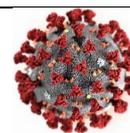


National COVID-19 Science Task Force (NCS-TF)



Type of document: Alert

In response to a request from: This statement was written in response to many queries from journalists, the population and procurement offices about mask types, quality and standards

Date of request: August 2020

Expert groups involved: Infection Prevention and Control in collaboration with the reMask consortium (<https://www.remask.ch/>)

Date of response: 24/09/2020

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Comment on planned updates : none

Clarification on face mask types, architecture, quality, handling, test and certification procedures

Summary of request/problem

This policy brief is to clarify differences between mask types, respective norms and certification processes for masks currently available in Switzerland. Available mask types have different functions and limitations. Some mask types are regulated, while for others, such as textile-based community masks that have been growing in importance during the COVID-19 pandemic, norms still need to be developed. A number of countries, including Switzerland, have, in the context of the present pandemic, published recommendations for manufacturers so as to define a minimum, non-formal yet explicit method to measure and attest the quality and performance of such community masks before they are put on the market. This document summarizes the different mask types currently available on the Swiss market, and provides information about their current quality requirements and related legal aspects.

Overview about mask types

Table 1: overview of the different types of face masks available in Switzerland

| | Protection mask | Medical mask | Community mask |
|-------------------------|--|---|--|
| Other terms used | Filtering face piece (FFP) 1, 2, and 3, N95, KN95, with or without breathing valve | Surgical mask | Textile mask, cloth mask, barrier mask, fabric mask |
| Primary function | Protecting the wearer from harmful substances in the air (particles, dust, aerosols) | Reducing the spreading of pathogens by the mask wearer while also protecting the wearer from droplets and other biological fluids | Reducing the spreading of pathogens by the mask wearer |
| Regulation | CH: PPE Ordinance of 25 October 2017 (PPEO) EU: PPE Regulation (EU) 2016/425 | CH: SR 812.213 Medizinprodukteverordnung – MepV EU: Medical Devices Directive 93/42/EEC | Not regulated |
| Certification / Marking | Yes, CE-marking with identification number of the notified body | Yes, CE-marking | No EU certification, NF certification in France |

| | | | |
|------------------------------|----------------------------------|------------|--|
| Swiss/European standard/norm | EN 149 | EN 14683 | No EU or Swiss standard, guidelines available: Recommendation of the National Science Taskforce CEN workshop agreement (CWA 17553) |
| Market surveillance | SECO subcontracted SUVA and BAFU | Swissmedic | Not defined |

Protection Masks

FFP masks are a personal protective equipment (PPE) used by both medical and other workers, which pre-existed the present Covid-19 pandemic. FFP masks must meet the requirements of European Standard EN 149 and must comply with the PPE-directive (EU/2016/425, SR 930.115 – Verordnung 2 über die Sicherheit von persönlichen Schutzausrüstungen (PSA-Verordnung)). Before they can be put on the market, FFP masks have to be certified by an accredited external agency, also called Notified Body (NB), and are classified into FFP1, FFP2 and FFP3 depending on their aerosol filtration efficiency for 0.3µm particles. FFP3 offers the highest level of filtration. For all FFP masks, the fit on the face of the wearer is a very important characteristic to avoid air leakage from the sides of the mask. As PPE, FFP masks offer a high level of protection, which limits wear comfort and may cause discomfort during prolonged use. Some of these masks are equipped with an exhalation valve (mostly FFP3) to allow ease of breathing; however, such valves cause FFP masks to not prevent spreading of pathogens by the wearer and are therefore not recommended in the context of the COVID-19. FFP-type masks are denominated as N95 (according to Standard NIOSH CFR 84) in the USA and KN95 (according to Standard GB 2626-2006) in China. FFP masks are usually made for single use, and are thus discarded (with care) after use.

In Switzerland, Suva is in charge of the market surveillance about conformity of FFP masks.

