Federal Agency for Medicines and Health Products
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Guidance for the reprocessing of surgical masks and filtering facepiece respirators (FFP2, FFP3) during the Coronavirus disease (COVID-19) Public Health Emergency – V 1.1 05.05.2020

Introduction

In the context of the coronavirus (COVID-19) public health emergency, the risk of shortage of surgical masks and filtering facepiece respirators (FFP2, FFP3) is a major public health risk. To face this situation, a general Task Force on shortages has been set up in which FAMHP is taking part with stakeholders.

Different methods for the reprocessing of these single-use masks have been proposed by different stakeholders. This guidance, developed by a sub-working group on re-use, is aimed to provide a reprocessing policy to help expand the availability of surgical masks and particulate filtering facepiece respirators (FFP2, FFP3) for healthcare professionals during this pandemicAs guidance document, the FAMHP decided to retake most of the information from section VI.A. on reprocessing of masks from the FDA guidance Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health. However, the FDA recommendations were adapted to the Belgian context and are outlined below.

The use of sterilisation methods for the reprocessing, disinfection, bioburden reduction of the masks or filters does not mean that the masks or filters are sterile after reprocessing. However, sufficient bioburden reduction should be demonstrated following our recommendations described below. It is recommended to follow the 'Good practices for the sterilisation of medical devices' (May 2017, SHC N° 9256) along with the relevant ISO standards cited in this document for cleaning, disinfection and sterilisation (as appropriate) of health care products. https://www.health.belgium.be/en/brochure-good-practices-sterilisation-medical-devices-9256

It is recommended, as far as possible, to apply reprocessing to used CE marked products coming from your usual suppliers.

The FAMHP will not assess the reprocessing activities in the scope of this guidance. However, you are requested to send a notification of such activities to coronashortages@fagg-afmps.be, using the template (right click and save on your desktop then send via e-mail). You are invited to keep the available information on reprocessing at the disposal of the competent authorities. To enhance the collaboration among the different stakeholders, FAMHP publishes the different

information provided for the reprocessing and related activities at the end of this document, including the contact points (see annex II).

The reprocessing activities of such products should be only foreseen as long as the shortage is confirmed; it is only a second option, as in case of choice, new surgical masks or FFP2 or FFP3 shall be used.

The reprocessing requester will be the entity legally responsible for the reprocessing requested and will ensure that the outsourced reprocessing rules are being conformed to this national guideline.

If the reprocessing is outsourced, it is highly recommended to manage it one to one; meaning that the same batch sent outside for reprocessing should return to the requester.

The initial manufacturer of the single use mask or filtering facepiece is being disengaged of any liabilities on the reprocessed product put on the market.

You can send your questions or comments about this document to coronashortages@fagg-afmps.be with the following subject: comments/questions related to Belgian national guidance on reprocessing of surgical masks and filtering facepiece respirators.

Recommendations for reprocessing of surgical masks and filtering facepiece respirators (FFP2, FFP3)

- A justification for the selected method(s) used for cleaning, disinfection and sterilisation of the specified surgical masks and filtering facepiece respirators (FFP2, FFP3). This should address the desired level of inactivation (microbial/viral) as well as the quality impact on the reprocessed items as detailed below (e.g. material compatibility, performance characteristics).
- A description of the process for disinfection/sterilisation, including:
  a) Critical cycle parameters (e.g. concentration of agent used, irradiation dose, time, temperature, F value, relative humidity as appropriate) required for bioburden and viral reduction.
  b) Information on chemical indicators (CI) and/or biological indicators (BI) can be used to demonstrate that your cycle is appropriately implemented and continues to be executed as intended. CI and/or BI should be placed evenly throughout the load to demonstrate that at all areas of a chamber the critical process parameters have been achieved. CI and/or BI should provide a worst-case challenge to the cycle.
- Validation of bioburden reduction/disinfection, including:
  a) Evidence to demonstrate that the selected method(s) will reduce bioburden on the masks in a reproducible manner. For sterilisation methods, a biological indicator with suitable resistance is typically used to demonstrate the required level of lethality (≥ 6 log reduction). This would also indirectly

