processes (until 3 or 10 cycles according to the treatment) do not seem to 281 deteriorate the protective performance of those face masks. Alternative cold sterilization 282 procedures, i.e radiations and EO treatment, are described in SI-2 section and in a preliminary IAEA 283 report (Cortella 2020). No degradation of PP and EO residues were found after treatment. Some 284 minor chemical modifications, were measured mostly due to the presence of anti-oxidants in new 285 masks.

286

|                         |                       | Washing Sterilisation                          |                                   |          |                           | Filtration analyses after treatments |  |   |           |           |            |  |        |        |        |        |        |
|-------------------------|-----------------------|--|-----------------------------------|----------|---------------------------|--------------------------------------|--|---|-----------|-----------|------------|--|--------|--------|--------|--------|--------|
| Batch                   | <u>Mask</u><br>number | Washing<br>60°C 12<br>min<br>Ultimate<br>(F+M) | Autoclave<br>121°C 20 γ<br>min 20 |          | y rays<br>0 kGY<br>40 kGy | Ethylene<br>Oxide                    | Bacterial filtration<br>efficiency<br>norm NF EN 14683<br>AC | Fractional bacterial filtration efficiency norm NF<br>EN 14683 AC |           |           |            | Fractionnal particle filtration efficiency |        |        |        |        |        |
| number                  |                       |  |                                   | 20 kGY   |                           |                                      |  | 3.3-<br>4.7μm   | 2.1-3.3µm | 1.1-2.1µm | 0.65-1.1µm | 3µm  | 2µm    | 1.6µm  | 1µm    | 0.67µm | 0.3µm  |
| L201,L203,<br>L204,L327 | 20                    | -  | -                                 | -        | -                         | -                                    | 99.98 ± 0.03%  | 100.00%   | 100.00%   | 99.93%    | 100.00%    | 99.99%<br>99.95%*                          | 99.96% | 99.90% | 98.26% | 80.06% | 40.17% |
| L202,L205,<br>L206      | 15                    | 1  | -                                 | -        | -                         | -                                    | 99.9 +/- 0.08%   | 100.00%   | 99.96%    | 99.52%    | 90.77%     | 99.99%<br>98.44%*                          | 99.88% | 99.71% | 98.48% | 88.85% | 35.25% |
| L209                    | 10                    | 3 cycles                                       | -                                 | -        | -                         | 3 cycles                             | 99.89 ± 0.05%  | 100.00%   | 100.00%   | 99.19%    | 91.58%     | 100%                                       | 99.9%  | 99.8%  | 91.8%  | 64.75% | 40.0%  |
| L212                    | 10                    | 3 cycles                                       | -                                 |          | 3 cycles                  | -                                    | 99.61 ± 0.37%  | 99.81%  | 99.50%    | 99.84%    | 60.00%     | 99.2%*                                     | 98.0%* | 94.0%* | -      | -      | -      |
| L215                    | 10                    | 3 cycles                                       | -                                 | 3 cycles | -                         | -                                    |  | -   | -         | -         | -          | 100%                                       | 99.85% | 99.7%  | 93.7%  | 60.33% | 30.37% |
| L216                    | 10                    | 1  | 1                                 | -        | -                         | -                                    | 99.8 +/- 0.11%   | 100.00%   | 100.00%   | 98.99%    | Und        | 100%                                       | 99.88% | 99.0%  | 96.9%  |        |        |
| L252                    | 10                    | -  | 10 cycles                         | -        | -                         | -                                    | 99.73 ± 0.33%  | 99.95%  | 99.94%    | 98.69%    | 77.60%     | -  | -      | -      | -      | -      | -      |
| L221                    | 10                    | 10 cycles                                      | -                                 | -        | -                         | -                                    | 99.79 ± 0.09%  | 100.00%   | 100.00%   | 99.16%    | 93.78%     | 98.97%*                                    | -      | -      | -      | -      | -      |
| L316                    | 10                    | -  | -                                 | -        | -                         | 3 cycles                             | 99.93 ± 0.10%  | 100.00%   | 100.00%   | 99.88%    | 76.00%     | 99.99%                                     | 99.99% | 99.8%  | -      | -      | -      |