Medical/surgical Masks

Medical masks were originally designed to protect patients against possible pathogens exhaled by medical personnel. In the context of the present pandemic, medical masks have been in great demand as they serve efficiently in protecting the population by preventing pathogens from leaving the mask bearer and thus from being transmitted to others in the vicinity of the bearer (this is called source control). At the same time, medical masks also protect the wearer, although to a lesser degree than do FFP masks. Medical masks are classified into three types, namely I, II and IIR, where Type II offers the highest level of filtration for 3 µm particles. Medical masks must meet the requirements of European Standard EN 14683 and have to comply with the directive on medical products (SR 812.213 Medizinprodukteverordnung – MepV, Directive 93/42/EEC). The European Directive 93/42/EEC will be replaced by the Regulation EU/2017/745 in 2021 and medical masks are classified as 'class I' medical devices. Type IIR masks, often termed surgical masks, have a fluid-repellent outer layer to offer better protection against splashes of biological fluids (blood during surgery or infectious airborne droplets in patient care). Medical masks have no requirement for the fit, but they must cover both mouth and nose. Medical masks are usually made for single use. Outside Europe, such masks are denominated as ASTM F-2100 in the USA and YY 0469-2011 (according to the standard GB 19083-2010) in China.

In Switzerland, Swissmedic is in charge of the market surveillance regarding conformity of medical masks.

Community Masks

“Community masks” have made their appearance in Switzerland mainly in the context of the present pandemic. In the public discussion, “Community mask” is a broad concept that embraces essentially all non-professional (including non-medical) masks that are destined to protect the greater public from infection by means of source control. Community masks range from home-made cotton masks to variously sophisticated textile masks. This mask type, which has the advantage that it can be produced and supplied locally, has been introduced to the Swiss market since the beginning of the pandemic. With the aim to reduce the transmission of the virus in the community (source control) and to protect “community mask” buyers from low quality products, a minimum performance level was rapidly defined within Switzerland. These voluntary minimum requirements and specifications were summarized in a policy brief published by the Swiss National COVID-19 Science Task Force on 25 April 2020 (and actualized XX September 2020). That document was intended to be a guideline for textile manufacturers for the production of community masks of sufficient quality, offering minimum protection. The recommendation defined quantifiable and measurable levels for the filtration efficiency for 1 µm particles, liquid splash resistance, the level of air permeability, as well as reusability after standard washing procedures.

Of note, these recommendations are not a standard, in the strict sense of the term. A “standard” is a carefully elaborated document that has, before it is finalized and used to certify products to be marketed, undergone a long process of tests and evaluations by a large number of laboratories, at least across one country, often across many countries (for example across the European continent for European standards). Such standards are legally binding. Present recommendations for community masks are neither a standard nor a document to be used for the certification of products. Still, the present recommendations can and should be used to define, now and within Switzerland, what is and what is not an acceptable mask to protect against the spread of SARS-CoV-2 in the greater public. Different private testing institutes like Testex or SQTS offer testing services to verify whether a given community mask fulfills the recommendations of both the past and present policy briefs on the topic. Labels emitted by such private institutions offer guidance to both industry and the public, even though they are not legally binding.

A number of countries other than Switzerland have published similar guidelines; it is thus important for testing institutions and manufacturers to refer to the guidelines and criteria that have been used for testing.

Table 2: detailed comparison of the different types of face masks and their technical specifications as defined in the appropriate norms or, in the case of community masks, or recommendation documents.

