MDR REPORT

CPH Global Medical ApS

MANUFACTURER
OF CLASS I MEDICAL DEVICES

CPH Global Medical ApS

Medical Device Regulation (MDR) Report

Contents

List of Acronyms

CPH – CPH Global Medical ApS
MDD – Medical Devices Directive
MDR – Medical Devices Regulation
Face mask - non sterile disposable
surgical face mask
FSCA – Field Safety Corrective Action
FSN - Field Safety Notice
UDI - Unique Device Identifier
SRN - Single Registration Number
NB - Notified Body
ISO - International Organization for Standardization
IEC - International Electrotechnical Commission
CA – Competent Authority
PPE – Personal Protective Equipment
QMS - Quality Management System
DI – Device Identifier
Eudamed - EU database on medical devices
MD - Medical Device
CS - Common Specification
PMS – Post Market Surveillance
IFU – Instructions for use
PMCF - Post Market Clinical Follow-up

Foreword by the CEO of CPH Global Medical ApS

This report is made by CPH Global Medical ApS (CPH) to meet the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR).

We can assure any competent authority and our customers that we have taken into consideration the regulations of the MDR in all aspects of our business and workflow. We will carefully follow the future MDR regulations to be compliant at any time.

Yours sincerely

Kenneth Berntsen

CEO and Partner

CPH Global Medical ApS

Introduction

The purpose of this document is to show that we as a manufacturer of a Class I, Rule I medical device – who has placed a non sterile disposable surgical face mask on the EU Union market –under our own name and trade mark - follow the regulation under the provisions of the MDR.

CHP is aware that the new MDR has changed the scope of the medical device legislation and it now extends its application to all economic operators in the supply chain (manufacturer, authorized representative, importer and distributor) as well as a broadened range of products.

CPH is familiar with that the MDR emphasis is placed on a life-cycle approach to safety, backed up by clinical data and new requirements such as transparency and traceability.

As a manufacturer we have affixed the CE mark to our product in accordance with Annex V and drawn up an EU declaration of conformity, including all the information required by Annex IV.

Prior to that, in this Report we will demonstrate conformity with the MDR and compliance with the general safety and performance requirements laid out in Annex I.

In order to show that we have accomplished the abovementioned tasks, CPH has carried out the following to be compliant with the MDR rules:

- CPH **quality management** system and a system for risk management according to Article10(2) and 10(9) has been put in place in the company workflow.
- CPH has conducted a **clinical evaluation** for our product in accordance with Article 61, as established in Article 10(3) and Annex XV.
- CPH has conducted a **conformity assessment** for our product according to Article 52(7).
- CPH has drawn up and keep up-to-date **technical documentation** related to our product as set out in Annexes II and III, in accordance with Article 10(4).
- CPH has drawn up an **EU declaration of conformity** in accordance with Article 19. See the Appendix.
- CPH has submited the required information to the electronic system for registration of economic operators - **Eudamed** - and has received confirmation that CPH comply with the registration obligation. In the future CPH will use the Single Registration Number - **SRN** - when applying to a Notified Body for conformity assessment and for further accessing Eudamed in order to fulfil our obligations related to registration of our products.
- CPH has registered our product in Eudamed and will assign the **Basic UDI-DI** to the product box, as defined in Part C of Annex VI, and provide this to the UDI database together with the other core data elements referred in Part B of Annex VI related to our product.
- CPH will assign the **UDI to the product packing** and, if applicable, to all higher levels of packaging, a UDI which will allow identification and traceability.

- CPH has ensured that our product is accompanied by the information needed to identify it and CPH as a manufacture, and any **safety and performance information relevant to the user**, or any other person, as appropriate (Article 10(11)). The information on our packing, set out according to Section 23 of Annex I, is provided in Danish since our product is placed on the Danish market. CPH ensure that the particulars / user guide on our packing is indelible, easily legible and clearly comprehensible to the intended user or patient.
- CPH has implemented a **post-market surveillance system** in accordance with Article 83 (Article 10(10)) for Class I products / devices. This system is integrated by CPH as an ordinary conduct of manufacturing and quality management system based on our post-market surveillance plan (Article 84). The CPH post-market surveillance plan is a part of the technical documentation specified in Annex III.
- CPH has implemented a **system for recording and reporting incidents and field safety corrective actions** as described in Articles 87 and 88 (Article 10(13)).
- CPH has put measures in place to provide sufficient **financial coverage** in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law. These measures will be proportional to the risk class, that Class I products / devices and the size of our company (Article 10(16)).

MDR Article 15 compliant

CPH has assigned a person in our organization who is responsible for MDR regulatory compliance, as established by Article 15.

Upon request, CPH will provide all the information and documentation necessary to demonstrate conformity of our product to competent authorities and we will cooperate with them on any corrective actions. We understand that if we as manufacture does not provide the requested information or documentation, the competent authority (CA) can adopt restrictive measures.

CPH will periodically investigate whether implementing and delegated acts, common specifications, technical standards and guidelines might be available on the European Commission website.

Definitions

For the complete list of definitions refer to Article 2 of the MDR. This is an excerpt of some definitions used in this report.

Accessory for a medical device - means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s) (Article 2(2)).

Benefit-risk determination - means the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer (Article 2(24)).

CE marking of conformity or CE marking - means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the MDR and other applicable Union harmonisation legislation providing for its affixing (Article 2(43)).

Clinical evaluation - means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer. (Article 2(44)).

Clinical data - means information concerning safety or performance that is generated from the use of a device and is sourced from the following:

- clinical investigation(s) of the device concerned,
- clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,
- reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,
- clinically relevant information coming from post-market surveillance, in particular the post- market clinical follow-up. (Article 2(48))

Conformity Assessment – The process demonstrating whether the requirements of the MDR relating to a device have been fulfilled. (Article 2(40)). This process depends on the medical device classification, according to the procedures described in the MDR, in particular Article 52 (7) applicable for class I devices.

Distributor - means any natural or legal person in the supply chain, other than the manufacturer or the importer that makes a device available on the market, up until the point of putting into service (Article 2(34)).

Field safety corrective action - means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market (Article 2(68)).

Field safety notice - means a communication sent by a manufacturer to users or customers in relation to a field safety corrective action (Article 2(69)).

Importer - means any natural or legal person established within the Union that places a device from a third country on the Union market (Article 2(33)).

Instructions for use - means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use, and of any precautions to be taken (Article 2(14)).

Label - means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices (Article 2(13)).

Medical device - means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Manufacturer - means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark*;* (Article 2(30)).