Table 1: Filtration efficiency after new masks treatments. The mean BFE corresponding to the NF EN 14683 AC norm is in bold format. The values under 98% are written in red. \* FPE results from LRGP Nancy for intercomparison with IMT Nantes. Und-: Undertermined

| Batch         | Mask   | Mask brand                    | Bacterial<br>filtration           | fractional bacterial filtration effiency norm NF EN<br>14683 AC |           |           |             | Fractionnal particle fitltration effiency |         |        |        |        |        |
|---------------|--------|-------------------------------|-----------------------------------|---|-----------|-----------|-------------|---|---------|--------|--------|--------|--------|
| number        | number | Mask brand                    | efficiency norm<br>NF EN 14683 AC | 3.3-4.7µm   | 2.1-3.3µm | 1.1-2.1µm | 0.65-1.1 μm | 3µm                                       | 2μm     | 1.6µm  | 1µm    | 0.67µm | 0.3µm  |
| L271,<br>L107 | 20     | Used Paul Boyé MPB-CH1        | 99.89 ± 0.11%<br>99.82 ± 0.12%    | 100.00%   | 100.00%   | 99.57%    | 73.33%      | 99.88%                                    | 98.91%  | 98.6%  | 94.89% | 68.72% | 39.54% |
| L272          | 10     | Used CA diffusion unknown ref | 98.18 ± 1.06%                     | 100.00%   | 99.65%    | 84.74%    | 20.00%      | 91.90%*                                   | 63.20%* | 44.6%* | -      | -      | -      |
| L103          | 10     | Unknown 1 (Blue 1)            | 98.91 ± 1.22%                     | 99.92%  | 100.00%   | 93.92%    | 46.67%      | 99.99%                                    | 98.9%   | 97.5%  | 82.41% | 45.92% | 28.3%  |
| L104          | 10     | Used Kolmi Op'R M36101        | 99.19 ± 0.26%                     | 99.93%  | 99.87%    | 95.30%    | 18.00%      | 99.39%                                    | 97.22%  | 93.45% | 71.47% | 37.69% | 25.85% |
| L105          | 10     | Used CA diffusion             | 99.09 ± 0.27%                     | 100.00%   | 99.91%    | 95.54%    | 3.16%       | 99.99%                                    | 97.78%  | 94.98% | 74.10% | 40.11% | 24.63% |
| L106          | 10     | Used Valmy                    | 99.82 ± 0.07%                     | 100.00%   | 100.00%   | 98.63%    | 88.00%      | 88.38%                                    | 87.48%  | 86.32% | 72.99% | 37.51% | 24.01% |
| L108          | 10     | Used unknown 2 (Blue 2)       | 99.62 ± 0.20%                     | 100.00%   | 99.97%    | 98.22%    | 20.00%      | 98.30%                                    | 98.62%  | 97.24% | 80.29% | 42.38% | 25.74% |
| L109          | 10     | Used unknown 3 (white light)  | 99.75 ± 0.08%                     | 100.00%   | 100.00%   | 98.19%    | 42.86%      | 98.25%                                    | 93.40%  | 92.09% | 75.16% | 36.00% | 17.81% |
| L110          | 10     | Used Euronda                  | 99.80 ± 0.12%                     | 100.00%   | 100.00%   | 98.75%    | 73.33%      | 99.99%                                    | 99.91%  | 99.66% | 94.23% | 61.40% | 33.14% |
| L111          | 10     | Used CA diffusion 1960        | 99.80 ± 0.09%.                    | 100.00%   | 99.96%    | 99.20%    | 91.25%      | 99.99%                                    | 99.96%  | 99.94% | 96.14% | 66.22% | 36.53% |

Table 2: Filtration efficiency of used mask after 5 washing steps followed by 5 autoclaving steps. The mean BFE corresponding to the NF EN 14683 AC norm is in bold format. The values under 98% are written in red. \* FPE results from LRGP Nancy for intercomparison with IMT Nantes.