| | | Protection against aerosols | | | Protection against droplets | | | Community mask specifications | | | Source control | |
|---|----------------------------|--|--------------------|----------------|--|---------------------------------|------------------------|-------------------------------|---|--|-------------------|-------------------------------|
| | | Overall protection against aerosols provided | Aerosol filtration | Inward leakage | Overall protection against droplets provided | Bacterial filtration efficiency | Breathing resistance | Splash resistance | Filtration efficiency (for particle size 1µm) | Breathing resistance (Pa/cm ²) | Splash resistance | Protection of others provided |
|  | Protection mask w/o valve | | | | | | | | | | | |
| | FFP3 | Yes | ≥99% | <2% | Yes | N/A | 1.0 mbar* | N/A | N/A | N/A | N/A | Yes |
| | FFP2 | Yes | ≥94% | <8% | Yes | N/A | 0.7 mbar* | N/A | N/A | N/A | N/A | Yes |
| | FFP1 | Yes | >80% | <22% | Yes | N/A | 0.6 mbar* | N/A | N/A | N/A | N/A | Yes |
|  | Protection mask with valve | | | | | | | | | | | |
| | FFP3 | Yes | ≥99% | <2% | Yes | N/A | 1.0 mbar* | N/A | N/A | N/A | N/A | No |
| | FFP2 | Yes | ≥94% | <8% | Yes | N/A | 0.7 mbar* | N/A | N/A | N/A | N/A | No |
| | FFP1 | Yes | >80% | <22% | Yes | N/A | 0.6 mbar* | N/A | N/A | N/A | N/A | No |
|  | Medical mask | | | | | | | | | | | |
| | Type I | No | N/A | N/A | N/A | ≥95% | <40 Pa/cm ² | N/A | N/A | <40 Pa/cm ² | N/A | Yes |
| | Type II | No | N/A | N/A | Yes | ≥98% | <40 Pa/cm ² | N/A | N/A | <40 Pa/cm ² | N/A | Yes |
| | Type IIR | No | N/A | N/A | Yes | ≥98% | <60 Pa/cm ² | >16.0 kPa | N/A | <60 Pa/cm ² | N/A | Yes |
|  | Community mask | | | | | | | | | | | |
| | nsc-tf | No | Partial ≥70%** | N/A | Yes | N/A | <60 Pa/cm ² | N/A | ≥70%** | <60 | >12.0 kPa | Yes |
| | AFNOR / CWA | No | Uncertain | N/A | No | N/A | <70 Pa/cm ² | N/A | ≥70% or ≥90%*** | <70 | N/A | Yes |
|  | Other mouth & nose cover | No | N/A | N/A | No | N/A | N/A | N/A | N/A | N/A | N/A | Uncertain |

* for an air flow of 30 l/min; ** for particles sizes above 1 µm; *** for particles sizes above 3 µm; for detailed technical specification see also the revised Policy Brief of 'Recommendation on minimal specification for CM and their use' from 24.9.2020; nsctf, Swiss National Covid-19 Science Task Force; AFNOR, association française de normalisation; CWA, CEN workshop agreement

Architecture and composition of protection- and medical masks

Standards define performance criteria to be met before masks (of either type) can be put on the market. However, design and materials of the masks are not regulated; certain designs have proven their efficiency and are, therefore, often found in agreed products.

Usually, both protection masks and medical masks are made of synthetic fibers. The main filtration function is guaranteed by a thin layer of non-woven (i.e., randomly distributed within a plane) melt-blown polypropylene fibers. Those fibers are inexpensive, non-toxic and sufficiently fine and densely packed within the layer to block particles (particle of 1 micrometer or less) from passing. At the same time the fibers are

packed so as to leave sufficient gaps for air to pass a rate comfortable for the wearer (this is expressed in Pa/cm² in Table 2, the non-intuitive units come from the prescribed measurement procedure). Some protection masks additionally have a valve (see Table 2), which is placed to ease expiration by the wearer; this makes wearing the mask more comfortable but eliminates its ability for source control.