Notified Body - means a conformity assessment body designated in accordance with the MDR (Article2(42)).

Placing on the market - means the first making available of a device, other than an investigational device,on the Union market (Article 2(28)).

Post-market surveillance - means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put intoservice for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions (Article 2(60)).

Risk - means the combination of the probability of occurrence of harm and the severity of that harm(Article 2(23)).

Serious incident - means any incident that directly or indirectly led, might have led or might lead to any ofthe following:

(a) the death of a patient, user or other person,
(b) the temporary or permanent serious deterioration of a patient's, user's or other person's stateof health,
(c) a serious public health threat; ((Article 2(65))

Serious public health threat - means an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time (Article 2(66)).

Unique Device Identifier (UDI) - means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market (Article 2(15)).

User - means any healthcare professional or lay person who uses a device (Article 2(37)).

CPH Global Medical ApS on the EU market: *Actions taken to comply with the MDR*

CPH as a manufacturer of Class I medical devices assure that in the process of placing our product on the EU market, we are compliance with all the requirements below, and we have taken the necessary steps to do so under the full MDR regulations. In the following we will demonstrate our conformity with the MDR regulation.

1) CPH Quality Management System (QMS) and compliance as a manufacturer

The applicable provisions of the MDR have been integrated into our QMS. This will allow us the correct assessment/decision to be made and the proper documented evidence to be created and ensuring compliance with the MDR, for example by means of an internal audit. The QMS will be maintained, kept up to date and continually improved by a person in our organization and will cover the following aspects:

- Updating our strategy for regulatory compliance
- Updating our general safety and performance requirements.
- Make sure that the responsibility of compliance with MDR are at our management attention at any time by monthly updates.
- Updating our resource management, including selection and control of suppliers and sub-contractors
- Updating our risk management
- Updating our clinical evaluation, including post market clinical follow-up (PMCF)
- Maintenance of our post-market surveillance system;
- Make sure to handle communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders frequently.
- Reporting any serious incidents through our post-market surveillance (PMS).

2) CPH product as a medical device under MDR

CPH confirm that our product – a non sterile disposable surgical face mask (face mask) - qualifies as a medical device as defined in Article 2(1) in accordance with its intended purpose and principal mode of action.

The face mask is used by covering the mouth and nose providing a barrier to minimize the direct transmission of infective agents between staff and patient. This intended purpose is normally used surgical procedures and other medical settings with similar requirements, but is today because of COVID 19 also used in public areas. A medical face mask with an appropriate microbial barrier should also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms. They are used by healthcare workers to prevent large respiratory droplets and splashes from reaching the mouth and the nose of the wearer and help reduce and/or control at the source the spread of large respiratory droplets from the person wearing the face mask

The face mask is made out of non-wowen material, melt blown material, an iron core for nose-bar and ear-loops made out of spandex. The facemask comes with no accessories.

3) CPH product as a Class I, Rule I medical device under MDR

CPH has consulted Annex VIII, Chapter III, 4.1. of the MDR and can confirm that our product - a non-invasive and non-sterile face mask - is correctly classified as Class I under Rule I.

4) Procedures done by CPH to comply with the MDR

Before placing our medical device – a face mask - on the market CPH we have conducted the following:

- Met the general safety and performance requirements for our face mask in the MDR
- Conducted a clinical evaluation of our face mask as described in the MDR
- Prepared technical documentation
- Assessed whether a Notified Body involvement was necessary before placing the face mask on the market
- Prepared instructions for use and labelling on the packing of the face mask

a) <u>General safety and performance requirements</u>

CPH confirm that our face mask meets the general safety and performance requirements set out in Annex I of the MDR

We have established and implemented a risk management system, which will allow for the identification and analysis of the hazards associated with our face mask, hereunder estimation and evaluation of the associated risks, elimination or control of residual risks and evaluation of the adopted measures based on the information collected from the post-market surveillance system.

To ensure this we have had the following two NBs (notified body) to test our face mask to ensure the safety of our face mask before placing it on the market. The tests will be updated regularly.

- Danish Technological Institute
- DHI

Moreover we have worked together with Astma & Allergy Nordic to make sure that our face mask do not cause any asthma or allergy when used.

The conclusion of these tests are that our face mask has the following approvals and certifications, which are enclosed in the Appendix :

- DS/EN 14683:2019 + AC:2019
- DS/EN ISO 11737-1:2018
- ISO 10993 – 1 (2009)(2018) / 10993-5 (2009 / 10993-10 (2010) / 10993-11 (2018) / 10993-17 (2009) / 10993-18 (2009)(2020)
- ISO 14971 (2021)
- ASTMA & ALLERGY NORDIC certified

b) <u>Clinical evaluation</u>

The following clinical evaluation of our face mask has been prepared according to the MDR.

We are as a manufacturer of medical device Class I aware that we are obliged to make the clinical evaluation available to the CA, the authorized representative and NB when needed.

In order to comply with the MDR, we have planned, conducted and documented the clinical evaluation in accordance with Article 61 and Part A of Annex XIV:

Test done on our face mask by NB
Our face mask face mask is intended to protect the user against bacteria and virus, especially from the COVID 19 virus. The face mask has through the abovementioned test as enclosed in the Appendix been clinical evaluated and tested by NB:

DS/EN 14683:2019 + AC:2019 has been performed by Dansk Teknologisk Institut to our face which has passed the following test:

- Level of CFU – (CFU/g) ≤ 30 - test passed
- Breathability - (PA/Cm2) < 60 - test passed
- Splash resistance – (kPa) ≥ 16,0 - test passed
- Bacterial filtration level (BFE) (%) ≥ 98 – test passed

DHI has performed an **exhaustive toxicology test** to make sure that the raw materials and by that the face mask is non-toxic. The face mask passed the test.

Astma & Allergy Nordic has conducted a comprehensive investigation of our raw materials and suppliers to make sure that no raw material or production method can cause asthma or allergy when used in the face mask. The raw material and suppliers passed the test.