validate sufficient reduction of virucidal activity since viruses like Covid-19 (lipid enveloped virus) are far less resistant towards disinfection/sterilisation techniques.
b) Validation of the number of times a specific mask can be reprocessed.
c) Evidence to demonstrate that soils (e.g., blood, mucus, sebum) are either removed or do not interfere with the bioburden reduction/disinfection processes. This information is important as it may limit the ability of masks contaminated with certain soils to undergo a specific process. Masks should be discarded if visual evaluation shows that they are too contaminated.
d) Identification of the materials (including filter and strap/elastic band) that are compatible / incompatible with your proposed reprocessing cycle.
e) Protocols and acceptance criteria for scale-up of the process, if applicable.

- Description of chain of custody and safeguards to prevent inadvertent exposure, including:
  a) Details regarding the chain of custody of the soiled masks from the point of collection in the healthcare facility, to the reprocessing facility, through the reprocessing cycle, repackaging, and distribution back to the healthcare facility.
  b) A description of the safety considerations through each step. At the facility where reprocessing will occur, also include a description of the safety considerations which will be in effect.
  c) Traceability on the number of times a specific type of mask has been subjected to reprocessing.

- Material compatibility, including:
  a) Evidence to demonstrate that the materials used in both the filters and the straps (elastic bands) are compatible with the proposed reprocessing cycle steps.
  b) Identification of any mask materials known to be incompatible with the method of reprocessing. For example, cellulose-based materials are incompatible with hydrogen peroxide as hydrogen peroxide will degrade cellulose.
  c) Evidence to demonstrate that the reprocessing residues remaining on the reprocessed items are insignificant to cause a health hazard or deleterious effect to the user.
  d) Identification of the number of repeated cycles that the mask and the straps (elastic bands) can withstand.

- The performance of the surgical masks and respirators is not reduced (after the intended number of times of reprocessing). As a reference, the intended performance of surgical masks, FFP2 and FFP3 are defined in different standards:

- Surgical masks: EN14683

Following the target population, there are 3 types of surgical masks :

Type I: only for patients and other persons to reduce the risk of spread of infections

Type II: principally intended for use by healthcare professionals in an operating room or other medical settings with similar requirements

Type IIR: principally intended for use by healthcare professionals. Masks with high performance regarding the fluid resistant to protect from blood borne pathogens.

As a reference, a comparative table of performance requirements of new surgical masks following applicable standards is provided in annex I.

- FFP 2 / FFP3: NF EN 149+A1:2009

We refer you to the information provided by SPF/FOD Economy[1] where an alternative test protocol is also proposed for FFP2/FFP3 masks without CE marking. In the latter case, the two essential requirements that should be addressed are:
  - the maximum total inward leakage allowed; It is a measure of the good quality of the hermetic seal of the face by the mask.
  - The maximum values allowed for the "penetration of the filter material"; It is a measure of the permeability of the material used in the mask.

- Fit test data:
  a) Evidence to demonstrate that repeated exposure to your reprocessing cycle steps does not decrease the ability of the mask to form a tight fit to the wearer's face.
  b) Evidence to demonstrate that the reprocessing cycle steps do not compromise the integrity of the elastic bands to maintain an appropriate fit to the wearer.

- Labelling
  a) Clear statement that the mask is reprocessed.
  b) Identification of reprocessor (name and address)
  c) Identification of how many times the mask may be reprocessed.
  d) Advise users to discard masks that are visibly damaged or that fit poorly.

[1] https://economie.fgov.be/fr/themes/entreprises/coronavirus/informations-pour-les/conformite-des-masques/coronavirus-masques-sans

https://economie.fgov.be/nl/themas/ondernemingen/coronavirus/informatie-voor-ondernemingen/coronavirus-conformiteitseisen

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Annex I:

Comparative table of applicable standards regarding performance of surgical masks