The blown polypropylene fiber main filtering layer is electrostatically charged, which further blocks the passage of very fine particles including virions. In medical masks the main filtering layer is generally fixed to two other layers, one on either side; those layers are also designed to serve functions that increase the performance of the mask. The inner (generally white and touching the wearer's face) layer is hydrophilic, meaning it is water-absorbent, so as to block and keep within the mask droplets produced by the wearer. The outer (generally blue or green) layer is often hydrophobic, meaning that it is water-repellent, so that it prevents droplets from the outside (and also, in Type IIR masks, incoming high-velocity splashes) from penetrating the mask. Figure 1 details the three-layered structure of a commercially available medical mask. The structure of FFP-type protection masks is more complex although particle filtering also generally relies on a layer of meltblown polypropylene fibers; Fig. 2.

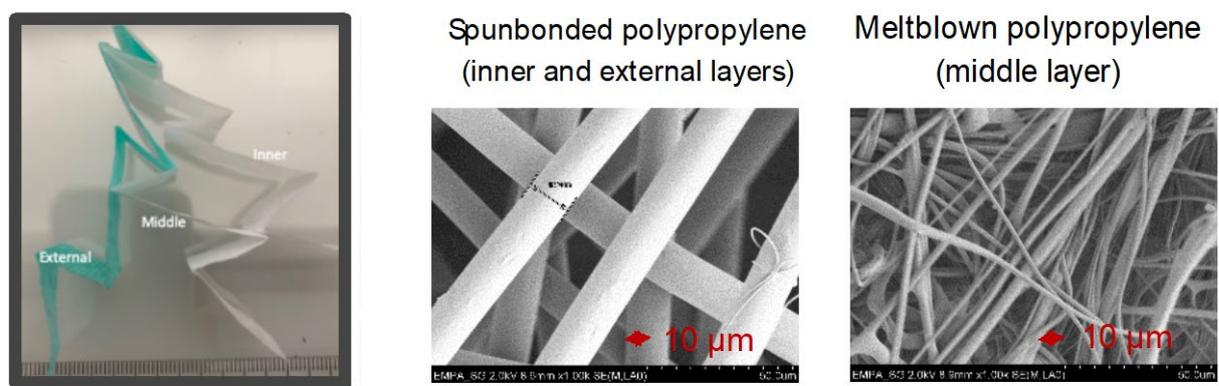


Figure 1 – The three layers of medical (or surgical) masks, with magnified scanning electron microscopy views of their microstructure.

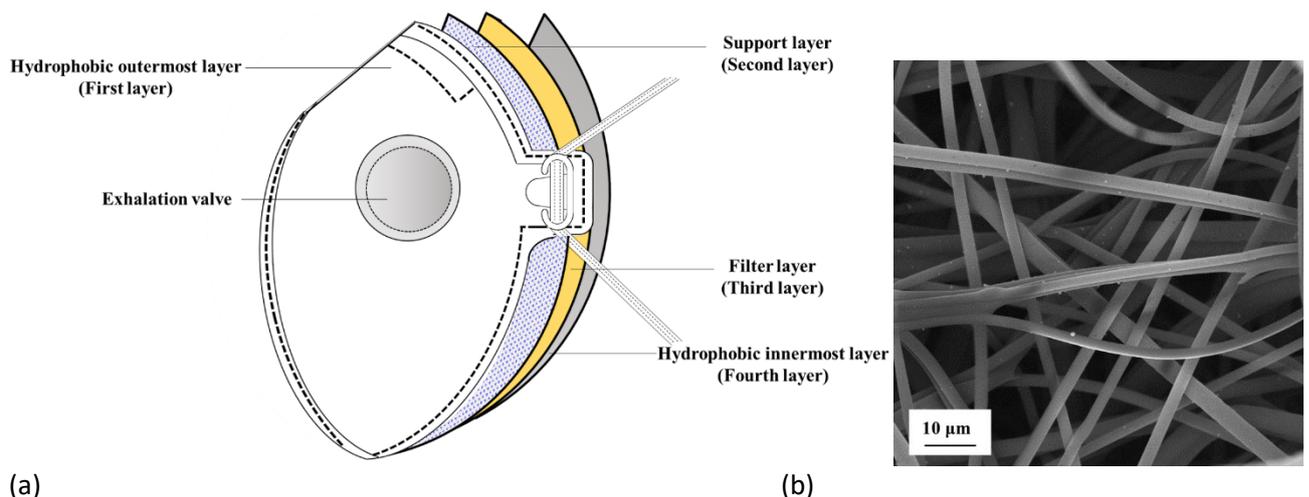


Figure 2 (a) Schematic of the various layers of an FFP2 mask with exhalation valve. (b) SEM image of its melt-blown (third) layer.

