Federal Agency for Medicines and Health Products
Eurostation II – Place Victor Hortaplein 40/40
1060 BRUSSELS
www.fagg.be - www.afmps.be

Guidance for the reprocessing of surgical masks and filtering facepiece respirators (FFP2, FFP3) during the Coronavirus disease (COVID-19) Public Health Emergency

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 pandemic.

As 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, 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.

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.

[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

- 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.

Bibliography:

Keene, B. (2014). Characterization of degradation of polypropylene nonwovens irradiated by gamma-ray. J. Appl. Polym. Sci. DOI:10.1002/app.39917, 10p.

Lindsley, W.G. & al. (2015). Effects of Ultraviolet Germicidal Irradiation (UVGI) on N95 Respirator Filtration Performance and Structural Integrity. Journal of Occupational and Environmental Hygiene, 12(8):509-17, 2015.

Lore, M.B. & al. (2012). Effectiveness of three decontamination treatments against influenza virus applied to filtering facepiece respirators. Ann. Occup. Hyg. 56: 92–101, 2012.

Viscusi, D.J. (2009). Evaluation of five decontamination methhods for filtering facepiece respirators. Ann. Occup. Hyg. 53: 825-827.

Price, A. & Chu, L. (2020). What are good ways to address the shortage of face masks by anesthesiologists?. Stanford Medicine - Anesthesia Informatics and Media Lab. Learnly. March 25th 2020, 9.p.

Lowe J.J. & al. (2020). *N95 Filtering Facemask Respirator Ultraviolet Germicidal Irradiation (UVGI) Process for Decontamination and Reuse*. Report Nebraska Medicine, 2020, 19 p.

Federal Agency for Medicines and Health Products
Eurostation II – Place Victor Hortaplein 40/40
1060 BRUSSELS
www.fagg.be - www.afmps.be

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)		
	FFP1	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%	/	/	/	/	/	/