Technical File

COVID-19 FFP2 mask 'Corona Protection Mask'
Product article number 434050

Koninklijke Auping BV

1 Content

2 Revision history

Version	Date	Status
0.1	March 29, 2020	Draft
1.0	March 30, 2020	Released
1.1	March 31, 2020	Released
1.2	March 31, 2020	Released
1.3	April 10, 2020	Released
1.4	April 15, 2020	Released

3 Product Description

The COVID-19 FFP2 mask 'Corona Protection Mask', article number 434050 is a disposable protection face mask. It is a face mask covering the mouth and nose, strapped to the face by means of elastic bands.

Intended Use

The corona protection mask can be used by healthcare professionals in various healthcare institutions in the Netherlands for the treatment and care of patients suffering of the corona virus. The corona protection mask increases the safety of healthcare professionals against the corona virus. It will protect the healthcare professionals against inhalation of the corona virus.

It is a single use product: for each contact with a patient suffering of the corona virus, the healthcare professional will use a new corona protection mask.

4 Risk assessment

4.1 Risk Management Procedure

Team members participating in the risk analysis are:

Member	Relevant knowledge
5.1.2e	Storage and usage of protection masks in healthcare
5.1.2e	Storage and usage of protection masks in healthcare
5.1.2e	Design of medical devices
5.1.2e	Production
5.1.2e	FMEA

The chosen method for risk analysis is FMEA, (see 4.2).

Risk assessment scores according to EN 14971:2012

Severity (S)		Effects to the user
1	Low	Inconvenience or temporary discomfort
2	Minor	Results in temporary injury or impairment not requiring professional medical intervention
3	Serious	Results in injury or impairment requiring professional medical intervention
4	Critical	Results in permanent impairment or life-threatening injury
5	Catastrophic	Results in user death

Occurrence (O)		Effect will occur
1	Improbable	$< 10-6$
2	Remote	$< 10-5$ and $\geq 10-6$
3	Occasional	$< 10-4$ and $\geq 10-5$
4	Probable	$< 10-3$ and $\geq 10-4$
5	Frequent	$\geq 10-3$

Explanation FMEA scores
The priority of risks = S*O,

De S and O values are estimated by the two members of safety team. The limiting value for a risk number to be acceptable or not is identified as 9.5.
The argumentation behind this is that if one of the members of the safety team takes the view that a life-threatening situation(S=9) may occur (O=2), the limiting value will be crossed. However: If both members decide the occurrence to be not very likely (O=1), the average score will not cross 9.5.

Beside a strict limiting value a second range is used which is known as the alarm range. This is the so called 'orange risk area' where we should also pay attention to. The choice of the limiting value has this alarm range build in, i.e. if one of the members of the safety team has a different opinion the average score will cross the limiting value immediately, and the risk will be paid attention to.

4.2 Failure Mode and Effect Analysis

See CPM-001-20_H4.2-FMEA_0.1

Conclusion:
The residual risks are all below the threshold.

The orange colour coded risks all but two describe situations which are and have been equal to all other certified masks. They concern e.g. the same adequate training of healthcare professionals.

The two risks typical for the COVID-19 FFP2 mask 'Corona Protection Mask' are

1. the attachment of the elastic band. We will create an extra control measure to control this attachment.
2. when hospitals exceed the indicated temperature range for storage. We will perform extra temperature tests to define the critical temperature limits exceeding the recommended temperature range as mentioned on the markings.

5 Essential Health and Safety Requirements Checklist (EHSR Checklist)

See CPM-001-20_H5-EHSR_0.1

6 Drawings

COVID-19 FFP2	Art.nr.	Quantity	Reference to technical drawing
Total assembly	434050		CPM-001-20_H6-5 (434050_b.pdf)

