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(54) FILTERING MASK AND MANUFACTURING METHOD THEREOF

(57) The invention relates to a wearable device (100) of personal protection, in particular a filtering mask, which device (100) comprises:

- a shell (G) obtained from a single shaped sheet made of plastic material, said shell (G) having a plurality of openings (11a),
- a removable filter element (60),
- means (70) for retaining the device to the user's face, wherein said filter element (60) is superimposed on said shell (G) by covering said plurality of openings (11a) and it is facing, under condition of worn device, frontally on the user's mouth and nose, wherein a flap (23) of the shell (G) is fixed reversibly on an external face (G'') of the latter by retaining a corresponding flap (62) of filter element (60) and in such a way as to define a portion of nasal bridge (N) of the device.

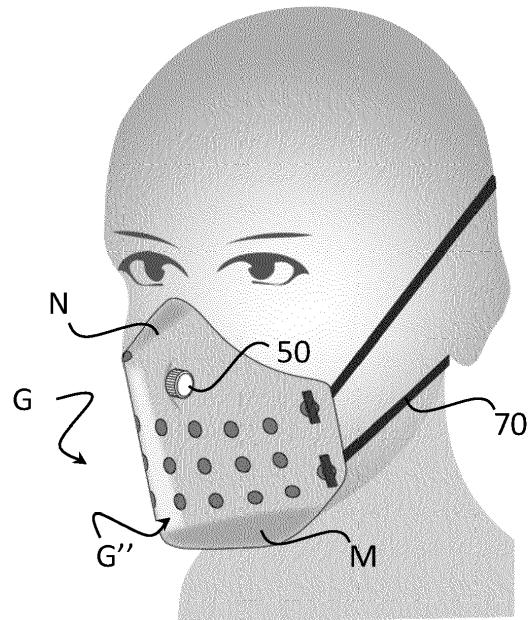


Fig. 8B

Description

Technical field of the invention

[0001] The present invention relates to the field of the devices of personal protection and of the medical devices.

[0002] In particular, the present invention relates to a device to protect the respiratory tract, preferably of the type compliant with UNI EN 149:2009 standard, with UNI EN 14683:2019 standard and to a method for implementing the device itself.

Background

[0003] As it is known, the market makes available several solutions related to individual devices to protect the respiratory tract.

[0004] The filtering masks, for example, are mainly disposable devices which are worn on the face so as to cover mouth and nose. Such devices allow to protect the user from contaminant agents transported by air (for example potentially dangerous particles, vapours and gases if inhaled) thanks to the presence of a filter element retaining them.

[0005] The surgical masks instead are medical devices which have the specific function of protecting the user from pathogen agents existing in the surrounding environment. These devices are mainly used by authorised personnel in hospitals or clinics, but in case of epidemics or pandemics their use is highly widespread even among the civil population.

[0006] Depending upon the features and the filtering power, both the filtering masks and the surgical masks can be classified according to one or more reference standards.

[0007] The known devices generally comprise a supporting body for said filter element and retaining means, such as for example elastic laces, strings or bands, to keep the mask in contact with the user's face under worn condition.

[0008] The filter element can be integrated in the structure of the mask or be removable. In the latter case the replacement with a new filter is possible, in case it has exhausted its own filtering power or the user wishes to equip the mask with a filter having different properties.

[0009] However, the devices of known art represent perfectible solutions under different profiles.

[0010] First of all, the structure of the known filtering masks is generally not very ergonomic since they are devised to be usable for a short time frame. They have components assembled roughly, by determining functional inefficiency and poor sealing between face and mask.

[0011] Moreover, the masks of the known solutions often cause discomfort for the user. For example, under worn condition, the mask can exert an excessive pressure on some areas of the face and, at the same time, it

can guarantee only an uncertain contact with other areas of the face.

[0012] An additional criticality profile particularly felt for the filtering masks of the known solutions is linked to their disposal at the end of their useful life. They are hardly recyclable disposable devices since, typically, they include components implemented from different materials, such as for example fabric or synthetic canvas (for the supporting body), plastic elements (in case the mask provides ventilation valves), parts made of rubber (such as the elastic laces to wear them), metal portions (sealing elements at the nasal bridge), and so on.

[0013] Moreover, the features of the known masks generally can be improved in terms of versatility and durability of the used materials, even in relation to the ease in supplying the latter, both under a profile of simplifying the techniques for manufacturing the mask and under a profile of ease in use and costs for the producer or user.

Summary of the invention

[0014] The technical problem placed and solved by the present invention is then to provide a wearable device of personal protection, in particular a filtering mask to protect the respiratory tract, which allows to obviate one or more of the above-mentioned drawbacks with reference to the known art.

[0015] Such problem is solved by a wearable device of personal protection according to claim 1. The invention further relates to a filtering mask shell and to a method for manufacturing a filtering device as defined in claims 13 and 17, respectively.

[0016] Preferred features of the present invention are set forth in the depending claims.

[0017] In the present context, the expressions "filtering device", "wearable filtering device", "respiratory mask" are synonym of "filtering mask" and they are to be meant in the widest meaning to comprise any individual protection device, or medical device, wearable on a user's face or a face of health care professional, preferably, in the form of half-mask, and specifically configured to protect the upper airways, such as nose and mouth, by filtering inhaled/exhaled air.

The filtering obtainable with the filtering mask of the invention is means to prevent the inhalation of contaminant agents and pathogen organisms, in form of powders, mists, fumes, gases or vapours, and of the substances transported therewith.

Preferably, the filtering mask and the relative implementation method as subject of the present invention relate to a device compliant with UNI EN 149:2009 standard, classifiable as filtering device FFP2 or FFP3, and/or compliant with NIOSH standard, classifiable as filtering device N95 or N99, or classifiable as medical device of class I, II, IIR according to UNI EN 14683:2019 standard.

[0018] According to an aspect of the present invention, an effective and simple filtering mask is provided, in terms of implementation technique and overall structure. Said

mask consists of a reduced number of distinct components, assembled to each other with simple mechanical procedures, without the use of glues, thermosetting or other types of permanent constraints. This allows at the end of the useful life of the product simply to disassemble (for example manually) the components and to be able to dispose them separately.

In a preferred embodiment, the mask of the invention comprises a supporting body, or shell, supporting a filter element, means for adjusting the adherence of the mask to the face and retaining means to allow the user to wear it.

The shell and, preferably, the adjusting means are made of reusable plastic material, suitable to a use in sanitary environment. The filter element is superimposed on the shell, by covering a plurality of through-openings obtained on the latter. Under condition coupled to the shell and of worn device, the filter element faces frontally on the user's mouth and nose. The specific positioning of the openings, in a central region of the shell, forces the inhaled air to cross the filter element by avoiding preferential routes.

The filter element can be removed from the mask, for example for a replacement or it can be re-user after washing. Analogously, the shell can be interchangeable. Advantageously, the mask, the present invention relates to, then has a very limited environmental impact thanks to the replaceability of the filter element and/or of the shell. Moreover, in its preferred configuration, the mask comprises components all made of washable, disinfectable materials, which can be re-used several times.

An additional advantage is to be able to provide a device of personal protection which can be re-used indefinitely over time which, according to need, can be equipped with diversified filtering properties.

Moreover, the shell of the mask of the present invention, and preferably even the filter element, is obtained from one single sheet made of shaped and suitably bent plastic material.

In an assembling step it is provided to bend an upper flap of said sheet made of plastic material and to constraint it to an external face of the latter, so as to retain a corresponding flap of filter element and to define a portion of nasal bridge of the device.