	EN 14683:2019 Surgery masks (Europe)			ASTM F2100-19 (FDA)			YY T 0969 – 2013 (China)	YY 0469-2011 (China)
	Type I	Type II	Type IIR	Level 1	Level 2	Level 3		
Bacterial filtration (BFE), (%)	=>95	=>98	=>98	=>95	=>98	=>98	=>95	=>95
Differential pressure (Pa/cm²)	<40	<40	<60	<50	<60	<60	=<49	=<49
Microbial cleanliness (cfu/g)	=<30	=<30	=<30	/	/	/	=<100 (refer to the standards for more details)	
Splash resistance (KPa)	Not required	Not required	=>16	10	16	21	/	16

Comparative table of applicable standards regarding performance of FFP2/FFP3

	NF EN 149+A1:2009 (Europe)			GB 2626-2019 (China)		GB 19083-2010 (China)			NIOSH 42 CFR 84 (USA)		
	FFP 1	FFP2	FFP3	KN95	KN100	Grade1	Grade 2	Grade 3	N95	N99	N100
Barrier filter	>= 80 %	>=94 %	>=99 %	>=95 %	>=99,97 %	>=95 %	>=99 %	>=99,97 %	>=95 %	>=99 %	>=99,97 %
Blood Penetration for Liquid Barriers	=< 22 %	=<8%	=<2%	=<8%	=<2%	/	/	/	/	/	/

Annex II – activities related to decontamination of surgical masks and PPE (FPP2/3).

Reprocessing of masks and FFP2 –

The following list is being published **with the aim to enhance the collaboration between the different actors**.
The procedures were neither assessed nor approved by the FAMHP and are under the responsibility of the user

Name	Contact	Adress	Technique	Product	Note
Steris Healthcare	johan van den Bergh (johan_vandenbergh@steris.com)	De Keyserlei 58-60 bus 19, 2018 Antwerpen, België / Belgique / Belgium	AMSCO V-PRO H2O2 sterilizer	FFP2 and N95 respirators and equivalent	
Decontex Holding NV	Zander Macharis - zma@decontex.com	Sint-Amandstraat 1, 8700 Tielt	Disruptive Liquid CO2	FFP2/FFP3	Turn-key solution for on site disinfection in a mobile disinfection cleanroom (ISO 6), designed with a Bio-Safety Level 3 and equipped with a liquid CO2-machine
BELGIUM DECONTAM (Belgian Central Re-use Decontamination processing plant)	Deliveries & pick-ups via BelgiumDecontam.be - Mr Mark Beerts	Taskforce Covid-19 Coloma Gebouw – Gem. St-Pieters Leeuw. Depauwstraat 25 B-1600 Sint-Pieters-Leeuw	Chlorine dioxide	FFP2, FFP3 masks, surgical masks, Approns (Schorten/Tabliers), Tyvex Coveralls, Goggles, Overshoes, Respiratory devices, and other critical Medical PPE and	https://belgiumdecontam.be/

				critical Medical Devices	
AMB Ecosteryl	Amélie Matton Amelie.matton@ecosteryl.com 0494892411	1, av N. Copernic 7000 MONS	Dry heating	Face mask, surgical mask, FFP2 + other PPE	In-site healthcare institution.
Materia Nova	(http://www.materianova.be/): Thomas Godfroid Thomas.Godfroid@MATERIANOVA.BE	Avenue Nicolas Copernic 3, 7000 Mons	Air Plasma Technology	PPEs Masks - Surgical Masks	
Lasea	https://www.lasea.eu/	Rue des Chasseurs Ardennais 10, 4031 Liège	UV Irradiation	PPEs Masks - Surgical Masks	
SalamanderU	Claude Dedry claude@salamanderu.com +32 476 23 93 13	Novalis Science Park Rue de la Science 8 6900 Aye, Belgium	The solution consists of a "CleanBubble®", containment flexible envelope, a vacuum unit fitted with a HEPA filter and a "DosyMist®" decontamination unit which generates	FFP masks	In site reprocessing directly on site of hospital