Labeling, user guide, type of face mask and quality
To make sure that the face mask is used intentionally and in conformity with Annex 1 in the MDR we have used the following risk management measures – label/ marking on the box, user guide, indication of type and quality of the face mask:

The following **label / marking** is in a clear and easily understandable way printed on the box of the face mask (translated from Danish):

- *CE label*
- *TYPE IIR*
- *50 pcs. pr. box*
- *Product information*
- *Instructions for use*
- *Warnings*
- *LOT number*
- *Manufacturer and manufacturer address*
- *Date of production*
- *Expiration date*
- *Barcode SRN*

- *Item number*

The following **user guide** is printed on the box of the face mask (translated from Danish):

- *Face mask must be used correctly. If you use it incorrectly, you risk spreading viruses and bacteria to yourself and others.*
- *Find the front page. In the case of disposable face masks, it is usually the colored side.*
- *Put on the mouthpiece by holding the ear elastics. Make sure the face mask fits snugly to your face (nose, cheeks and chin).*
- *Do not touch the face mask during use. Change it often and always if it is wet or dirty.*
- *Remove the face mask by grasping the elastics and immediately throw it in a rubbish bin. Put it in a bag until you are near a rubbish bin or if you need to recycle it after very short use.*
- *Storage instructions, shelf life and disposal of packaging.*
- *Store dry, at room temperature and not in direct sunlight.*
- *Shelf life - unopened: 5 years.*
- *Disposal of packaging: Can be reused or incinerated.*

The following is mentioned on the box indicating which **type of face mask and the quality**:

- *TYPE IIR*
- *Bacterial filtration level (BFE) (%) ≥ 98*

It is also noted on the packing that the face mask is compliant with DS/EN 14683:2019 + AC:2019 and is Astma & Allery Nordic certified.

Additional information regarding the use of face mask, alternative treatment and literature list
As **additional information** CPH has on the website www.cphmedical.com specified the purpose and use of the face mask in the following way:

- *Face mask protect against bacteria and viruses. Type 2 or IIR which is CE approved and minimizes the spread of infection.*
- *The face masks are recommended for use by healthcare professionals in operating rooms or in environments with similar hygiene requirements to reduce cross-contamination. The face masks are used in situations where there is a risk of splashes and splashes. The patient and the environment are protected against infection.*
- *How do you use a face mask correctly?*
- *Face mask must be used correctly. If you use it incorrectly, you risk spreading viruses and bacteria to yourself and others.*
- *Wash hands or use rubbing alcohol before use.*
- *Find the front page. In the case of disposable face masks, it is usually the colored side.*
- *Put on the face mask by holding the ear elastics. Make sure the face mask fits snugly to your face (nose, cheeks and chin).*
- *Do not touch the face mask during use. Change it often and always if it is wet or dirty.*
- *Remove the face mask by removing the ear loops and immediately throw it in a rubbish bin or put it in a bag until you are near a rubbish bin.*
- *Wash hands or use hand sanitation / alcohol after use.*

(this is a picture of the box containing CPH face mask and a face mask)

We are as a manufacturer aware that the MDR reinforces the need to take into considerations an **alternative treatment options** as required as part of clinical evaluation for the MDR. Alternatives to a EN 14683:2019 + AC:2019 non sterile disposable surgical face mask can be a visor or other practical arrangement covering the mouth and nose. Visors are normally too expensive to use as a disposable device.

We have also gathered the following **literature list** that show how to use the face mask properly and the effect a face mask will have in a pandemic situation:

- *https://www.sst.dk/da/udgivelser/2020/saadan-bruger-du-mundbind*
- *https://www.google.com/search?client=safari&rls=en&q=undersøgelser+om+mundbind&ie=UTF-8&oe=UTF-8*
- *https://ugeskriftet.dk/nyhed/forsker-bag-studie-mundbind-reducerer-kun-i-mindre-grad-risikoen-blive-smittet-med-coronavirus*
- *https://www.dr.dk/nyheder/indland/verdens-stoerste-undersoegelse-af-mundbind-klar-usikkert-om-mundbind-beskytter-mod*
- *https://www.berlingske.dk/samfund/danske-laeger-kender-svaret-om-mundbind-derfor-er-det-hemmeligt*
- *https://videnskab.dk/krop-sundhed/virker-mundbind-saadan-bruger-du-evidenspyramiden-til-at-finde-svar*
- *https://www.berlingske.dk/videnskab/nyt-kaempestudie-masker-halverer-din-smitterisiko-men-dansk-professor-er*

Clinical evaluation follow-up, benefit-risk determination

The plan will cover the post-market **clinical follow up** (PMCF) plan as referred to in part B of Annex XIV or a justification as to why it is not applicable. The PMS report of article 85 is part of the clinical evaluation documentation.

A certified EN 14683:2019 + AC:2019 non sterile disposable surgical face mask has a very high and positive benefit-risk ratio since there is no known risk to wear a face mask and as a comprehensive article in BMJ (British Medical Journal) shows there can more than 50% better protection against virus and bacteria (as COVID 19) and approximately 100% better security against splashes of any kind to penetrate the face mask for the wearer of the face mask.

c) Technical documentation

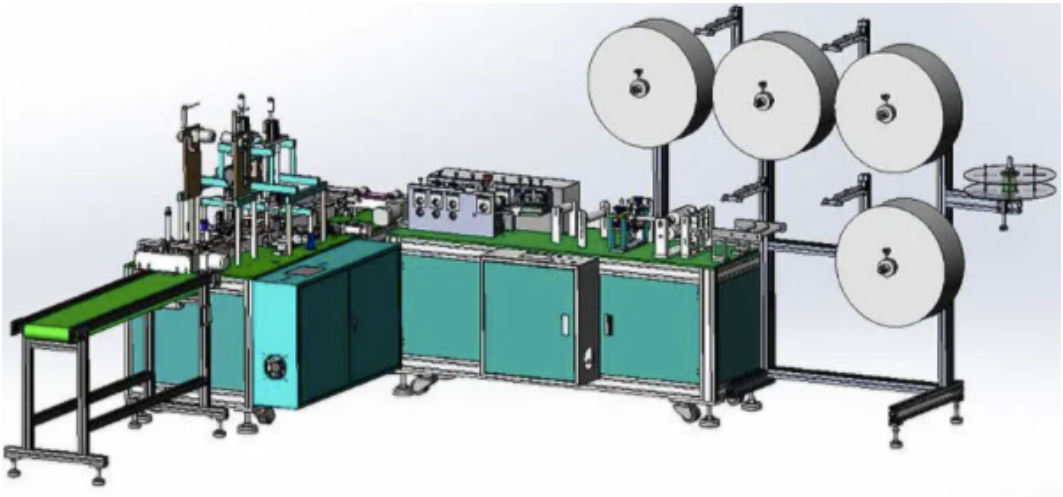
The following technical documentation has been prepared according to Annex II and III and prior to drawing up the EU declaration of conformity.