The differences between the two sets of spectral PFE measurement can be explained by the use of two different experimental devices inducing differences in (i) the filtration section which a ratio of 6 (168 and 28.3cm<sup>2</sup>), (ii) distribution, and concentration of the liquid particle size of the DEHS generated by the two systems, (iii) the particle counting systems, which are based on two different principles of particle size measurements (optical counter based on light diffraction and aerodynamic sizer based on time of flight).

293 For submicron-sized particles (impaction plate collecting size fraction between 1.1 to 0.65µm for 294 BFE, and particle size of 1, 0.67 and 0.3µm for PFE), the BFE and PFE values are different but show 295 the same tendency for FE to decrease with particle size and the influence of the treatment processes, 296 which altered the efficiency for those fine particles but without degrading the mean BFE values. We 297 have noticed that this loss of efficiency for submicron-sized particles is effective after the first wash 298 and stabilized at the same level after several washes, regardless of the washing process (SI-6b). At 299 submicron-size, the filtration involves other mechanisms than inertial impact that can particularly 300 include electrostatic mechanisms. This electret effect (Lin 2017, Hossain 2020) of the polypropylene 301 fibres is permanently destroyed during the first wash because the washing agents bind to the surface 302 and cannot be removed. This effect can be mimicked by the rinsing of a new mask in isopropanol (SI-303 6c). Results show that the discharging of a mask leads to the same spectral collection efficiencies 304 than those of a washed mask, confirming the loss of electret effect as a result of the first washing 305 cycles.

Used medical masks come from hospital departments and consist of 9 different reference brands (Table 2). They have undergone 5 washing cycles followed by 5 autoclave cycles. After sterilization and washing, the filtration properties were conserved for all the samples, with a minimum mean BFE of  $98.2\% \pm 1.2$  for the sample with the lowest filtration performance, which is above the NF EN 14683 standard threshold. The comparison of spectral BFE and spectral PFE (Table 2 and SI-6d) confirms the good protection performances of the used masks after 5 decontamination procedures for particle sizes higher than  $2\mu m$  (BFE>99.6%<sub>CFU</sub> and PFE>97.2%<sub>OPTICAL</sub>). Even if some differences can be observed

between these 9 reference brands, results show a preservation of the spectral BFE and PFE for particle size higher than 2 $\mu$ m whatever the mask. A significant decrease of spectral efficiencies (both BFE and PFE) is observed for particle size smaller than 2 $\mu$ m, even though the BFE shows a good filtration performance of greater than 91.2% for submicron particle sizes in the range 0.65 $\mu$ m to 1.1 $\mu$ m.

318 To check the influence of a hole or a notch that can occur accidentally in the mask during the 319 recycling process, we deliberately damaged a series of mask after one use/washing/autoclave cycle 320 and tested their FE. Holes were created in the center of the masks in two ways. The first was to 321 pierce the mask material with a blunt cylindrical tool such as a Phillips screwdriver to create holes 322 from 1 to 5mm. The second was to use a razor blade to make cuts of 7 and 10mm. Those techniques punctured the mask material and created a rough-sided hole from 1 to 5mm or a clean side cut of 7 323 and 10mm without explicit removal of the material within the confines of the punctured hole. 324 325 Indeed, an accidental explicit removal of material with a hole puncher is highly unlikely compared to 326 a tear (as we have simulated with the razor blade cuts). The figure SI-6e shows results of PFE 327 measurements performed on amedical mask (L101) and on the same mask with holes of different 328 sizes on the center part of the mask face (L102 with hole of respectively 1, 2, 3, 4, 5mm and cuts of 7 329 and 10mm size). Due to the multi layer media constituting the mask, even in the case of big holes 330 (>3mm) no significant influence is observed for spectral efficiency for particle diameter higher than 331  $1\mu m$  (apart for the test performed with a hole of 2mm for which a slight decrease of PFE is 332 observed). For particle sizes lower than 1µm, the presence of holes in the mask can contribute to a 333 slight decrease of the spectral efficiency compared with the mask without any hole.