It will be appreciated that the invention then provides a method for implementing a filtering mask quickly, through simple bending procedures and with cheap raw materials, to the advantage of an extremely simplified production process which evidently reflects into modest costs even in terms of final product.

According to a preferred embodiment, the above-mentioned means for adjusting the adherence of the mask to the face, allows to fix the upper flap to the external face of the shell.

Advantageously and differently from the known filtering masks, the means for adjusting the adherence of the mask to the face has at least two technical effects synergic to each other. Or, said adjusting means allows to

obtain in one single compact device both a reversible constraint of the filter element and an adjustment of the mask shape in a critical region, such as the nasal bridge. In this way the ergonomics and, above all, the sealing of the mask can be considerably improved with respect to possible vents due to the reduced adherence of the edges of the mask to the face, through a correct assembly of the components constituting it.

[0019] The compactness of the mask of the invention further guarantees the non-interference with additional face personal protection devices.

[0020] Other advantages, features and use modes of the present invention will result evident from the following detailed description of some embodiments, shown by way of example and not for limitative purposes.

Brief description of the figures

[0021] The figures of the enclosed drawings will be referred to, wherein:

- Figure 1 shows a plan schematic view of a preferred embodiment of a shaped sheet therefrom the shell of the filtering mask according to the present invention is obtained;
- Figure 2 shows a plan schematic view of a preferred embodiment of a filter element of the filtering mask according to the present invention;
- Figures 3A and 3B show respectively an overall view and a decoupled view of a preferred embodiment of the means for adjusting the adherence of the filtering mask of the invention;
- Figure 4 shows a preferred embodiment of the retaining means of the filtering mask of the invention to the face;
- Figures 5A-5D show a preferred sequence of the steps of the method of the invention to implement the shell of a filtering mask from the shaped sheet illustrated in Figure 1;
- Figures 6A-6N show a preferred sequence of the steps of the method of the invention to implement a filtering mask by coupling the shell obtained according to the steps illustrated in Figures 5A-5D with the filter element illustrated in Figure 2;
- Figures 7A-7E show a preferred sequence of the steps of the method of the invention to connect the retaining means illustrated in Figure 4 to the filtering mask;
- Figures 8A-8B show a preferred embodiment of the filtering mask obtained with the method of the invention under condition worn on a user's face, according

to a front and partially rotated view, respectively.

Detailed description of preferred embodiments

[0022] By firstly referring to Figures 8A and 8B, a preferred embodiment of a wearable device of personal protection according to the present invention is illustrated. Said device, or filtering mask, is shown under condition worn on a user's face and it is designated as a whole with reference 100.

[0023] In general terms, the mask 100 comprises a supporting body G, or shell, for a removable filter element (not shown in Figures 8A and 8B), retaining means 70 to allow the user to wear the mask and means for adjusting the adherence of the mask to the face. The latter are designated with reference 50 and therefor the arrows in Figure 8A exemplify an activation and relative adjustment mode.

[0024] As it is visible, in a preferred embodiment, the filtering device 100 is shaped as half-mask covering the user's upper airways (nose and mouth) extending, in particular, from the nasal bridge to the middle cheek, by covering preferably the chin-maxillary region.

[0025] In the illustrated embodiment, the retaining means 70 comprises one or more strings, laces, or bands, preferably made of elastic material, suitably coupled with the shell G, or even with the filter element. In the illustrated example, the retaining means 70 fixes the mask 100 to the user's auricle, however, once fixed to the shell they can even be tied up behind the nape or in any way it results more advantageous.

[0026] The above-mentioned components constituting the mask 100 can all be assembled and disassembled therebetween, from an assembled condition and vice versa.

[0027] The shell G represents the most external component of the mask 100 and comprises a plurality of openings 11a configured to allow the passage of the air to be inhaled/exhaled.

[0028] The openings 11a can be holes and/or slots passing through the thickness of the shell G, each one (or in groups) having the same or different size. Advantageously, the positioning of said plurality of openings 11a on the shell G is so that, under condition of worn mask 100, they face frontally on the mouth and nose.

[0029] By further referring now to Figure 1, a preferred embodiment of the shell G is shown in plan, under not assembled condition with the additional components of the mask 100.

[0030] As it is visible, the shell G is obtained from one single, suitably shaped, planar sheet. Said suitably flexed and/or bent sheet assumes, under assembled condition with the additional above-mentioned components, the shape of shell G shown in Figures 8A and 8B.

[0031] Upon an activation of the adjusting means 50, the shell G can modify its shape, preferably at the portion of nasal bridge N of the device 100, as it will be described more in details hereinafter.

[0032] In the preferred embodiment, the sheet comprises a central region 11, a flap 23 and, preferably, two lobes 40a, 40b placed side by side. Said flap 23 and said two lobes 40a, 40b are positioned respectively opposed with respect to said central region 11.

[0033] Under assembled condition, said flap 23 and said lobes 40a, 40b are intended to position at the nose and the chin, respectively. Therefore, they will be designated for convenience as upper flap 23 and lower lobes 40a, 40b.

[0034] In a preferred variant of the mask 100, the two lower lobes 40a, 40b are overlapped and retained together, preferably with reversible joint, by defining a concave lower portion M of the mask 100 intended to house the chin.

[0035] By further referring to Figures 5A-5D a sequence is shown exemplifying the steps to implement a shell 100 comprising the above-mentioned concave portion M.

[0036] As it is visible, a first lobe 40b of said two lobes 40a, 40b comprises a first liftable tongue 45. By keeping the second lobe 40a below the first lobe 40b, the first tongue 45 is inserted in a corresponding eyelet 42 obtained in the second lobe 40a. Subsequently, the respective peripheral edges 44, 46 of the first 40b and the second 40a lobe, are inserted in corresponding eyelets 43, 41 obtained in the second 40a and first 40b lobe, respectively.

[0037] The sheet, or shell G, preferably has a thickness comprised between 0.3 millimetres and 1.5 millimetres. Advantageously, the sheet or shell is made of washable, antibacterial, hypoallergenic and disinfectable material.

[0038] Said shell (by referring to the component under assembled condition) that is sheet (by referring to the component under not assembled condition), is preferably made of plastic, flexible material or having properties so as to be deformable elastically. For example, said plastic material can include a polymeric material included in the list comprising polyurethane, polypropylene, polycarbonate, or any combination thereof.

[0039] The sheet can be shaped through flat die cutting techniques or other technique for removing material. Said plurality of openings 11a is obtained in the central region 11 of the sheet G and, by further referring to Figure 2, it is intended to be covered by the filter element 60.

[0040] Figure 2 shows a plan view of a preferred embodiment of the filter element 60 under not assembled condition with the additional components of the mask 100. Under assembled condition, the filter element 60 results to be overlapped to the shell G by covering said plurality of openings 11a. Upon wearing the mask 100, the filter element 60 faces frontally on the user's mouth and nose.

[0041] In a preferred embodiment, the filter element 60 is shaped so as to correspond substantially to the shape of the shell G, then by providing a corresponding central portion 69 and an upper flap 62, wherein at least said central portion 69 is made of filtering material. The filter element 60 can further comprise two lower lobes 66, 65.

[0042] Preferably, the filter element 60 is implemented as a multilayer structure, for example made of overlapped textile materials, wherein said layers are suitably constrained to each other. The constraint can be obtained by heat-sealing, sewing, *needle punching* techniques or equivalent fastening techniques. In each case, the constraint guarantees specific filtration features, such as breathability, filtering power, and so on. The number and type of the materials constituting the filter element 60 is selected based upon the filtration capability which is to be obtained.