We are as a manufacturer of medical device Class I aware that we are obliged to make the technical documentation available to the CA, the authorized representative and NB when needed.

The technical documentation has been prepared following review of the general safety and performance requirements and relevant technical provisions of the MDR and covers all the relevant aspects from Annex II and III.

Production process, AQL, packing, packaging, storage
CPH face mask **production** is done by certified CE machinery with the capacity to produce approximately 50.000 face mask on a daily shift of 8 hours.

The machine is divided into three parts where one holds, calibrates the non-wowen fabric rolls and feed the three different layers of non-woven into the folding and cut unit. Hereafter the ear loop are welded on the unit by ultra sound and the finished face masks are packed into boxes directly from the packing table.



During production, one face mask out of every 200 pieces are taken out for control and a physical check is performed on the strength of the ear loops, and the nose bar is checked for placement and flexibility. This is done according to the **AQL** 1.5 standard.

When the face mask are finished and packed, they are also checked as a security measure according to the AQL 1.5 standard.

AQL stands for "Acceptable Quality Level" and refers to an internationally applied quality standard for measuring the percentage of defects in the face masks produced.

- The testing process includes checking batches of face mask during and after production to see the quality.
- The most common AQL values in Denmark and Europe are between 1.5 and 4.0
- The lower the AQL number, the less chance of defects.
- An AQL of 1.5 means that the face mask is significantly less likely to have critical defects than face mask that just meet the 4.0 AQL standard.
- AQL example:

Table A

SAMPLE SIZE CODE LETTERS							
	General Inspection Levels			Special Inspection Levels			
Lot Size	I	II	III	S1	S2	S3	S4
2 to 8	A	A	B	A	A	A	A
9 to 15	A	B	C	A	A	A	A
16 to 25	B	C	D	A	A	B	B
26 to 50	C	D	E	A	B	B	C
51 to 90	C	E	F	B	B	C	C
91 to 150	D	F	G	B	B	C	D
151 to 280	E	G	H	B	C	D	E
281 to 500	F	H	J	C	C	D	E
501 to 1200	G	J	K	C	C	E	F
1201 to 3200	H	K	L	C	D	E	G
3201 to 10000	J	L	M	C	D	F	G
10001 to 35000	K	M	N	D	D	F	H
35001 to 150000	L	N	P	D	E	G	J
150001 to 500000	M	P	Q	D	E	H	K
500001 and over	N	Q	R	D	E	H	K

ANSI/ASQ Standard Z1.4 - 2008

Table B

SINGLE SAMPLING PLANS FOR NORMAL INSPECTION

Sample Size Code Letter	Sample Size	Acceptable Quality Levels (Normal Inspection)																							
		0.065		0.10		0.15		0.25		0.40		0.65		1.0		1.5		2.5		4.0		6.5	
		Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
A	2																			↓		↓	
B	3																	↓		0	↑	0	1
C	5															↓		0	1				
D	8															0	1	↑		↓		1	2
E	13													↓		↑		↓		1	2	2	3
F	20											↓		0	1			1	2	2	3	3	4
G	32									↓		0	1	↑		1	2	2	3	3	4	5	6
H	50							↓		0	1	↑		1	2	2	3	3	4	5	6	7	8
J	80					↓		0	1	↑		1	2	2	3	3	4	5	6	7	8	10	11
K	125			↓		0	1	↑		1	2	2	3	3	4	5	6	7	8	10	11	14	15
L	200	↓		0	1	↑		1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22
M	315	0	1	↑		1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	↑	
N	500	↓		1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	↑			
P	800	1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	↑					
Q	1250	2	3	3	4	5	6	7	8	10	11	14	15	21	22	↑							
R	2000	3	4	5	6	7	8	10	11	14	15	21	22	↑									

The packing of the face mask is done daily by the packers wearing face masks, nitrile gloves and hair nets to ensure that the CFU level is within the EN 14683:2019 + AC:2019 specifications. The face mask is packed in boxes of 50 pieces. The boxes are then affixed with the LOT number, as well as the date of production and other markings required by the regulations. After this the boxes are packed in export boxes- 50 pcs per box / 30 boxes per. export carton / 20 export cartons per pallet.

All packaging is done in FSC sustainable cardboard

To make sure that storage of the face mask in boxes is done correctly the face mask boxes have printed storage instructions:

- Store dry at room temperature and no direct sunlight.
- Shelf life in unopened boxes is 5 years.
- Disposal of packaging -reuse or incinerate

Specification of the face mask, raw material and quality control

The face mask is intended to protect the user against bacteria and virus, especially from the COVID 19 virus. The face mask has the following specifications:

- TYPE IIR
- Level of CFU – (CFU/g) ≤ 30

- Breathability - (PA/Cm2) < 60
- Splash resistance – (kPa) ≥ 16,0
  Bacterial filtration level (BFE) (%) ≥ 98
- Trade name: CPH face mask 001 adult size
- Basic UDI-DI as per Part C of Annex VI

The following five raw materials are used to produce the face mask:

- Outer layer non-woven 25 gr. Polypropylene from Hunan Xinlong Nonwovens Materiale Co., Ltd.
- Non-woven melt blown 25 gr. B-25 polypropylene from Tongxiang Dino Textile Co. Ltd.
- Inner layer er non-woven 25 gr. Polypropylene from Hunan Xinlong Nonwovens Materiale Co., Ltd.
- Nose bar TA-PMS01 iron core without nickel Polyolefin Polymer to cover the iron core is produced by TeachAdhension System Ltd.
- Ear loop: polyamide 6 fibre og 9-140D Polyeruthane fibre from Jianusu Shuanliang Spandex Co.

Quality control is performed in several stages of the production:

- As Asthma Allergy Denmark certified, we have to use the same materials from a single supplier when we produce face masks. Therefore, non-wovens and other raw materials are approved by our office in China before being sent to Denmark.
- When the raw materials arrive at our warehouse batch, they are numbered and stocked with batch numbers so that we can identify each individual batch during and after production.
- On arrival at warehouse, all raw materials are registered and assigned a batch number that has direct reference to the supplier invoice.
- The raw materials are always divided into the received batch numbers - and these numbers are used from each part of raw material to form a later LOT number of the finished face mask.
- From the raw material warehouse, the raw materials are individually brought into production as needed

(picture from CPH warehouse)

The post-market surveillance system, documentation
The technical documentation on our post-market surveillance (PMS) to been drawn up in accordance with Articles 83 to 85.

CPH as manufacture will keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market (Article 10(8)).