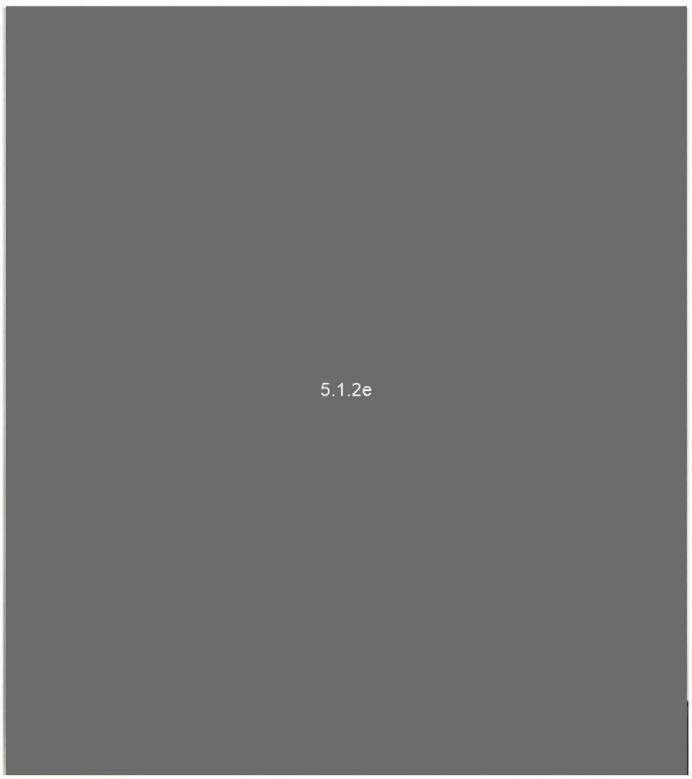
434050	Art.nr.	Quantity	Reference to technical drawing
Sub assembly 'Sealed half 4 layers Corona protection mask'	P50842	2	CPM-001-20_H6-6 (p50842.pdf)
Nose clamp Corona Protection Mask	P33337	1	CPM-001-20_H6-3.pdf
Headband Corona Protection Mask	P33338	2	-

P50842	Art.nr.	Quantity	Reference to technical drawing
Layer 1	P33333	Spunmelt 55	CPM-001-20_H6-4 (p33331 snijdeel enkel.pdf)
Layer 2	P33335	InnovaFiltec 20	CPM-001-20_H6-4 (p33331 snijdeel enkel.pdf)
Layer 3	P33335	InnovaFiltec 20	CPM-001-20_H6-4 (p33331 snijdeel enkel.pdf)
Layer 4	P33334	Spunmelt 47	CPM-001-20_H6-4 (p33331 snijdeel enkel.pdf)

7 List of components

Table 1 List of components

NR	Part	Art.nr.	Material	Supplier	Reference to file(s)
a	Layer 1	P33333	Spunmelt 55	Schaafsma Paper Group	CPM-001-20_H7-1A.pdf CPM-001-20_H7-1C.pdf CPM-001-20_H7-1D.pdf
b	Layer 2	P33335	InnovaFiltec 20	DSM	CPM-001-20_H7-2.pdf
c	Layer 3	P33335	InnovaFiltec 20	DSM	CPM-001-20_H7-2.pdf
d	Layer 4	P33334	Spunmelt 47	Schaafsma Paper Group	CPM-001-20_H7-4.pdf CPM-001-20_H7-1C.pdf CPM-001-20_H7-1D.pdf
e	Nose clamp Corona Protection Mask	P33337	Aluminium strip	GOMA B.V.	GOMA B.V. Ruurloseweg 80A NL-7255 MA Hengelo Gld
f	Headband Corona Protection Mask	P33338	EH3R7-008-D00	Juritex	



8 Test reports

We did some pretests in the design process of the COVID-19 FFP2 mask 'Corona Protection Mask'.

	Onze pretest
7.7 Practical performance	User test with 10 regular users of FFP2 masks. *See explanation A*
7.9 Leakage **7.9.1 Total inward leakage** a. face seal leakage b. exhalation valve leakage (not applicable) c. filter penetration.	Ad a) *See explanation B* Ad b) Not applicable Ad c) *See explanation B*
7.9 Leakage **7.9.2 Penetration of filter material**	*See explanation C*
7.12 Carbon dioxide content of the inhalation air	We did no test for 7.12
7.16 Breathing resistance 3 samples AR	*See explanation D*

Explanation A User test (7.7)

The independent and experienced users of FFP2 masks were asked to rate the COVID-19 FFP2 mask 'Corona Protection Mask' on a 1-5 scale (1=inadequate, 2=poor, 3=reasonable, 4=good, 5=excellent)

User	1	2	3	4	5	6	7	8	9	10
a) head harness comfort;	3	3	4	3.5	4	4	4	4	4	4
b) security of fastenings;	4	4	5	5	5	5	4	4	5	5
c) field of vision;	3	4	5	3.5	5	4	4	4	4	4
breathing resistance	4	3	4	5		4	4	4	4	3
Average score	**3.5**	**3.5**	**4.5**	**4.25**		**4.25**	**4**	**4**	**4.25**	**4**

d) any other comments reported by the wearer on request:
User 1: Elastic straps are too tight
User 2: mask is too tight
User 3: Mask is quite tight, however still no pressure on face, comfort is good, air leakage is minimal, maybe add rubber edge for seal?
User 4: Elastic straps are quite tight
User 5: Elastic straps might be a bit too tight after a while
User 6: For such a mask, it's comfortable!
User 7: Flexible -> pleasant
User 8: maybe the upper side should have another colour *)
User 9: nothing to add
User 10: Comfortable! No condensation on your glasses! Great

*) The samples had no marking: the difference between upper and bottom side wasn't clear.