[0043] In a preferred embodiment, the filter element 60 comprises a multilayer structure made of non-woven fabric. Still more preferably, each layer of said structure is implemented from polymeric material with a weight comprised between at least 20 grams/square meter and at least 60 grams/square meter.

[0044] In a second preferred embodiment the filtering material consists of multilayer fabric comprising filtering fabric containing activated carbon nanoparticles, coupled to non-woven fabric.

[0045] By way of example, in order to obtain a mask 100 with filtering capability of 95% (mask FFP2) the filter element 60 could consist of at least three layers wherein:

- a first layer of *nonwoven* comprises polypropylene or polyester, produced with *Spunbond* technology, and weight of at least 20 gr/sqm;
- a second layer of *nonwoven* comprises extruded polypropylene with *meltblown* technology, and weight of at least 60 gr/ sqm;
- a third layer of *nonwoven* made of polypropylene produced with *spunbond* technology, and weight of at least 20 gr/ sqm.

[0046] By referring now to Figures 3A and 3B, a preferred embodiment of the means 50 for adjusting the adherence of the mask 100 to the face is illustrated.

[0047] Said adjusting means 50 is configured for bending and fixing reversibly the upper flap 23 of the shell G on an external face G" of the latter, by retaining the corresponding upper flap 62 of the filter element 60 and by defining a portion of nasal bridge N of the mask 100.

[0048] The adjusting means 50 fulfils the function of maintaining the sheet G and the filter element 60 coupled to each other, and under bent condition, so that said filter element 60 defines a (concave) region suitable to receive frontally the user's mouth and nose.

[0049] The adjusting means 50 further allows an adjusting of the width of the mask 100 at the nasal area. The adjusting means 50 is preferably made of hypoallergenic plastic material.

[0050] In the preferred embodiment, the adjusting means 50 comprises a screw 51 nut 52 coupling. In the illustrated examples, said coupling is engaged in corresponding pairs of through holes (24, 63) and (25, 64)

obtained on said shell G and said filter element 60.

[0051] Preferably, said pairs of through-holes are positioned symmetrically to each other with respect to a sagittal plane which crosses the device 100 when it is worn.

[0052] As it is visible in the embodiment illustrated in Figure 8A, by means of the rotation of the nut 52 with respect to the screw 51 and depending upon the physiognomy of the user's nasal septum, it is possible to approach opposed portions of the shell G and of the filter element 60. In this way, it is possible to adjust the optimum adherence of the mask 100 to the face.

[0053] Preferably, the nut 52 has internally a V-like thread which allows an approaching (or moving away) adjustment with steps having stroke of 180°.

[0054] The screw 51, in the illustrated example, comprises a head portion 51a having an abutment surface with the external face G" of the shell G. Advantageously, said abutment surface has a tilted profile so as to correspond and adhere to the external face G" of the shell G and to prevent the rotation of the screw 51 itself during the adjustment with the nut 52.

[0055] Going back to Figures 1 and 2, in a preferred embodiment, said filter element 60 can include second openings 61 configured to implement a reversible joint with an edge element 21 of the shell G.

[0056] Preferably, said edge element 22 is obtained at the upper flap 23.

[0057] Said second openings 61, for example in form of holes or slots, are absent at the central portion 69 of the filter element 60 and, preferably, are obtained at its own upper flap 62. Correspondingly, the shell G is preferably shaped so as to offer, at the respective upper flap 23, said edge element 22. Preferably, said edge element 22 comprises an apex 21 so as to insert with joint in said in said second openings 61.

[0058] Advantageously, the fact of providing said edge element 21, 22 and said second openings 61 allows in a simply way to obtain a correct positioning of the filter element 60 with respect to the shell G.

[0059] By further referring to Figures 6A-6N a sequence is shown exemplifying the steps to obtain the coupling of the sheet G with the filter element 60 through the adjusting means 50.

[0060] As it is visible, the edge element 21, 22 of the sheet G is inserted into the second opening 61 of the filter element 60 (Figures 6A-6B).

[0061] The screw 51 is then inserted in corresponding first through-holes 24, 63 of the sheet G and of the filter element 60, respectively. The insertion direction is so as to cross first of all the external surface G" of the sheet G and, subsequently, the filter element 60 (Figures 6C-6D).

[0062] The screw 51 is then inserted at corresponding second through-holes 64, 25 at first of the filter element 60 (Figure 6E) and then of the sheet G (Figure 6F), respectively.

[0063] By bending the sheet G said corresponding first and second through-holes 24, 63, 64, 25 (Figure 6G),

sliding on the screw 51, approach to each other. In this way, opposed portions of the sheet G (and of the filter element 60) approach to each other and the upper flap 23 of the sheet G and the flap 62 of the filter element 60 remain free.

[0064] Both upper flaps 23, 62 are bent and fixed reversibly on the external face G" of the so-obtained shell G (Figure 6H).

[0065] As it is visible in Figure 6I, both upper flaps 23, 62 result to be overlapped and the screw 51 can be inserted in an additional corresponding through-hole 26 obtained in the upper flap 23 of the shell G. The above-mentioned through-holes 24, 25, 26, 63, 64 result to be all overlapped.

[0066] The nut 52 is screwed onto the screw 51, by closing the coupling (Figure 6L). The upper flap 62 of the filter element 60 is kept by the upper flap 23 of the shell G so that a portion of nasal bridge N of the mask 100 remains defined.

[0067] Then it is possible to adapt manually the filter element 60 inside the shell G, by keeping overlapped the lower flaps 65, 66 of the filter element 60 on the corresponding lobes 40a, 40b of the shell G, in order to make the two components perfectly overlapped. By screwing and unscrewing the nut 52 it is possible to adjust the width of the portion of nasal bridge N so as to obtain an optimum adherence depending upon the physiognomy of the user's face.

[0068] Figures 6M and 6N show the shell G and the filter element 60 in coupled configuration, wherein the inner portion (that is the concave region suitable to receive frontally the user's mouth and nose) and the external face G" of the shell G are visible, respectively.

[0069] As mentioned previously, the mask 100 comprises retaining means 70 to be worn by the user. Figure 4 shows a preferred embodiment of said retaining means, under not assembled condition with the additional components of the mask 100. The retaining means 70 preferably comprises one or more elastic elements, in form of ribbon, string, band, lace or the like.

[0070] Said retaining means is removable from the device 100, it preferably comprises mobile ends 71 and, by further referring to Figure 1, they can be inserted in third openings 31-34 obtained on the shell G. In a preferred variant, said third openings are obtained correspondingly on said shell G and said filter element 60, on the latter designated with the references 67a, 67b, 68a, 68b. In this way it is possible to further improve the coupling sealing and the correct positioning between filtering element 60 and shell G.

[0071] Said third openings are positioned in opposite way and laterally with respect to the central region 11 of the shell G and, in case, with respect to the central portion 69 of the filter element 60.

[0072] Preferably, said mobile ends 71 are made of stiff plastic material. Each end is configured to rotate by 90° so as to assume a reversible T-like configuration to be inserted and cross said third openings.

[0073] By further referring to Figures 7A-7E a sequence is shown exemplifying the steps to obtain the coupling of the retaining means 70.

[0074] Once inserted, by rotating it in the opposite direction, the T-like shape of the end prevents it from being extracted from the opening, by sealing thanks to the tension applied once the mask 100 is worn.

[0075] When the mask is not worn, the retaining means can be removed easily with inverse procedure with respect to their insertion, that is by rotating the end by 90° and by pulling it so as to get it out of the respective opening.