Tu ensure availability of documentation in case of request by the CA, CPH will provide the required technical documentation in an official Union language determined by the Member State concerned (Article 10(14)). In this case in English.

d) Notified Body involvement

CPH as a manufacture of Class I medical confirms that a NB involvement is not necessary since our face mask devices in not placed on the market in sterile condition, having a measuring function or being reusable surgical instruments.

5) EU Declaration of Conformity

CHP has draw-up the EU declaration of conformity for our company, as referred to in Article 19, as we fulfil the obligations imposed by Article 52(7), and we declare that the face mask concerned fulfil the requirements of the MDR which apply to them. Enclosed in the Appendix.

We will continuously update the EU declaration of conformity and will translate it into any official union language or languages required by Member States in which the face mask is made available.

6) CE marking

CPH has affixed in a visible, legible and indelible form the CE marking on the packing of the face mask and the CE marking also appear on the instructions for use.

The CE marking format is in compliance with Annex V.

7) Eudamed, SRN and UDI-DI

CPH as a manufacturer of a Class I medical device has registered our face mask in Eudamed under the registration nr.:

IM0020993268

CPH has been validated in Eudamed and we have obtained the SRN from said electronic system

We will use the SRN when applying to a NB for conformity assessment and for accessing Eudamed in

order to fulfil its obligations under Article 29. Moreover it is available for our customers.
CPH registration in the Eudamed system also includes the UDI-DI as defined in Part C of Annex VI (in accordance with the rules of the issuing entity referred to in Article 27):

- SRN: DK-MF-000017573
- UDI-DI: 57000022462Mundbind3Q

We have done the necessary registration in Eudamed, SRN, UDI-DI and we have a confirmation from GS1 and the Danish health authority that the marking on product packing is due from May 2025.

CPH notes and is aware of the following:
The Unique Device Identification system will allow the identification and facilitate the traceability of devices (as referred on Article 27).

The Basic UDI-DI as defined in Part C of Annex VI is the primary identifier of a device model. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.

For Class I devices placed on the market according to MDD, after the date of application of MDR manufacturers will have in consideration the guidance documents applicable to legacy devices timelines and registration in Eudamed.

9) Post market surveillance (PMS)

CPH is aware that after placing the Class I device on the market, a post market surveillance (PMS) has to be carried out to make sure that we are observant to new rules and regulations and to the market.

a) Experience from our Post-Market Surveillance

We as a manufacturer have put in place the required post market surveillance (PMS) system and actively keep this PMS up to date in accordance with Article 83 of MDR.

This system is a part of our QMS and be supported by the CPH PMS plan.

A PMS report will be prepared according to Article 85 every year – first time Janaury 2022, summary-zing the results and conclusions of the analysis of all of the data from the market. The report can be requested by the CA at any time.

b) Vigilance

We as manufacturer is responsible for reporting all serious incidents and field safety corrective actions (FSCA) to the relevant CAs, according to Article 87 (1) of the MDR.

In case of a serious incident, we are obliged to make investigations, according to Article 89, which will include a risk assessment of the incident.

We will involve the distributors of our face mask and, where applicable, the authorized representative and importers in the system, in order to obtain the information needed from the market to ensure that required actions are followed and completed in a timely manner.

Serious incidents and FSCAs will be submitted via this electronic Eudamed system only.

We will report any serious incident immediately after they have established the casual relationship between that incident and our face mask or that such a causal relationship is reasonably possible.

The timeframe to report serious incidents will not exceed the following upper limits:

- In the event of a serious public health threat, a report will be submitted not later than 2 days after becoming aware of the threat. (Article 87 (4))
- In the event of death or an unanticipated deterioration in a person's state of health a report will be submitted not later than 10 days after becoming aware of the serious incident. (Article 87(5))
- In all other cases not later than 15 days after becoming aware of the serious incident (Article 87 (3))

Where necessary to ensure timely reporting of serious incidents, we will submit an initial report that is incomplete followed up by a complete report. If, after becoming aware of a potentially reportable incident. Serious incidents will be reported only to the competent authority of the country in which the serious incident occurred via Eudamed.

We as a manufacturer will provide a final report to that competent authority via Eudamed setting out its findings from the investigation. The report will set out conclusions and - where relevant - indicate corrective actions to be taken.

We are aware of if a competent authority notifies us of a suspected serious incident, we are obliged to:

- submit a report of this serious incident to the notifying competent authority via Eudamed within the timeframes described above;
- submit an explanatory statement, to the competent authority, if the we believes the suspected serious incident does not fulfil the reporting criteria.

In all other cases CPH will follow the MDR rules regarding informing the Eudamed system.

As part of the procedure, CPH has introduced follow-up on products that have been marketed and / or delivered to the market.

As a follow-up on deliveries, CPH follows up with calls and emails asking customers about their experiences with delivered products.

Questions asked to customers:

- Product brand
- LOT number - production and expiration date
- Whether the customer has experienced any deviations from the product's ability

- Has the customer experienced incidents such as nuisances, allergies, other incidents that have bothered the customer
- How satisfied the customer is with the product on a scale of 1-10.

- If the customers are satisfied and have nothing to report, this is noted by CPH and the customer is followed up every month thereafter until the expiry date of the product.
- If the customer reports any deviations or incidents, these are registered by CPH and it is registered on LOT numbers, suppliers, invoices.
- If the deviations or incidents are of a minor degree, they are not reported to the Danish Medicines Agency, but are handled between the customer and CPH.
- In addition, CPH informs the supplier of the deviation or incident and the supplier must then confirm that it is corrected in production in the future.
- If the incident is such that it is necessary to involve the Danish NB, this is done in writing and with documentation of the deviation / incident.
- After this, the supplier becomes involved and must confirm and approve that the production is improved and new guidelines are implemented. If compensation or replacement production is required of the product in question, this replacement is sought from the supplier.

It is the Customer Service Department in CPH that provides calls / email correspondence to customers. The Procurement / Production department at CPH is responsible for communication with the supplier and produces the necessary information in connection with any deviations / incidents.

c) Non-conforming products

If we as a manufacturer have reasons to believe that a medical device which we have placed on the market or put into service is not in conformity with the MDR we will immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate.

We will inform the distributors of the device in question and, if applicable, the authorized representative and importers.