Conclusion: in the use instructions, we added the sentence '*If necessary, stretch the elastic bands a bit for better comfort.*'

Explanation B face fit and filter penetration (7.9.1)
We did a Face FIT-test with the PortcountPro+ 8040 by ProCare. We compared with a Halyard mask:

	Halyard mask	Auping 5 layers	Auping 4 layers
OSHA score	500	<100	150
Particles outside mask	1300 - 1400	1300 - 1400	1300 - 1400
Particles inside mask	0 (breath in) 4 (breath out)		4 (breath in) 20 (breath out)

On the basis of an equal time for breathing in and breathing out:
P = 20/1300 ((1+1)/1)x100 = **3%**

Explanation C penetration of filter material (7.9.2)
To get a first impression of the required filter of the COVID-19 FFP2 mask, we tested the material with a particle measurement device. Our target was: the material should filter 95% of 0.3mu particles, 97% of 0.5mu particles and 99% of 5mu particles.

The table below shows the results. We compared our three designs A, B and C with the FFP2 1862 mask made by 3M. With each design we did 3 measurements.

Test results

			Particle size (mu)	0.3	0.5	5
			Our target (%)	95	97	99
			FFP2 3M 1862	99,1	99,7	100
A	PP meltblown 55		Measurement 1	95,7	99,3	100
	InnovaFiltec (20 en 30 grams)		Measurement 2	95,8	99,3	99,8
	PP meltblown 47		Measurement 3	95,7	99,3	100
B	PP meltblown 55		Measurement 1	98,2	99,6	99,8
	InnovaFiltec (20 en 30 en 20 grams)		Measurement 2	98,4	99,7	100
	PP meltblown 47		Measurement 3	98,5	99,7	100
C	PP meltblown 55		Measurement 1	97,4	99,2	100
	InnovaFiltec (20 en 30)		Measurement 2	97,5	99,3	100
	Sawascreen		Measurement 3	97,4	99,3	99,8
	PP meltblown 47					

Explanation C Breathing resistance (7.12)
We added to the user test (see explanation A) their experience of the breathing resistance.

9 Quality Plan

General
The general quality management process of Auping is described in document '*Kwaliteit bij Auping*'. Production process stages are defined in value stream maps.

Raw materials and components
Specifications of components are listed at material certificates. Components are purchased based on specifications in the ERP-system. For the FFP2 masks, the filter material is purchased with dedicated suppliers that are ISO-9001 certified.

Standardization of working processes
Process steps are executed by production personnel using detailed working instructions:

- detailed description of tasks, document template '*Positie standaard*'
- checklists for inspection of intermediates
- checklists for final products
- checklists for inspection and calibration of equipment

Production Personnel is trained for specific tasks using the 'training-on-the-job' principle. Competences are registered in competence matrices for each employee. Competences of temporary personnel are registered in cooperation with the job agency.

Quality control
In process quality control is executed by the production personnel using checklists and based on visual inspection of intermediates. Criteria for non-conformities are visualized, using a standard template, document name '*Goed / Fout document*'. In these documents 'False' and 'Wrong' are clearly indicated using pictures and/or drawings.

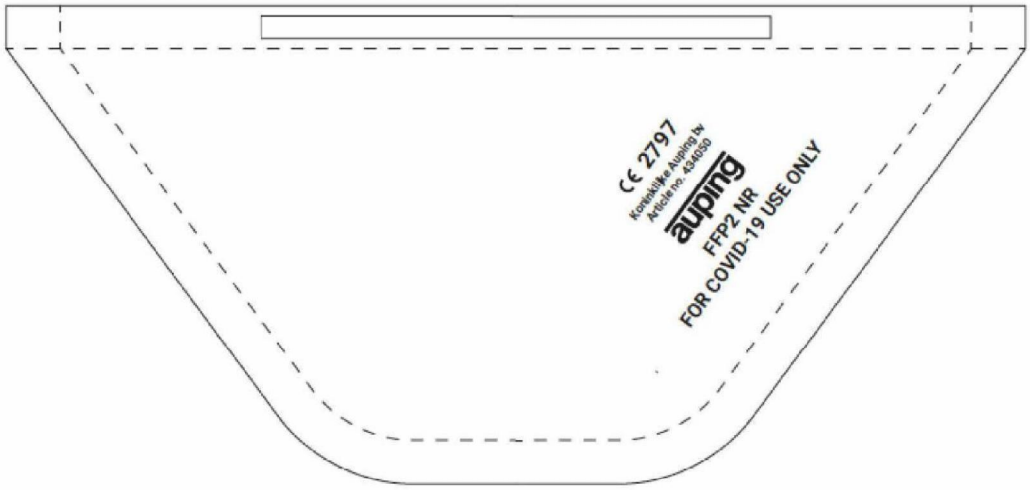
Quality of final product is executed by the Quality Department according the CMF procedure (*annex L*). Quality control including the non-conforming products procedure is described in the CMF procedure (*annex L*).