			nebulization of hydrogen peroxide. The solution can disinfect up to 350 FFP2 masks in a 6 hours cycle.		
Psimco BVBA	Docus Tom, info@psimco.be, www.psimco.be, 02/7930432	Heimbeekveld 32 - 1860 Meise	UV technology	Face masks FFP2 & 3, glasses, face shields, telephones, stethoscopes, ventilation components, blood pressure monitors, thermometers, tablets, …	Could be done on site. We can disinfect in a cycle of 1 minute, mouth masks FFP2 & 3, glasses, face shields, telephones, stethoscopes, ventilation components, blood pressure monitors, thermometers, tablets, ... We also have a UV robot with which we can disinfect 500 mouth masks FFP2-3 per cycle. This way we can disinfect 1500 masks per day.
Sterigenics Fleurus	Hildebrand MP MPHildebr@eu.sterigenics.com	Zoning Industriel Fleurus, Zoning Industriel,Avenue de l'espérance, 6220 Fleurus	Gamma irradiation	FFP2, surgical masks	Off site
MPG bv	Marc Jacobs, CEO	Bioincubator, Gaston	Cold atmospheric plasma with	Face masks, PPE masks, surgical masks, medical	Possible in and off-site.

		Geenslaan 1, B-3001 Leuven	addition of active compounds. The core technology was originally developed by VITO. See also: https://plasma.vito.be/en and https://bit.ly/34W0TAD	textile such as protective gowns	
Aptar CSP Technologies	**francois.bidet@aptar.com**	Zone Industrielle du Sandholz Rue du Sandholz, 67110 Niederbronn-Les-Bains, France	Chlorine dioxide	FFP2/FFP3	Individuals can manage the decontamination process themselves, which will empower them and allow management to focus on operational issues.

Support to reprocessing:

Name	Contact	Activity	Technique	Product	Note
IPARC	International Platform for Art Research & Conservation Email leen.gysen@iparc.eu	Material support	NA	containers	
ULG	danielle.marin@uliege.be	Scientific support	UV irradiation - Air Plasma - Ethylene Oxide - Dry Heating – Peroxide hydrogen	PPEs Masks - Surgical Masks	

Test on reprocessed masks

Name	Contact	Activity	Technique	Product	Note
Hex	info@hex-group.eu www.hex-group.eu Rue Auguste Picard, 20 6041 Gosselies	Test laboratory, calibrations and analyzes. More than 30 tests, analyzes or calibrations covered by BELAC accreditation according to ISO 17025.	• Realization of the complete ATP protocol - Particle penetration test on test bench EN 149 and EN 13274 and FIT TEST • Realization of the partial ATP protocol (1st test of the ATP protocol) - Breathability test - differential pressure according to EN 14683 + AC: 2019 (if an EFB filtration efficiency test is required, forward to the CENTEXBEL laboratory) • Test protocol on "citizen" barrier protection mask. Based on the AFNOR guide that has published on the manufacture and testing of this type of mask.	FFP masks or equivalent. Surgical mask Barrier protection masks	
Nelson	ServiceCenter@nelsonlabs.com InfoEurope@nelsonlabs.com InfoEurope@nelsonlabs.com	Labs testing for mask reprocessing	Face Mask & Respirator Testing Requirements There are different testing requirements for face masks depending on whether you are located	Surgical mask and FFP2/3	

	+32 (0) 16 40 04 84 Nelson US Headquarters: 6280 S. Redwood Road Salt Lake City, UT 84123 USA ServiceCenter@nelsonlabs.com +1 (801)290-7500 Nelson Labs Europe: Romeinsestraat 12 3001 Leuven Belgium		in the US or Europe. Download our Face Mask Testing Requirements and our Respirator Testing Requirements PDFs to assist you in determining which tests are required for your location. Protective Barriers Testing Services Offered • Bacterial & Viral Filtration Efficiency (BFE/VFE) • Particle Filtration Efficiency (PFE) • Respirator Precertification Tests – NIOSH • Surgical Face Masks and General-Use Masks – ASTM F2100 & EN 14683 • Surgical Gowns and Drapes – AAMI PB70 & EN 13795		
Centexbel	Grace Hollogne	Labs testing for mask reprocessing	Face Mask & Respirator Testing Requirements	Surgical masks (and to be checked for FFP2/3)	https://www.centexbel.be
Idewe	info@ibeve.be	Labs testing for mask Alternative Test Protocol (ATP)	Face Mask & Respirator Testing Requirements	FFP2/3	https://www.idewe.be/fr/-/richtlijnen-gebruik-mondmaskers