10) APPENDIX

Test Report

Report no.: 956936-01

DANISH
TECHNOLOGICAL
INSTITUTE

Gregersensvej
DK-2630 Taastrup
+45 72 20 20 00
Info@teknologisk.dk
www.teknologisk.dk

Customer: CPH Global Medical ApS
Holmetoften 14-16
2970 Hørsholm

Samples: One kind of medical face masks; CPH Medical, Medical face mask Model: CPH medical Type IIR 17.5 x 9.6 cm (see page 2)

Sampling: 5 masks of one lot, measurement on five areas on each mask. The samples have been received here on 27 November 2020

Period: The testing has been carried out on 8 December 2020

Procedure: Method for determination of breathability (differential pressure) DS/EN 14683:2019+AC:2019

Result: The masks pass the requirement for type IIR. The requirement is ΔP less than 60 Pa/cm² at 8 L/min for type IIR. For 0 out of 5 tested masks, the averages of five measurements on a mask is over the limit.

The standard requires an AQL of 4 %, with 5 samples the product pass if 0 are over the limit. If 1 or more are over the limit they fail.

	Pressure ΔP	Pressure / area ΔP/area
	Pa	Pa/cm²
Average	281	57
Std Dev.	11.6	2.4

	Type IIR Limit
	<60 Pa/cm²
FAIL	0
PASS	5

Storage: According to the general terms and conditions of The Danish Technological Institute

Conditions: The test has been performed according to the conditions laid down by DANAK (The Danish Accreditation), cf. www.danak.dk, and the general terms and conditions of The Danish Technological Institute. This test report may be reproduced in extract only if the Laboratory has approved the extract in writing.

Place: Danish Technological Institute, Taastrup, Plastics and Packaging Technology

Signature:

Jakob S. Engbæk
Senior specialist

Mobile: +45 72 20 24 85
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Section Leader

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ilac-MRA DANAK
Test Reg. no. 300

Test

Measurement of differential pressure over mask with a flow of 8 L/min over an area of 4.9 cm^2 (a circle 25 mm in diameter). Performance requirement for type I and type II is < 40 Pa/cm^2 and for type IIR < 60 Pa/cm^2 in DS/EN 14683:2019+AC:2019.

Test methods

Following the standard: Method for determination of breathability (differential pressure) DS/EN 14683:2019+AC:2019. In annex C of this standard there is a figure (C.1) showing the setup. Air is sucked through the section for the mask with a pump, flow is controlled with a mass flow controller. The mask is held between two metal rings with a centre hole 25 mm in diameter. A differential pressure meter is used to measure the differential pressure and a flow meter is used to monitor the flow into the setup. During testing, the setup is clamped. The differential pressure meter and the flow meter have been calibrated by an external laboratory.

All the tested masks have a uniform surface. Measurements are conducted on five areas on each mask.

The masks were in a box with 84.1 %RH and 22.4 °C prior to tests. The tests were performed in a room with 50 % RH and 23 °C. One mask at a time is taken from the box to the test setup.

Samples

Medical facial masks, from CPH Global Medical ApS , marked "Medical face mask Model: CPH medical Type IIR 17.5 x 9.6 cm "

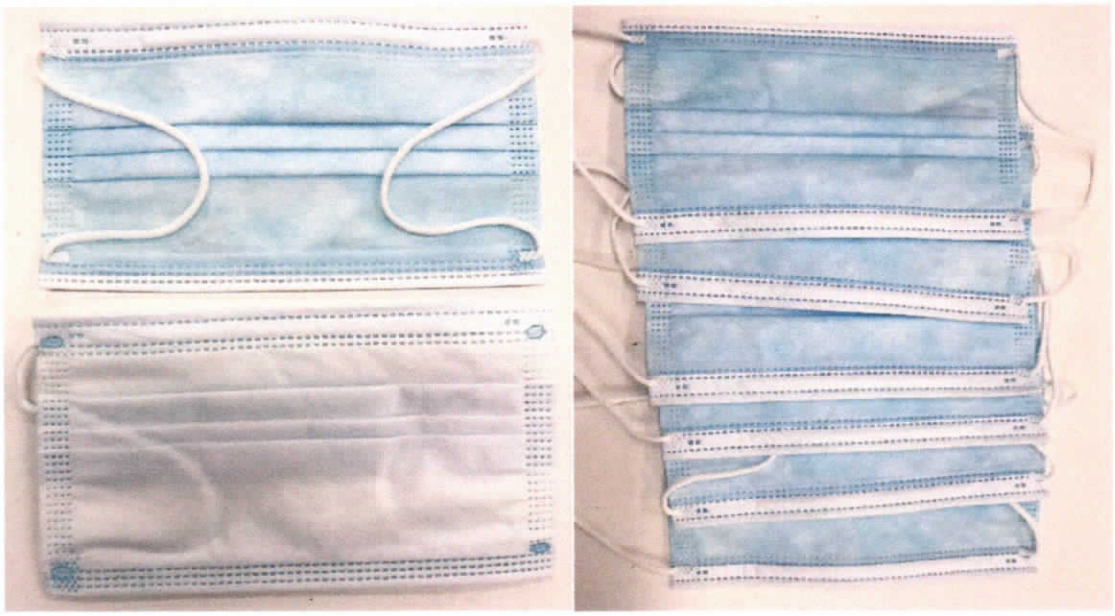

Figure 1, Picture of two masks and 6 samples where we see similar stitching and color. Masks are unfolded for test.

Equipment

Differential pressure meter: DP measurement Buckingham, marked DPM1 (ID: 187390), calibrated 23 November 2020. Brooks mass flow meters, with controller unit. Two vacuum pumps, Vacuubrand ME1. Mesalab defender 520H flow calibration unit, calibrated 4 December 2020, (ID: 187863). Sample holder and setup according to DS/EN 14683:2019+AC:2019.

Test results

All the results are shown in the enclosure, a summary is shown in the table below.

	Pressure ΔP	Pressure / area ΔP/area
	Pa	Pa/cm²
Average	281	57
Std Dev.	11.6	2.4

	Type IIR Limit
	<60 Pa/cm²
FAIL	0
PASS	5

Table 1. Summary of results, differential pressure measured over 4.9 cm² at a flow of 8 L/min of air, number of masks that pass and fail.