[0076] In the illustrated example, and by further referring to Figure 1 and Figure 2, both the shell G and the filter element 60 provide four corresponding holes, positioned in pairs laterally with respect to the central region/portion 11, 69. In particular, a first pair F1 comprising the holes 31, 68b, a second pair F2 comprising the holes 32, 67b, a third pair F3 comprising the holes 33, 67a and a fourth pair F4 comprising the holes 34, 68a.

[0077] It is possible using one or two elastic elements to assembly the retaining means, depending upon the assembly procedure. At least three different configurations are possible:

[0078] According to a first configuration, two elastic elements are provided wherein the two mobile ends of a first elastic element are inserted in said first and fourth pair of the holes F1, F4, respectively. The two mobile ends of the second element are inserted in said second and third pair of the holes F2 and F3. All mobile ends are anchored according to what previously described. The two elastic elements preferably have different length so as to adapt to the shape of the user's nape.

[0079] According to a second configuration, the two mobile ends of the first elastic element are inserted in said first and second pair of the holes F1 and F2, respectively. The two mobile ends of the second elastic element are inserted in said third and fourth pair of the holes F3 e F4, respectively. All mobile ends are anchored according to what previously described. The two elastic elements preferably have same length and each one is shaped so as to be fixed to a respective auricle.

[0080] According to a third configuration, one single elastic element is provided, the two mobile ends thereof are inserted in said pairs of holes with sequence F1, F3, F4, F2. All mobile ends are anchored according to what previously described. In this way, with one single elastic element two strings are obtained, to be used as in the first above-mentioned configuration.

[0081] The present invention has been sofar described with reference to preferred embodiments. It is to be meant that other embodiments belonging to the same inventive core may exist, as defined by the protective scope of the herebelow reported claims.

Claims

1. A wearable device (100) of personal protection, in particular a filtering mask, which device (100) comprises:

- a shell (G) obtained from a single shaped sheet made of plastic material, said shell (G) having a plurality of openings (11a),
- a removable filter element (60),
- means (70) for retaining the device to the user's face,

wherein said filter element (60) is superimposed on said shell (G) by covering said plurality of openings (11a) and it is facing, under condition of worn device, frontally on the user's mouth and nose, wherein a flap (23) of the shell (G) is fixed reversibly on an external face (G") of the latter by retaining a corresponding flap (62) of filter element (60) and in such a way as to define a portion of nasal bridge (N) of the device.

2. The device (100) according to claim 1, wherein said shell (G) is made of flexible and washable material.

3. The device (100) according to claim 1 or 2, wherein said shell (G) has a constant thickness, wherein said thickness is comprised between 0.3 millimetres and 1.5 millimetres.

4. The device (100) according to any one of the preceding claims, wherein said shell (G) comprises a concave lower portion (M) intended to house the chin and defined by overlapping lobes (40a, 40b) of said shaped sheet.

5. The device (100) according to any one of the preceding claims, wherein said filter element (60) comprises second openings (61) configured to implement a reversible joint with an edge element (21) of said shell (G).

6. The device (100) according to any one of the preceding claims, wherein said filter element (60) has a multilayer structure made of non-woven fabric.

7. The device (100) according to the preceding claim, wherein each layer of said structure is implemented from polymeric material with a weight comprised between at least 20 grams/square meter and at least 60 grams/square meter.

8. The device according to any one of the preceding claims, wherein said flap (23) is fixed by adjusting means (50) of the adherence of the device (100) to the face.

5 9. The device (100) according to the preceding claim, wherein said adjusting means (50) comprises a screw-nut coupling (51, 52) inserted in corresponding through holes (24, 25, 63, 64) obtained on said shell (G) and said filter element (60) symmetrically with respect to a sagittal plane which crosses the device (100) when worn.

10 10. The device (100) according to any one of the preceding claims, wherein said retaining means (70) is removable from the device (100) and comprises mobile ends (71) inserted in third openings (31, 32, 33, 34, 67a, 67b, 68a, 68b) obtained correspondingly on said shell (G) and said filter element (60).

15 11. The device (100) according to any one of the preceding claims and classified as a filtering half-mask according to UNI EN 149:2009 standard.

20 12. The device (100) according to any one of the preceding claims and classified as a medical device according to UNI EN 14683:2019 standard.

25 13. A shell (G) of filtering mask (100), which shell (G) comprises a single shaped sheet made of plastic material having a central region (11) and an upper flap (23), wherein said central region (11) has a plurality of openings (11a) intended to be covered by a filter element (60) at an internal face (G') of said shell (G) and wherein said upper flap (23) is fixed reversibly on an external face (G") of said shell (G) so as to define a portion of nasal bridge (N) of the mask (100), wherein the shell (G) comprises at least an edge element (21) at said upper flap (23) and configured to receive with reversible joint said filter element (60).

30 14. The shell (G) according to claim 13 having a constant thickness, wherein said thickness is comprised between 0.3 millimetres and 1.5 millimetres.

35 40 15. The shell (G) according to claim 13 or 14, comprising a concave lower portion (M) intended to house the chin and defined by overlapping lobes (40a, 40b) of said shaped sheet.

45 16. The shell (G) according to any one of claims 13 to 15, wherein said shell is made of flexible and washable material.

50 17. A method for manufacturing a filtering device (100) wearable on a user's face to protect the respiratory tract, comprising the steps of:

- providing a sheet (G) made of shaped plastic material comprising:
 - a central region (11) equipped with a plurality of openings (11a)

- an upper flap (23)

- providing a filter element (60) to be coupled to a first face (G') of said sheet (G) so as to cover said plurality of openings (11a); 5
- bending said sheet (G) so that said filter element (60) defines a region suitable to receive frontally the user's mouth and nose;
- fixing said upper flap (23) to the second face (G") of said sheet (G) so as to retain a corresponding flap (62) of said filter element (60) and to define a portion of nasal bridge (N) of the device (100); 10
- connecting to said sheet (G) means (70) for retaining the device to the face. 15

18. The method for manufacturing a filtering device (100) according to claim 17, wherein said sheet (G) comprises two lower lobes (40a, 40b) and the method further provides for fixing said two lower lobes (40a, 40b) one on top the other one to define a concave portion (M) of said first face (G') intended to house the user's chin. 20

19. The method for manufacturing a filtering device (100) according to claim 17 or 18, wherein the step of fixing said upper flap (23) to said second face of the sheet (G) is obtained through adjusting means (50) of the adherence of the device to the face. 25

20. The method for manufacturing a filtering device (100) according to claim 19, wherein said adjusting means (50) reversibly fix said filter element (60) to said shaped sheet (G). 30

21. The method for manufacturing a filtering device (100) according to any one of claims 17 to 20, wherein said filter element (60) is fixed to said first face (G') through second openings (61) configured to implement a reversible joint with an edge element (21) of said sheet (G). 35

22. The method for manufacturing a filtering device (100) according to any one of claims 17 to 21, wherein the filter element (60) is obtained by binding together a plurality of layers made of polymeric material by heat-sealing, sewing or *needle punching*. 40

23. The method for manufacturing a filtering device (100) according to any one of claims 17 to 22, comprising the step of activating said adjusting means (50) to vary the width of said portion of nasal bridge (N). 45

24. The method for manufacturing a filtering device (100) according to any one of claims 17 to 23 classifiable as filtering half-mask according to UNI EN 149:2009 standard. 50

25. The method for manufacturing a filtering device (100) according to any one of claims 17 to 24 classifiable as medical device according to UNI EN 14683:2019 standard. 55