Over time, the outer and central layers of protection- and medical masks as well as the outer surface of community masks, will collect all that may have been blocked while wearing the mask. The outer layer is

potentially contaminated and thus, a source for contamination itself, particularly by touching. The inner layer contains the flora of the wearer and should not be touched by anybody else. Thus, removing and storing of used masks must take such considerations into account to avoid self-contamination and cross-contamination of others: using single use storage bags; performing hand hygiene after handling.

It is also important to realize that any hole, crack or tear in the mask will create breeches by which undesired particles can pass. Mechanical damage to the mask can reduce mask performance. It is therefore important to handle masks with care by avoiding piercing, tearing or even folding.

Those two factors, if well considered and managed, dictate most processes that underlie the proper use of masks for both source control and protection of the wearer. As one among many examples, folding a used mask in four and storing it in a pocket with its outer surface touching hands or clothes is clearly a bad idea. Similarly, touching the mask to adjust it while wearing it in public and then touching the eye or nose carries the risk of transferring infectious particles from the mask to wearer. In general, common sense, coupled with knowledge that the masks must not be mechanically damaged and that they will contain infectious particles should guide wearing, storing and disposing.

Considerations regarding sustainability and the environment

At this point, no evidence based assessment of the ecologic effects of disposable medical masks as compared to reusable textile masks (which need to be disposed after the maximum number of washing cycles has been achieved) can be made. Ecological effects not only depend on the amount of waste but also on the type of waste and the committed resources for production.

Cleaning and decontamination of medical and protection masks

The shortage of masks during the first crisis of the COVID-19 pandemic highlighted the need for procedures, at least temporary, to extend their lifespan by reprocessing.

Legally, the re-use of an approved single-use protection or surgical mask, other than for personal use, is similar to the launch of a new product. It would only be possible in the case of serious shortage of protective equipment. An employer who wishes to recycle and redistribute FFP masks or equivalent to his employees will therefore only be able to do so (outside of a shortage situation) once it has been demonstrated that the masks, after decontamination, still have performances corresponding to their certification..

For FFP masks, as well as for surgical masks (used in healthcare environments), reprocessing must absolutely be carried out using protocols that have demonstrated their effectiveness in terms of decontamination without damaging the masks or reducing their efficacy (protection against aerosols in particular). For FFP masks, a few decontamination methods have been validated or are in the process of being validated by the Swiss COVID-19 task force [1]. The re-use of medical masks (outside healthcare environments) has the same legal constraints as the recycling of FFP mask or equivalent. Since surgical masks do not have any requirements in terms of aerosol penetration, it is likely that a number of decontamination or sterilisation procedures can be used. However, these procedures have yet to be demonstrated. .

Community type masks should be cleaned and recycled according to the manufacturer's recommendations. As a general rule, machine washing with a regular detergent and at 60°C is sufficient. The number of cleaning cycles may vary depending on the material (at least 5 cycles for a community mask following the recommendations of the Task Force). In any case, the mask should be discarded if it is deformed or if the attachments are damaged (poor fit to the face).