Table with all measurements:

Medical face mask Model: CPH medical Type IIR 17.5 x 9.6 cm						
Sample	Position	Air flow	Pressure ΔP	Average pressure	Pressure per area ΔP/area	
Units:		L/min	Pa	Pa	Pa/cm^2	
1	1	8.06	299.8			
1	2	8.06	279.3			
1	3	8.06	282.4			
1	4	8.07	276.3			
1	5	8.06	307.0	289	59.0	PASS
2	1	8.07	303.9			
2	2	8.07	272.2			
2	3	8.06	277.3			
2	4	8.06	271.1			
2	5	8.07	289.6	283	57.7	PASS
3	1	8.07	269.1			
3	2	8.06	259.9			
3	3	8.06	258.9			
3	4	8.07	234.3			
3	5	8.06	270.1	258	52.7	PASS
4	1	8.06	289.6			
4	2	8.06	286.5			
4	3	8.07	269.1			
4	4	8.06	273.2			
4	5	8.07	290.6	282	57.5	PASS
5	1	8.06	308.0			
5	2	8.07	296.7			
5	3	8.06	272.2			
5	4	8.06	265.0			
5	5	8.05	312.1	291	59.3	PASS
Average		8.06	280.6	280.6	57.3	
Std. Dev.		0.01	17.76	11.58	2.36	
Max		8.1	312.1	290.8	59.3	

Table 2. Measurements on all masks. 5 places on each mask

Aim

The aim is to test usability of protective medical face masks Type IIR

Samples

The masks were from CPH Medical, Lot 20201119YH. A photo of a box is shown below (Figure 1).

Figure 1 The box of the masks

Enclosure:

Analysis report, revision 1

REPORT NUMBER:
15007, rev. 1

DANISH
TECHNOLOGICAL
INSTITUTE

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DMRI@teknologisk.dk
www.DMRI.com

Init: MAJO/MT/AGLK
Proj. no.: 2004214
Encl.: 1

Client:
Company: CPH Global Medical ApS
Address: Holmetoften 16
Town: DK-2970 Hørsholm

Item: 5 face masks, CPH Medical – Lot no. 20201119YH.

Sampling: Sampling took place at the microbiological laboratory DMRI on 12 January 2021.

Period: The analyses were made from 12 to 20 January 2021.

Method:
5 Bioburden SM 113, according to DS/EN ISO 11737-1:2018 ("Sterilization of health care products – Microbiological methods") and DS/EN 14683:2019+AC:2019 ("Medical face masks – Requirements and test methods").

Stomaching has been used as an extraction method.

The following substrates have been used to grow the filtered samples:
Tryptone Soya Agar (TSA) at 30°C for 3 days (aerobic bacteria).
Sabouraud Dextrose agar (SDA) 20°C for 7 days under aerobic conditions (yeast and mould).

Result: The results from the analysis are shown in enclosure 1.
The samples as well as the results are registered in LIMS under request id 2-21-00007.

Remarks: Five masks were analysed. Two boxes were received, and two and three masks, respectively, were analysed from the two boxes.

The line containing the text "Contact: Kenneth Berntsen" has now been deleted.

This analysis report replaces analysis report no. 15007 of 21 January 2021.

Terms: This analysis was conducted accredited in accordance with international requirements (ISO/IEC 17025:2017) and in accordance with the General Terms and Conditions of Danish Technological Institute. The analysis results solely apply to the tested item. This analysis report may be quoted in extract only if Danish Technological Institute has granted its written consent. The customer may not mention or refer to Danish Technological Institute or Danish Technological Institute's employees for advertising or marketing purposes unless Danish Technological Institute has granted its written consent in each case.

Place: 22 January 2021, Danish Technological Institute, DMRI, microbiological lab

Signature:
Anette Granly Koch
Product manager

ilac-MRA DANAK TEST Reg nr. 302

Enclosure 1

CPH Medical – Lot no. 20201119YH

Sample ID	CFU on TSA (cfu/g)	CFU on SDA (cfu/g)	Total CFU per mask (cfu/g)	Requirements	Evaluation (accepted/not accepted)
2-21-00007-001	<1	<1	<1	According to DS/EN ISO 11737-1:2018, the microbial purity of masks must be ≤30 cfu/g	accepted
2-21-00007-002	5.0	<1	5.0		accepted
2-21-00007-003	<1	<1	<1		accepted
2-21-00007-004	<1	<1	<1		accepted
2-21-00007-005	1.0	<1	1.0		accepted

TSA: Tryptone Soya Agar (TSA) at 30°C for 3 days (aerobic bacteria).

SDA: Sabouraud Dextrose agar (SDA) (yeast and mould).

TEST REPORT N° 6_04/12/20

Issue date *04/12/2020*

Esteemed Company
Danish Technological Institute
Gregersensvej, 1
00000 Taastrup DK-2630 (-)

Sample type	Materials
Sample received on	30/11/2020
Sample description	Medical Mask - CPH Medical [1]
Sampling site	Sampling performed at the Customer's premises
Sampler	Client
Sampling method	Internal to the Client**
Sample pack	Sample packed in plastic bag
Sample Condition / Seals	Sample delivered in a manner and quantity suitable for carrying out the required analytical investigations.
Transport by	Courier service
Temperature	---

Sample Protocol 15_301120 del 30/11/20

Description Medical Mask - CPH Medical

				UNI EN 14683:2019 Table1		
Testing *Start date - End date*	**Result**	**U.M**	**Method**	**I**	**II**	**IIR**
Bacterial Filtration	99,6	%	EN 14683:2019/AC 2019 App B	≥95	≥98	≥98
Efficiency *01/12/2020 - 03/12/2020*						
Negative Control	0					
1) Positive Control	1864	UFC				
2) Positive Control	1971	UFC				
1) BFE	99,8	%		≥95	≥98	≥98
2) BFE	99,6	%		≥95	≥98	≥98
3) BFE	99,7	%		≥95	≥98	≥98
4) BFE	99,8	%		≥95	≥98	≥98
5) BFE	99,7	%		≥95	≥98	≥98

Additional information

The analytical determinations were performed on 5 specimens, cut from complete masks / original fabric that makes up the mask.
Each sample is 100mm × 100mm in size and includes all mask layers in the order they are inserted into the full mask.
Each sample is conditioned at (21 ± 5) ° C and (85 ± 5)% relative humidity for at least 4 hours.
The test is performed with the inside of the mask in contact whit the bacterial suspension.
The test area has a size of 49 cm².
The flow rate during the test is equal to 28.3 l/min.

The final test value is the lowest BFE result found in the tests performed.

(**) Sampling not subject to ACCREDIA accreditation

(1) Information provided by the customer, the laboratory declines all responsibility.