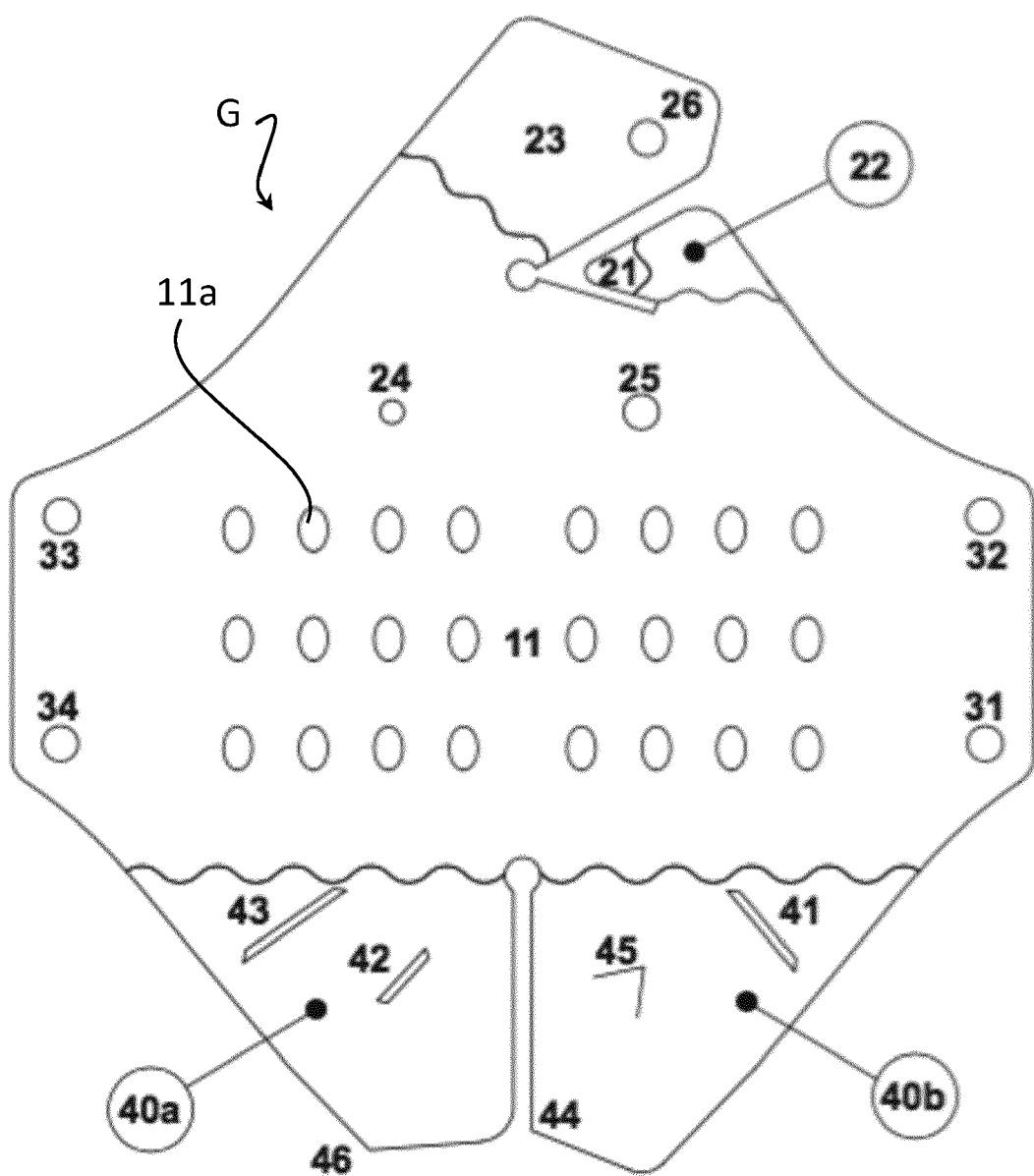


Fig. 1

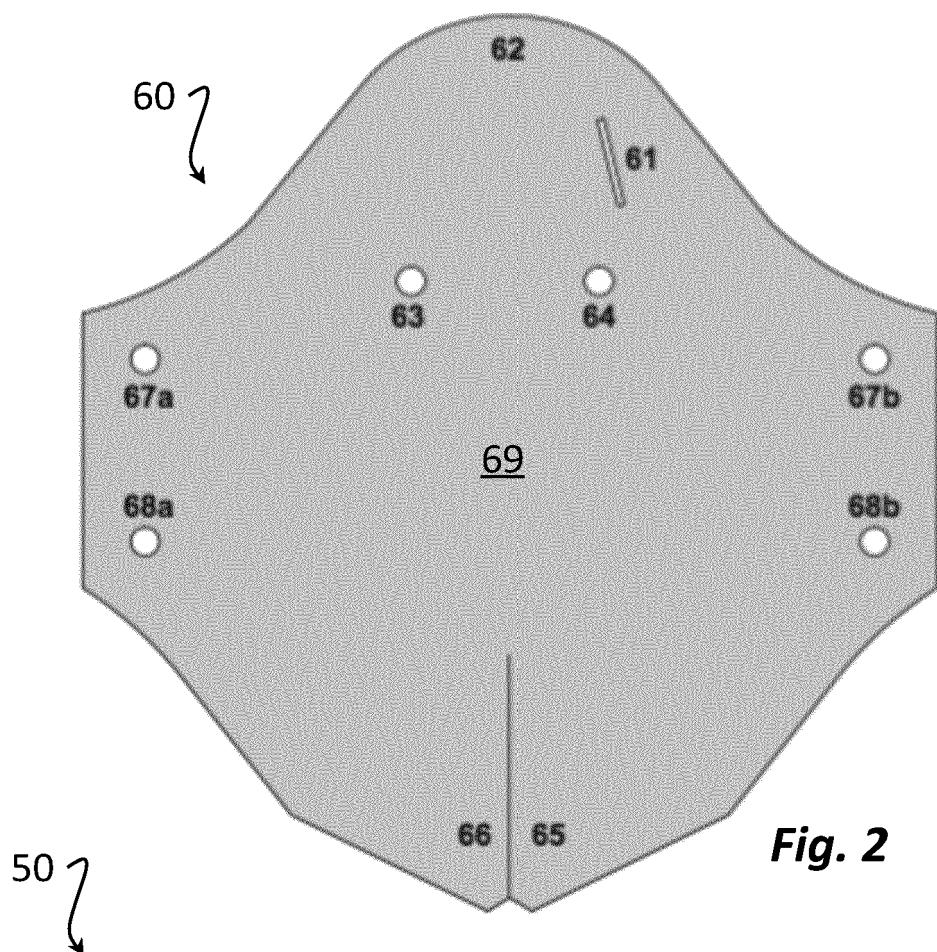


Fig. 2

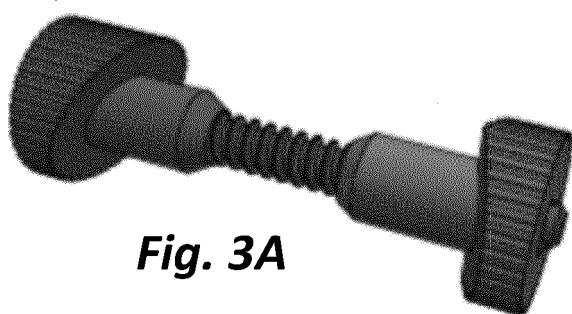


Fig. 3A

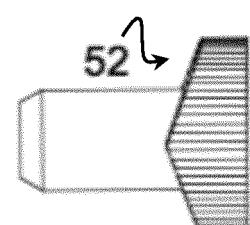
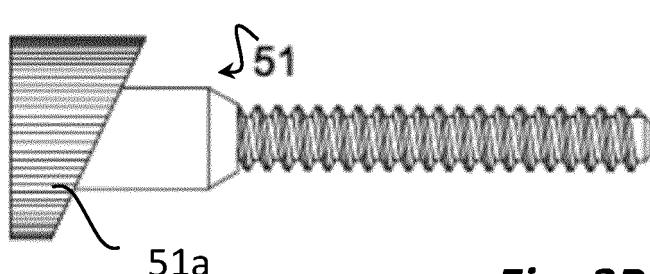