Recommendations of the Science Taskforce

During the shortage of face masks at the height of the first wave of the COVID-19 pandemic, Swiss small and medium-sized enterprises (SMEs) and the Swiss Federation via the Krisenstab were looking for alternative strategies to address supply challenges. Textile-based facemasks were prototyped in collaboration; however, no definition of quality attributes for such masks were available. Therefore, the Swiss National COVID-19 Science Task Force provided, early in the crisis, recommendations defining community mask specifications in collaboration with a consortium of experts that had previously and informally assembled at the inception of the crisis (called the reMask consortium, <https://www.remask.ch/>). The purpose of the recommendations was to guide the industry in the development of textile masks of high quality for source control and some efficacy for protection, and they were based on current scientific knowledge on the subject (see also updated Policy Brief Recommendations for minimal specifications for the community masks for Swiss manufacturers dated 24.9.2020).

As of September 2020, the Swiss National COVID-19 Science Task Force recommends the use of community masks meeting the recommendations outlined in the updated policy brief of September 2020 for source control in the greater public. Non-medical face masks that have not been tested against the recommendations or do not pass them, are not recommended, as they offer no guarantee of adequate protection.

Beyond community masks, the Swiss National COVID-19 Science Task Force recommendations are in line with the WHO guidelines (FFP masks for aerosol-generating procedures, surgical masks for droplet precaution).

Situation on the availability and quality of face masks as per 31.8.2020

During the first wave of the COVID-19 pandemic, procurement of face masks became a challenge because the demand worldwide largely exceeded production and shipping capacities. The global demand resulted in over 76'000 new face mask manufacturers registered as business between January 1st and June 12th, six times more than the total number of companies registered before the pandemic [2]. Additionally, new suppliers, often without prior experience in the technology, in manufacturing and/or distributing medical and protection devices, established new import channels of face masks into Switzerland. Consequently, and similarly to other countries, many face masks (surgical and FFP masks) distributed on the Swiss market were of low quality [3-6]. A study submitted recently by the reMask expert group to a scientific peer-reviewed journal has demonstrated that more than 50% of FFP masks tested in three Swiss laboratories did not meet the minimum performance requirements for safe use by healthcare workers. This result is in line with what was published by the US Centers for Disease Control and Prevention (CDC), which regularly updates results of filtration efficiency measurements performed on FFP masks without US certification. On August 29, their list included 354 tested FFP masks of which 54% did not meet the required 95% of filtration capacity. To the best of our knowledge, no study has yet reported similar results for surgical masks; however, Swissmedic has identified an increasing number of non-conforming masks, or of masks pretending to be in conformity on the basis of misleading or counterfeit documentation, or declarations of conformity that have no legal or regulatory significance [7, 9].

Next steps in Europe / Harmonization

At the height of the first wave of the COVID-19 pandemic, the Swiss National COVID-19 Science Task Force reacted to the shortage of face masks by providing expert consensus on minimal quality requirements for textile masks, as did similar initiatives in other countries. The consensus was based on (sparse) available information and consultation with specialists from various fields of expertise, and in liaison with task forces from other countries. Today, two guidance documents are available in Switzerland for reusable textile face masks: one developed by the CEN Workshop (European Committee for Standardization) and directed by

AFNOR (France), and another (differing only slightly) from the Swiss National COVID-19 Science Task Force (See Table 2). A number of countries have released similar guidance documents.

As mentioned above, none of the documents are mandatory or legally binding.

All recommendations are consensus documents, which need to be checked against the day-by-day reality of production, use and reducing cross-transmission in the greater public. The future course of the COVID-19 epidemiology will provide more solid information to drive decision-making and harmonisation between the various stakeholders such as industry, regulators, scientists, and countries. Since there is a public interest to move towards a European technical standard, this process should be done within the frame of CEN or ISO.

Open scientific questions / next steps:

Several interdisciplinary consortia are funded by InnoSuisse or SNF NRP 78to:

- Optimize breathability, filtration efficacy and face fit
- Assess the durability and effects of regeneration methods on mask performance
- Develop and integrate detection and sensing systems for airborne viruses
- Compare the efficacy of wearing surgical masks and FFP2 masks during COVID-19 patient care
- Improve antiviral efficacy of textile masks

Safety and sustainability of textile facemasks compared to disposable masks are also addressed scientifically to build a sound knowledge base for the next generation of face masks.