Changes
The change procedure is described in the document 'Wijzigingenproces' (*annex E*).

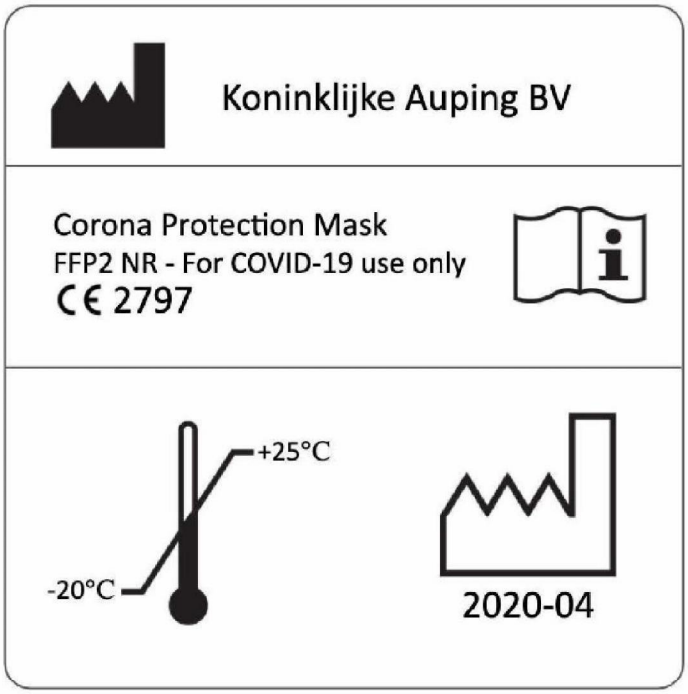
Document	Reference (file name)
CMF procedure annex L	CPM-001-20_H9-1
Wijzigingenproces annex E	CPM-001-20_H9-2

10 Marking (labels)

Marking on the COVID-19 FFP2 mask:



Marking on the box containing 10 bags. Each bag contains 20 COVID-19 FFP2 masks.



11 User information

See CPM-001-20_H11-use information-NL for the User information in Dutch
See CPM-001-20_H11-use information-UK for the User information in English

12 PPE to fit an individual user

Not applicable.

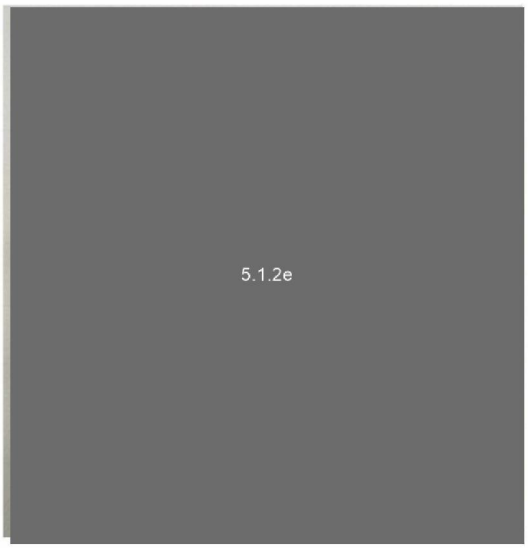
13 Draft EU Declaration of Conformity

1. PPE (product, type, batch or serial number):
COVID-19 FFP2 mask 'Corona Protection Mask', art. no. 434050

2. Name and address of the manufacturer and, where applicable, his authorised representative:
Koninklijke Auping BV
Maagdenburgstraat 26,
7421 ZC DEVENTER

3. This declaration of conformity is issued under the sole responsibility of the manufacturer:
Koninklijke Auping BV
Maagdenburgstraat 26,
7421 ZC DEVENTER

4. Object of the declaration (identification of PPE allowing traceability; where necessary for the identification of the PPE, a colour image of sufficient clarity may be included):



5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation:
CE PPE

6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:
It concerns a COVID 19 Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425

7. Where applicable, the notified body BSI Netherlands 2797 performed the EU type-examination (Module B) and issued the EU type-examination certificate ... (reference to that certificate).

8. Where applicable, the PPE is subject to the conformity assessment procedure ... (either conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) or conformity to type based on quality assurance of the production process (Module D)) ... under surveillance of the notified body ... (name, number).

9. Additional information:
Signed for and on behalf of: Koninklijke Auping BV
Deventer, March 29th 2020:

5.1.2e

(signature):

14 Letter of authorization

Not applicable