Fig. 3B

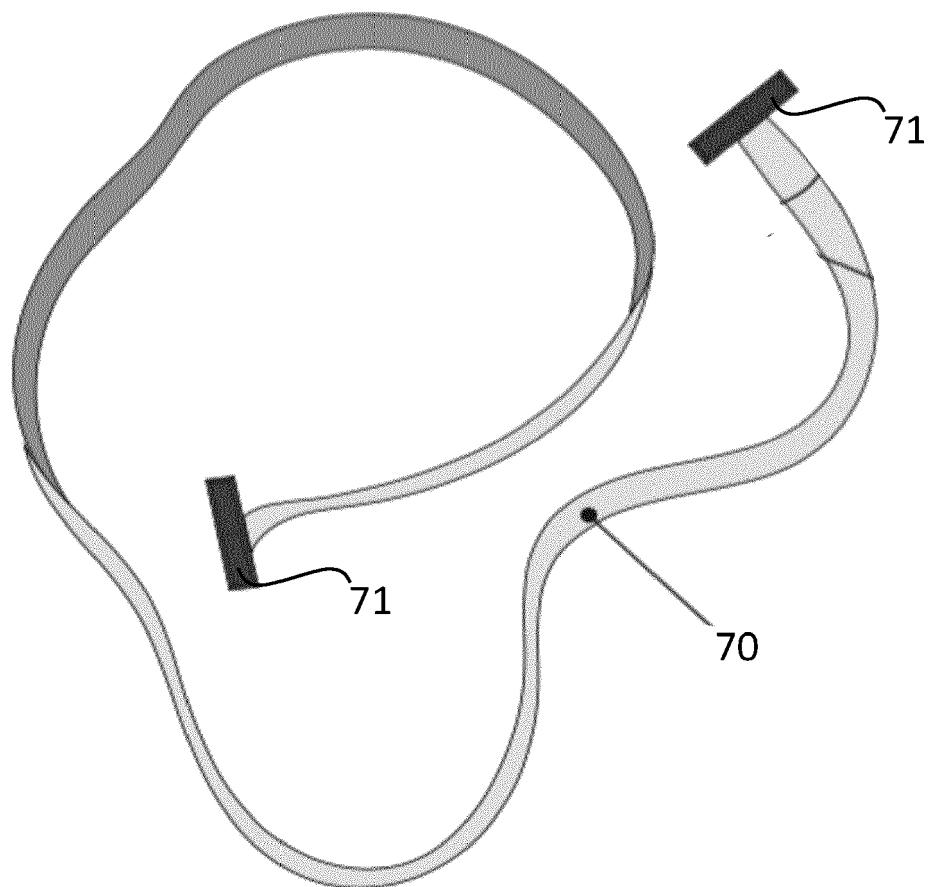


Fig. 4

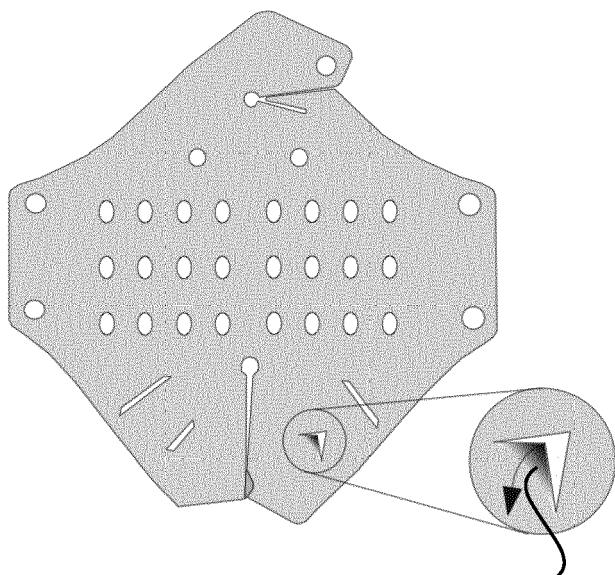


Fig. 5A

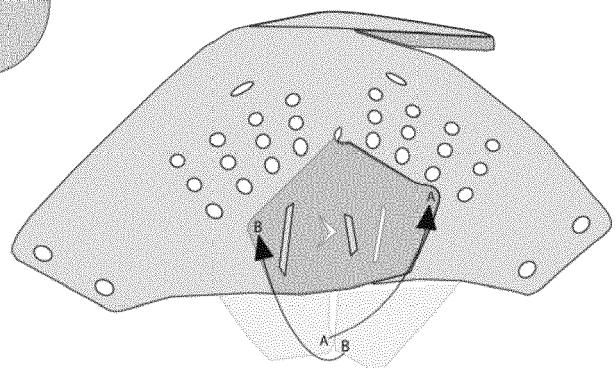


Fig. 5B

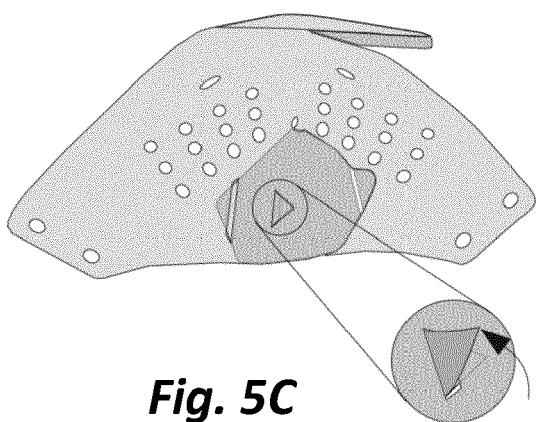


Fig. 5C

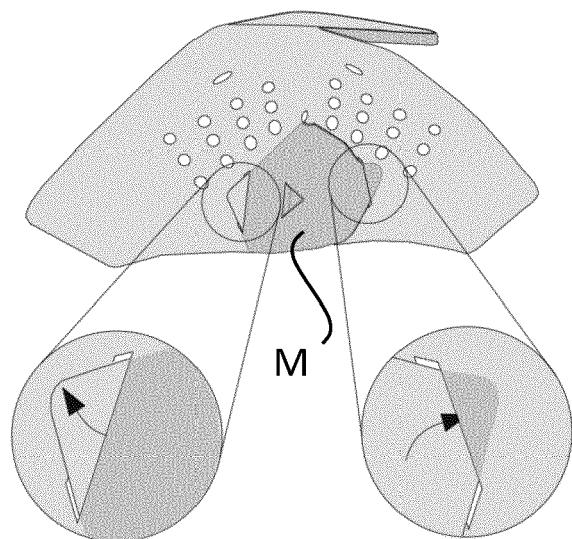


Fig. 5D

Fig. 6A

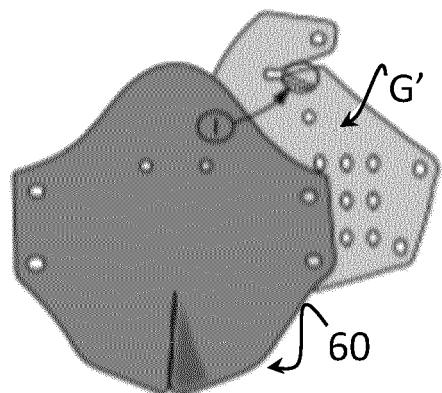


Fig. 6B

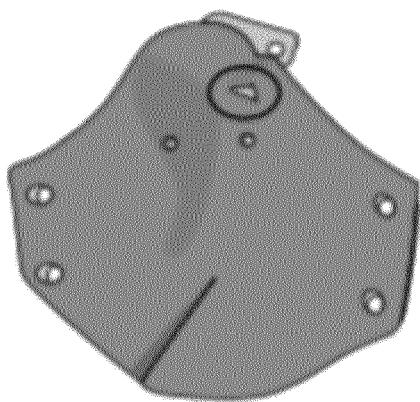


Fig. 6C

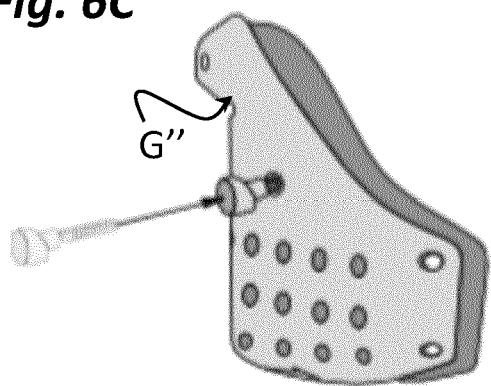


Fig. 6D

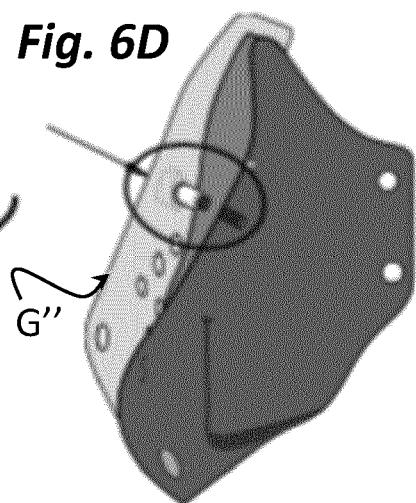


Fig. 6E

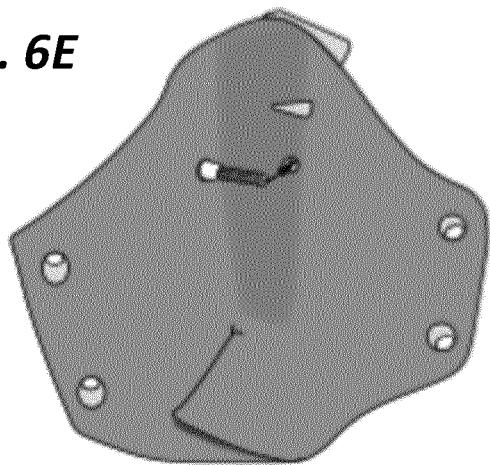


Fig. 6F

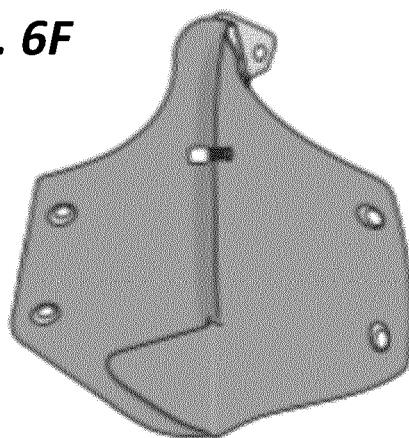


Fig. 6G

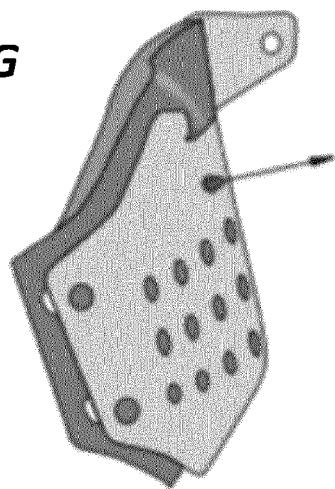


Fig. 6H

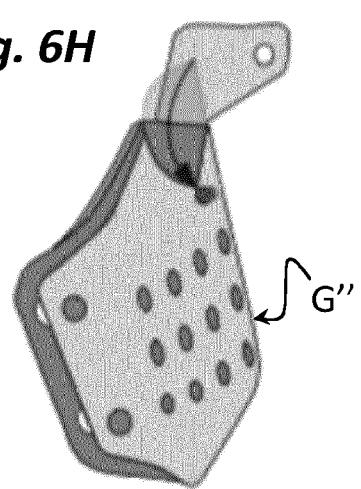


Fig. 6I

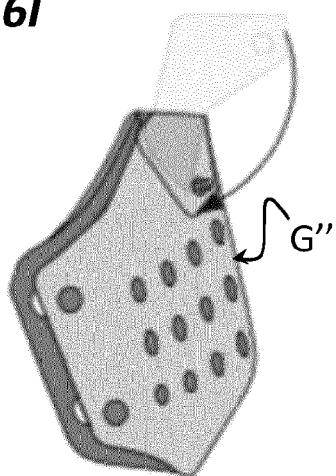


Fig. 6L

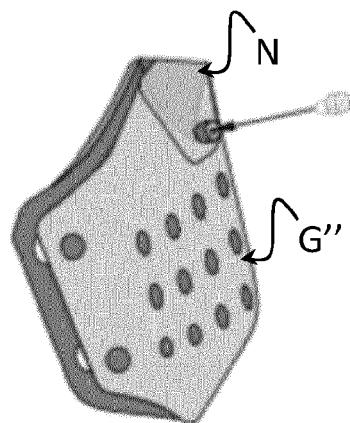


Fig. 6M