334 3.5. Breathability after Workflow

The breathability performances (resistance to air flow) were not significantly affected regardless of the particular decontamination process. When compared with untreated masks, breathability values remained within the variability range of measurements made on the untreated masks (variation due to the intrinsic local heterogeneity of the fibrous structure composing the masks) and

were always under normative values, i.e. of 40Pa/cm<sup>2</sup> for a type I or II and 60Pa/cm<sup>2</sup> for a type IIR. 339 340 The Mann-Whitney U test (Murray 2008), a non-parametric statistical test applied to data, confirmed 341 that the breathability of treated masks (regardless of the type of treatment) is not significantly 342 different from that of the untreated masks. Thus, we can conclude that the sterilization and washing 343 cycles do not alter the structure of the non-woven media.

344 3.6. Projection resistance after Workflow

The projection resistance ("R" function) was tested on an experimental set-up aiming to 345 346 reproduce the test conditions recommended by ISO 22609:2004 Standard. This set-up was 347 developed, validated and implemented on new or washed masks with a synthetic blood formulation. The "R" function was lost after a few washing steps, regardless of the particular brand of type IIR 348 349 mask. It appears that washing changes the surface properties of the outer layer of a washed mask 350 which leads to the loss of the protective function (SI-5c). The projection resistance is not maintained 351 after recycling, which means that medical team working in an operating room should not wear 352 washed IIR masks.

353

# 3.7. Chemical and structural characterizations

The two broad ranges from 2835 to 2952 cm<sup>-1</sup> and from 1165 to 1452 cm<sup>-1</sup> of FTIR spectrum are 354 355 characteristics of polypropylene. The FTIR analysis does not reveal significant oxidation processes 356 after cleaning (SI-8a).

357 SEM images of treated masks are presented in SI-8b. No significant morphological modifications 358 were noticed, except for MPB-CH1 melt-blown layer containing thinner fibres (SI-8b). However, these 359 modifications do not impact the filtration that remains very high (Table 2).

360

361 4. Discussion

362 4.1. Cleanliness, filtration and breathability of Type II medical masks remain compatible with EN14683 after up to ten cycles of washing cycles at 60°C with detergent 363

364 Reuse must ensure the conservation of the paramount properties of the mask. We have proven 365 that the process of washing/sterilizing the masks retains their cleanliness, their filtration capabilities 366 and their breathability. However, the R function is lost in the cleaning process. This does not detract 367 from the function of the masks in a domestic usage, but requires a modified usage of reused maks in 368 the hospital environment. Although reused masks can no longer be used appropriately where blood 369 or bodily fluid splashing can occur, such as in operating rooms, the reused masks can be used 370 appropriately in other areas of the hospital. It is important to note that in any case type IIR masks are 371 already dedicated to operating rooms.

372 The cleanliness of the masks is obtained by washing. This washing step is mandatory to respect 373 good hygiene practice before any other treatment and acceptability for the user. The aim of the 374 washing step is to eliminate all traces of biological contamination (secretions, mucus) and to lower 375 the level of initial contamination (due to the 12min contact with disinfectant). Moreover, it tackles a 376 large part of the problem of wearing a mask that is not your own. Indeed, even if a mask is sterilized, 377 it is difficult to wear a used dirty mask that has not been washed. The SARS-CoV-2 is a virus sensitive 378 to the combined action of detergents, mechanical movements and heat which occur in a washing 379 machine. The commonly accepted recommendation for cloth-tissue mask is a washing step at 60°C, 380 or even lower (FNAM 2020). As recommended for community use of masks, a sterilization step 381 described in SI-2c is not recommended.

The results of excellent FE remaining after even 10 cycles of washing has very positive sanitary consequences on the wearing of used/washed masks in the domestic environment, especially in the context of severe constraints on mask shortage or indeed the reduction of discarded single-usage masks on the environment.