Glossary

Hygiene mask:

The expression hygiene mask is frequently used in the debate of face masks. However, the expression is not clearly defined for any particular type of face mask (is used for community as well as surgical masks) and therefore creates misunderstanding. We recommend differentiating between the three above categories, namely ultrafiltrating mask, surgical/medical mask and community mask.

Recommendation:

Recommendations can be issued by any body, expert or not, and are not legally binding. The validity and acceptance level of recommendations depends on the issuing organization / expert group and whether they are perceived by authorities and/or the general public as being credible. Although recommendations as such are never legal documents, national health authorities can declare them mandatory, which then makes them legally binding in given jurisdictions.

Technical standard:

A technical standard is an agreement on specific quality attributes of a product, assuring a defined and measurable (and hence certifiable) quality level. Technical standards are developed according to an established process and published by a consortium of laboratories, manufacturers and public authorities, generally across at least an entire country, or a larger international community. A technical standard requires harmonization and agreement on critical quality attributes, which can be tested by certified test laboratories or companies.

Test laboratories / companies:

Accredited institutions that test and provide test reports on the quality of a product according to technical standards or given norms (not to be confounded with notified bodies to issue certificates). In Switzerland we have several organisations qualified to test face masks. (*note by Andreas: should this not be community masks instead of face masks ?)

European Standard (EN):

European norms (EN) are standards and rules, which are approved by the European Committee for Standardization (CEN). A new EN can be proposed by any member of the CEN (Switzerland is a member of

CEN and Swiss experts can participate in the development of EN via SNV (Schweizerische Normen-Vereinigung). After workshop-based, cross-country agreement, a technical committee will be mandated to develop an EN draft and share this with the CEN members until consensus is achieved. Thereafter, the draft will be formally accepted as an EN and will be re-evaluated every 5 years.

Notified body [8]:

A notified body, in the European Union, is an independent accredited organisation that has been designated by a member state to assess the conformity of certain products, before being placed on the E.U. market, with the applicable essential technical requirements. These essential requirements are publicised in European directives or regulations. A manufacturer can use voluntarily European harmonised standards to demonstrate that a product complies with some (or all) of the EU essential requirements; a notified body can use the same harmonised standards to assess the conformity to these essential requirements. Conformity assessment can include inspection and examination of a product, its design, and the manufacturing environment and processes associated with it.

Certification:

Document confirming passing of all necessary tests (according the well-defined norms) giving the right to label and market the product accordingly. Certification is made by a notified body.

Market surveillance:

The purpose of market surveillance is to ensure the reliability and accuracy of the product information and the presence of the declared product characteristics and to ensure that products made available on the market do not present a risk to users.

Swiss stakeholders in the field of mask quality (non-prioritized and non complete list):

Schweizerischer Normenverband, ArmaSuisse, Testing labs, like Testex or SQTS, FOPH, Swissmedic, SECO, SUVA, BfU,

Unresolved issues

-N/A-

References and other useful documents

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- [7] https://www.swissmedic.ch/swissmedic/en/home/medical-devices/overview-medical-devices/information-on-specific-medical-devices/nicht_konformen_medizinischen_gesichtsmasken.html
- [8] https://en.wikipedia.org/wiki/Notified_body

[9] <https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/marktueberwachung/qualitaetsmaengel-und-chargenrueckrufe/chargenrueckrufe.html>

Policy brief of the Science Taskforce on community mask spec and recommendations: <https://ncs-tf.ch/de/policy-briefs/community-mask-spec-and-recommendations-25-april-20-en-2/download>

Policy brief of the Science Taskforce on community mask spec and recommendations update Sept 2020

French guideline for community masks: <https://masques-barrieres.afnor.org/>

European specification for community masks:

https://www.cencenelec.eu/news/press_releases/Pages/PR-2020-004.aspx