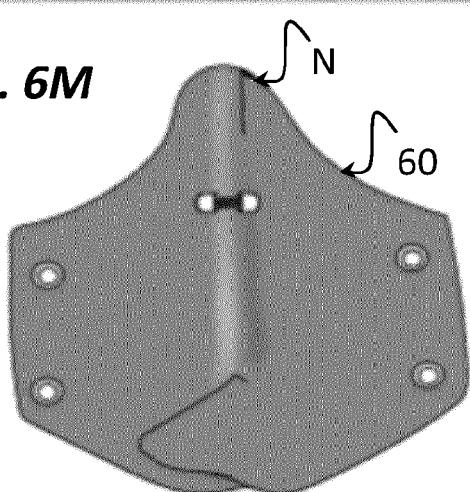


Fig. 6N

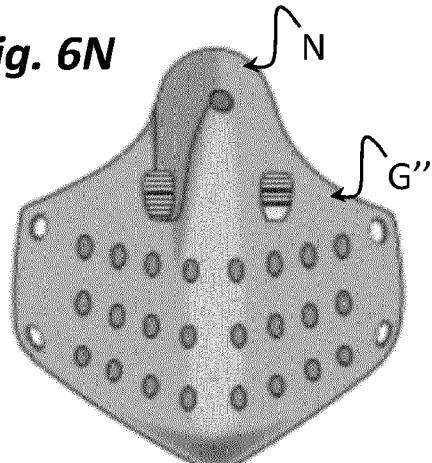


Fig. 7A

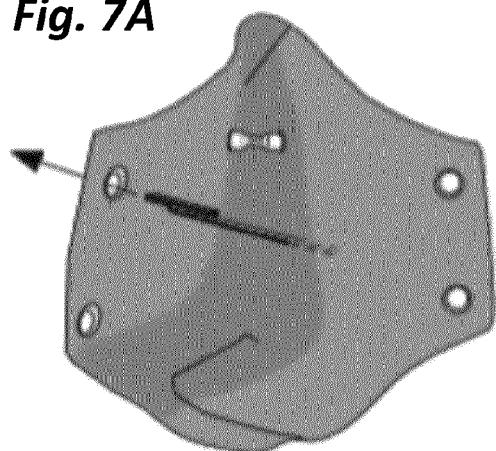


Fig. 7B

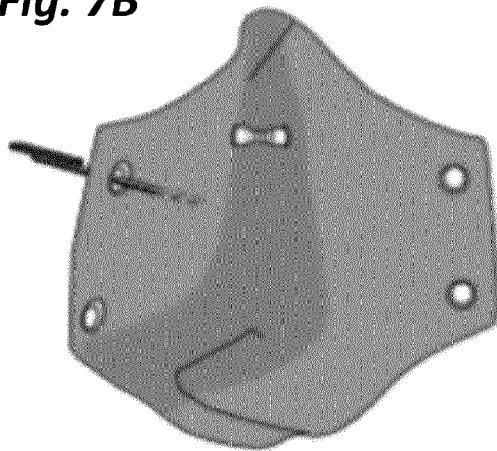


Fig. 7C

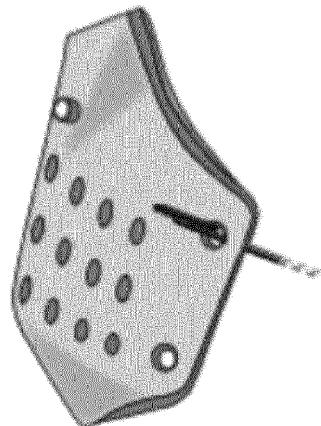


Fig. 7D

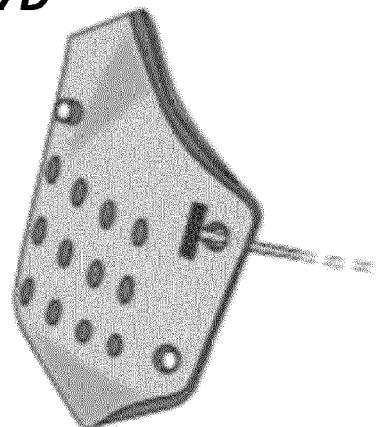
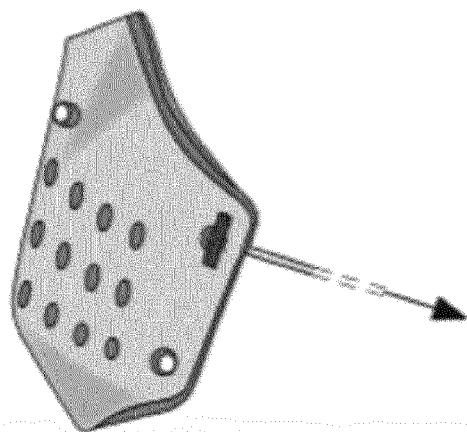


Fig. 7E



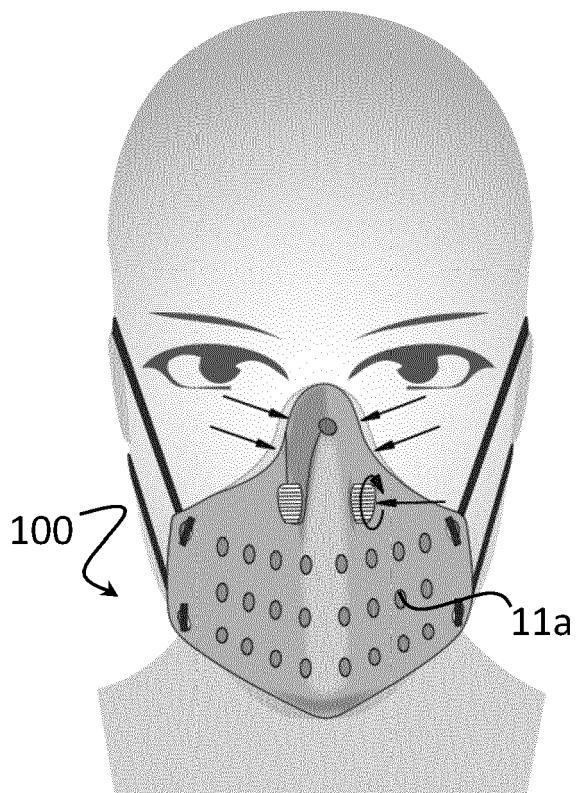


Fig. 8A

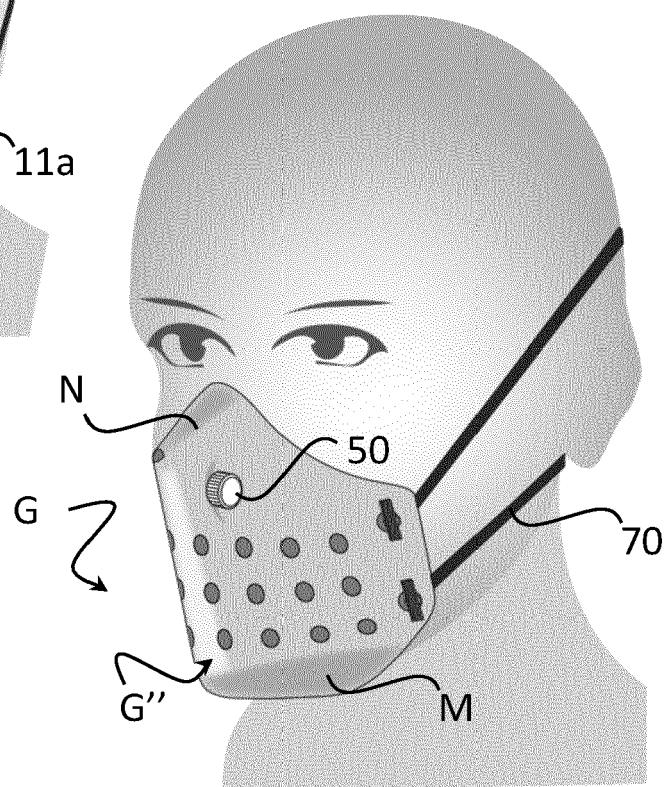


Fig. 8B



EUROPEAN SEARCH REPORT

Application Number

EP 21 17 4770

5

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
10	A JP H06 335535 A (K SEVEN KK) 6 December 1994 (1994-12-06) * abstract; figures 1,4-6 *	1-25	INV. A41D13/11 A62B23/02
15	A US 1 523 884 A (EDOUARD LEDUC JOSEPH) 20 January 1925 (1925-01-20) * claim 1; figures 1-4 *	1-25	
20	A GB 2 241 896 A (SMITH KARL WINGETT) 18 September 1991 (1991-09-18) * claim 1; figures 1-4 *	1-25	
25			
30			TECHNICAL FIELDS SEARCHED (IPC)
35			A41D A62C A62B
40			
45			
50	1 The present search report has been drawn up for all claims		
55	Place of search The Hague	Date of completion of the search 8 October 2021	Examiner D'Souza, Jennifer
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**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 21 17 4770

5 This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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08-10-2021

10	Patent document cited in search report	Publication date	Patent family member(s)	Publication date
15	JP H06335535 A	06-12-1994	NONE	
20	US 1523884 A	20-01-1925	NONE	
25	GB 2241896 A	18-09-1991	NONE	
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