# 386 4.2. <u>Collective treatment of the masks needs a sterilization step</u>

387 Mask reuse in a collective reprocessing generates more complexity, taking into account good 388 hygiene practice and healthcare waste management. Although Kane et al, 2018, describe that 389 "introducing circular economy principles into design for healthcare is challenging", it is nonetheless

an important point to address. It is critically important to consider the bacterial and fungal cleanliness of the recycled masks used in a healthcare environment. It is indeed required to eliminate all potential risks of bacterial or fungal cross-contamination of masks potentially exposed to microbiological agents of the wearer or of its environment.

394 The 4 log<sub>10</sub> spores reduction obtained with washing is in accordance with an experiment 395 performed in Bangkok's hospital (Luksamijarulkul 2014), which evaluates the bacterial and fungal 396 contamination on used medical masks worn by the HCW. The authors collected 230 used masks from 397 214 HCW and found that the maximal bioburden was less than 10<sup>3</sup>CFU/mL/piece on the outside area 398 of the masks and less than  $10^{2}$ CFU/mL/piece in the inside area of the masks (p<0.001). In principle, 399 this first washing step should be sufficient to eliminate the microorganisms that are present on the masks. Nonetheless, in the special case of a pandemic, especially for a virus pandemic, it is important 400 401 to reduce the contamination risk to ensure a health and safety state (Bernard 2020). Moreover, the 402 analysis of the variability of the cleanliness of washed masks suggest that a safety state is not 403 achieved by a washing step procedure using masks coming from the hospital. The issue can also 404 come from organisms that can be found in an hospital: Hepatitis B Virus or Mycobacterium 405 tuberculosis are also thermoresistant up to 80-100°C (Doig 2002, König 2019. Thus, other methods 406 have to be applied after the washing process to ensure a perfect recycling quality.

The reuse of cleaned mask is somehow not sufficient to provide enough safety for HCW and a sterilization step is mandatory, not to have a sterile status of the device but to minimize this risk of cross-contamination of resistant germs like spores or mycobacteria. The existing circuits of sterilization process of autoclavable tools and dirty laundry transfer circuit (Figure 3) greatly facilitated the operating procedure in a healthcare environment.



Figure 3: Waste management. Existing circuit (blue and grey), Masks Reuse and Recycling circuit (green) 413 414 The industrial sector can also consider a collective recycling. Some companies have already shown 415 a willingness to make progress in the ecological consequences of polypropylene recycling by creating 416 specific recycling branches dedicated to medical masks. Despite those good intentions, those small 417 number of companies do not have sufficient financial resources to expand those recycling activities. 418 Nonetheless, those examples add value to the global waste management, because before the masks are either discarded or recycled they are first reused. The risk of cross contamination in the industrial 419 420 sector is often less present than in hospitals and the washing step is probably enough to guarantee 421 the safety. This risk can be evaluated on a case-by-case base. However, the possibility of sterilizing is 422 still possible with access to different technology platforms described in table 3.

| Methods   | Washing                                    | Autoclave        | β Radiations  | γ Radiations    | Ethylene oxide               |  |
|---|--|------------------|---------------|-----------------|------------------------------|--|
| Location  | Hospital                                   | Hospital         | IONISOS       | CEA/IONISOS     | IONISOS                      |  |
| Number of treated masks/cycle                               | 5000 1200 170 000                          |                  | > 1 million   | up to 1 million |                              |  |
| Conditions  | Detergent<br>+disinfectant<br>+60°C/12 min | 121°C/20<br>min. | 25 kGy vacuum | 25 kGy vacuum   | 850 mg/L-40°C-<br>65% RH/12h |  |
| Treatment duration  | 2h   | 7h               | <1h           | 12h             | 60h                          |  |
| Estimated global<br>recycling time<br>(including transport) | 1 <u>d</u>                                 | ay               | 3 <u>days</u> | 3 <u>days</u>   | 6 <u>days</u>                |  |

#### 423

424

Table 3: Comparison of different treatments capacity and duration for medical mask reuse in collective settings.

425 The presence of autoclaves in sterilizing unit facilitates this process but the major drawback is the 426 number of units that can be treated at the same time. The  $\beta$  and  $\gamma$  technologies have some 427 differences in the process. Gamma ray technologies make it possible to deliver the dose to a large 428 volume of masks but slowly, while electron beam technologies, on the other hand, make it possible 429 to achieve the same dose in a fraction of a second, but in a smaller volume. The net result is that  $\beta$ 430 and y technologies are comparable in processing capacity. Density is also a relevant factor that 431 influences on the penetration of radiation, and thus on the processing capacity. At this stage of the 432 study, there will be no noticeable difference between  $\beta$  and  $\gamma$  radiation because the number of 433 masks was small. They were wrapped into vacuum bag to reduce the thickness of each bag (more 434 than one half-volume reduction), allowing the handling and the cleanliness of the masks until their 435 reuse. A performance qualification study will have to be carried out in each case when the process 436 will be industrialised.

437 EO treatment and irradiation treatments  $\beta$  and  $\gamma$  are cold sterilisation alternative techniques to 438 autoclave treatment. Despite the fact that the logistics have to be created unlike the 439 washing/autoclave circuit, they are useful tools to process a huge quantity of masks at the same time 440 in a single run.

#### 441 4.3. <u>Biocompatibility preliminary data</u>

442 The results of FTIR and SEM analyses performed on the treated masks are very reassuring: they tend to indicate that the treatment yields no major modification of the physico-chemical 443 444 components of the masks. Besides, most of the reusable cloth-tissue masks contain as much 445 polypropylene as medical masks, and are certified for reuse after between 10 and 50 washing cycles. 446 No adverse event related to wearing washed cloth-tissue masks was reported, although millions of 447 such masks were washed and reused all over the world. Therefore, demonstrating biocompatibility 448 will be necessary only for manufacturers wishing to demonstrate full consistence to EN 14683 of 449 washed masks.

# 4.4. <u>The conformity with the French Standardization Association (AFNOR) SPEC \$76-001: 2020</u> allows not only to issue recommendations for the public, but also to perform a clinical trial in real conditions

453 The washing conditions for reusable cloth-tissue masks are described in similar rules for each 454 country (FNAMHPS 2020 for France). Our washing conditions were more demanding (60°C instead of 455 40° C). The conformity according to the French AFNOR SPEC S76-001: 2020 for cloth-tissue masks of 3 456 brands of medical masks washed up to 10 times under these conditions has been checked with 457 success by independent certified actors (SI-7). This conformity, in accordance with European CWA 458 17553:2020 and US F2299/F2299M-03 regulations, allows to recommend the reuse of washed 459 medical masks instead of cloth-tissue masks to guarantee a higher level of filtration. Indeed, the 460 quantity of 3µm particles emitted towards the entourage of a person in 6minutes without any face 461 protection is equivalent to the quantity emitted in 1hour with a 90% filtering cloth-tissue mask or in 462 5hours with a medical face mask filtering at 98% (SI-0).

The loss of the CE marking led to the loss of legal status for the treated masks (which are nonreusable Medical Devices). A legal status is recovered by the AFNOR certification that will allow to test wearing/treatment cycles in a future clinical trial. The main objective of this clinical trial will be to demonstrate that at least 10 cycles of use/washing and at least 5 cycles of

use/washing/sterilization can be done in real conditions with full compatibility with EN14683 norm
(including complete test of biocompatibility, which as previously discussed was not completely tested
in the present work).

470 4.5. Mask end of life

471 The major issue is the limit of cycles that can be done. We arbitrarily stopped after 10 cycles of 472 washing, which preserves the filtration properties of the masks. The number of cycle treatments will depend on wearing, washing and storing conditions. How to know when the mask is no more usable? 473 474 The answer is probably "when it does not fit well to the face". This answer is due to several reasons. 475 First of all, the structure of the mask: each layer is a non-woven material. When a cut in the fibres 476 occurs, the thread is not uncoiled. Holes or notches in a cloth-tissue mask, which are woven or 477 knitted, will have a devastating effect on the filtration. Secondly, the 3 layers of material can slide 478 one on the other and this phenomenon plugs cracks or holes so that the filtration capability is 479 maintained, as shown in figure 3b. Finally, the most fragile parts of the mask are actually the nasal 480 bar, the ear loop elastic band and especially their welding spot on the corners of the mask. The 481 accumulation of lint can be observed after several washes at home with short cut fibres going out of 482 the mask outside layers. This pilling leads to uncomfortable wear and can define the end of life of the 483 mask even if filtration properties remain efficient.

## 484 4.6. Economic perspective

The reuse of medical mask opens new perspectives. The mask reuse has also a significant economical effect on households: The price of a tissue mask, with a guarantee of 50 washes, can reach up to 50 times the price of a medical mask. Thus, a medical mask washed 10 times is 10 times cheaper. The cost of washing is zero has the masks are washed with the washing of domestic clothes. In collective treatment, the recycling price has to be evaluated according to the number of masks used per day, the presence of a recycling process or the strategic partnership with appropriate companies.

# 492 4.7. Ecologic perspectives

493 Covid-19 pandemic has led to a widespread of environmental contamination of plastics, 494 comprising the polypropylene medical masks. At a large scale or in highly specific environment, the 495 low cost of disposable masks compared to the cost of recycling its polypropylene is probably not a 496 viable economical target, because of the low weight/volume of each mask, its infectious risk and the 497 lack of existing recycling circuit. However, the ecological cost will more expensive at the end-of-498 mask-life. The rational reuse of medical mask and their end-of-live management is critical, particularly in pandemic periods when decisive turns can be taken. The reuse is the first step of a 499 500 recycling process.

The use of disposable masks in the general population gives rise to their larger consumption to help fight high transmissible mutants but their reuse up to 10 times will compensate or will even reduce their environmental impact. For lower scale uses, the possibility to safely recycle medical masks is cost-effective, and an eco-friendly gesture.

Ecological consequences must be taken into account: a non-woven mask is easily recycled as it is only composed of pure polypropylene when the nasal bar and the elastic bands are removed. This is not the case for woven masks that often uses a mix of synthetic fibres and has to follow a specific recycling. However, the recycling of domestic usage of medical masks has not been yet envisaged.

509

# 510 **5.** Conclusion

511 We have proven that the lifetime of type II medical face masks can be extended by reusing them 512 after washing and decontaminating treatments. Those treatments consist in washing steps and/or 513 washing sterilizing cycles. The use of a detergent and a disinfectant during the washing step allows 514 not only to clean the device but also to reduce the presence of germs. The masks retain their 515 breathability and their filtration capability up to 10 cycles of washing or 5 washing cycles followed by 516 5 autoclaving cycles without major structural and chemical modifications. Cold sterilizations, like 517 radiations or EO treatment have also been tested with success. These experiments prove that those 518 "disposable" masks remain reusable, with the exception of the anti-projection resistance that is not 519 conserved, so that the masks cannot be reused in operating rooms. As washed medical masks 520 remains more efficient in terms of filtration than cloth-tissue masks, we can recommend their reuse 521 according to the cloth-tissue mask regulations. A clinical trial in real conditions with full compliance 522 with EN 14683 norm will allow the manufacturers to claim that type II medical face masks can be 523 considered as Medical Devices after washing (followed or not by a sterilization process). This will 524 require modifications of laws and regulations in countries like France, where legal prohibitions 525 prevent any reuse of a "single-use" Medical Device. However, we have demonstrated here that type 526 II medical face masks are compliant with the regulations applicable for reusable cloth-tissue masks. 527 This may have a tremendous impact in terms of public health and ecology. In terms of public health, 528 wearing a type II medical face mask provides a much better protection than a cloth-tissue mask. In 529 terms of ecology, reusing 10 times a type II medical face mask would reduce the burden associated 530 with the waste management and the consumption of polypropylene.

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