Direttore Tecnico Dott. Giuseppe Mazza – Iscritto all'Ordine dei Chimici della Campania n. 1147
Artea Srl Via Piana Sn 82030 Ponte Bn - Tel/Fax 0824 874 510 - e-mail: info @arteasrl.eu - pec: arteasrl @registerpec.it
Sito internet: www. arteasrl.eu Capitale sociale € 25000,00 i.v. - P. IVA e CF 01401230626

FOLLOWS TEST REPORT N° 6_04/12/20

Issue date *04/12/2020*

Legislative notes

(14683en) = EN 14683: 2019 Facial masks for medical use - Requirements and test methods - Table 1 "Performance requirements for masks for medical use".

I = Type I medical face mask
II = Type II medical face mask
IIR = Type IIR medical face mask

Declaration of Conformity

For the parameters analyzed, according to the EN 14683: 2019 Table 1 standard, the sample complies with the performance characteristics envisaged for TYPE II medical masks.

The results contained in this Report refer exclusively to the sample as received in the laboratory

The results refer to the tested sample only and do not imply a lot or whole lot approval; if the Customer is responsible for the Sampling phase, the results refer to the sample as received. The Laboratory declines all responsibility for the calculated results considering the sampling data provided by the Customer.

The samples are kept in this laboratory until the completion of the tests, excluding the official samples.

The uncertainties associated with the test results were calculated with a coverage factor k = 2 equal to a confidence level of 95%.
In the event that a declaration of conformity is formulated, for the purposes of the acceptability of the analytical data with respect to a limit value / guide value, the estimated uncertainty and / or estimated confidence interval is not taken into account.

It is absolutely forbidden to modify even partially the data contained.

U.M =Unit of measure LOQ =Quantification limit Ref.=Normative reference PP=Internal method (Test procedure)

---------- ***End of the test report*** ----------

Technical Director
Dott. Giuseppe Mazza

Document digitally signed by Dr. Giuseppe Mazza - Order of Chemists of Campania N.1147

Direttore Tecnico Dott. Giuseppe Mazza – Iscritto all'Ordine dei Chimici della Campania n. 1147
Artea Srl Via Piana Sn 82030 Ponte Bn - Tel/Fax 0824 874 510 - e-mail: info @arteasrl.eu - pec: arteasrl @registerpec.it
Sito internet: www. arteasrl.eu Capitale sociale € 25000,00 i.v. - P. IVA e CF 01401230626

Test report

REPORT NUMBER:
956936

DANISH
TECHNOLOGICAL
INSTITUTE

Gregersensvej
DK-2630 Taastrup
Telephone +45 72 20 20 00

info@teknologisk.dk
www.teknologisk.dk

Client:	CPH Global Medical ApS Holmetoften 16 2970 Hørsholm Denmark
Subject:	Facial masks CPH Medical, Type II R, (see page 2)
Sampling:	50 masks have been received here on 27 November 2020, 32 of the masks were tested.
Test Period:	The testing has been carried out on 9 December 2020
Test requirements:	Clothing for projection against infectious agents- medical face masks -Test method for resistance against penetration by synthetic blood (fixed volume horizontally projected) ISO 22609:2004(E) according to criteria in EN14683, Due to availability the synthetic blood used PVA as thickener not acrysol G 110.
Test performed by:	Senior Consultant Søren Bastholm Vendelbo
Results:	The masks passed the test
Remarks:	No remarks
Terms:	The test has been performed according to the conditions laid down by DANAK (The Danish Accreditation), cf. www.danak.dk, and the general terms and conditions of The Danish Technological Institute. This test report may be reproduced in extract only if the Laboratory has approved the extract in writing.
Test place:	Technological Institute, Plastics and Packaging Technology, Taastrup
Signature:	

Søren Bastholm Vendelbo
Senior Consultant

Mobile: +45 72 20 16 24
Mail: sbv@dti.dk

Test responsible, signatory

Jens Christiansen
Section Leader

Mobile: +45 72 20 24 98
Mail: jec@dti.dk

Co-reader

ilac-MRA DANAK
Test Reg. no. 300

Aim
The aim of this test is to measure the splash resistance of protective medical face masks.

Samples
Medical facial masks with ear loops type IIR. The mask was from CPH Medical. A picture of the mask is shown in Fig. 1. Fig 2 shows the packaging with lot-number.

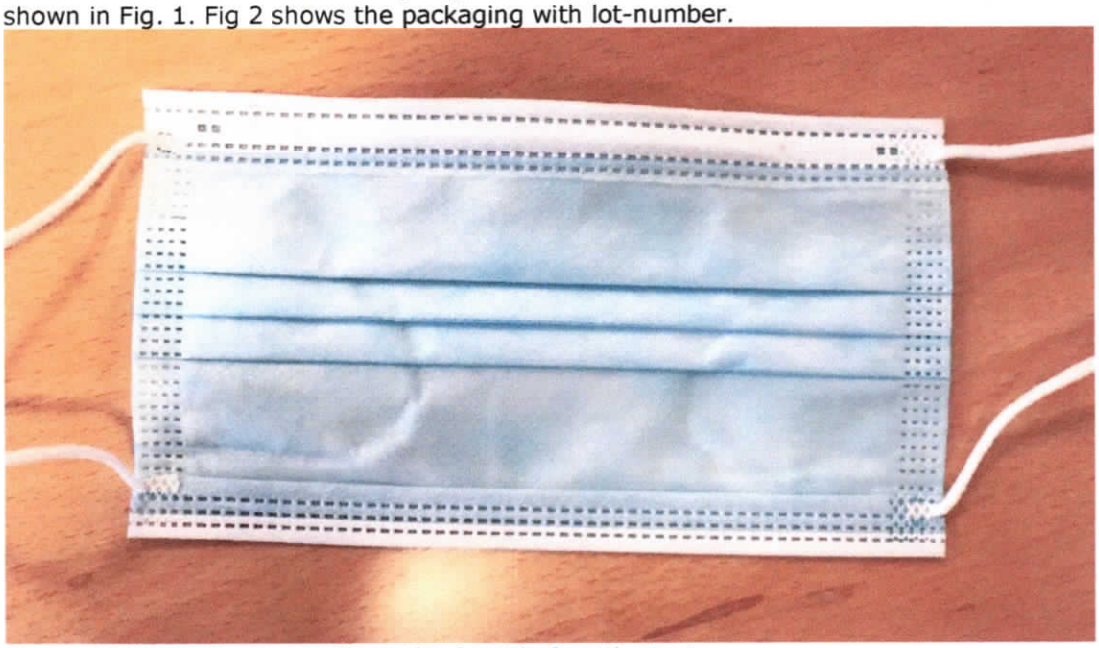

Figure 1 The mask as seen from the front before the test.

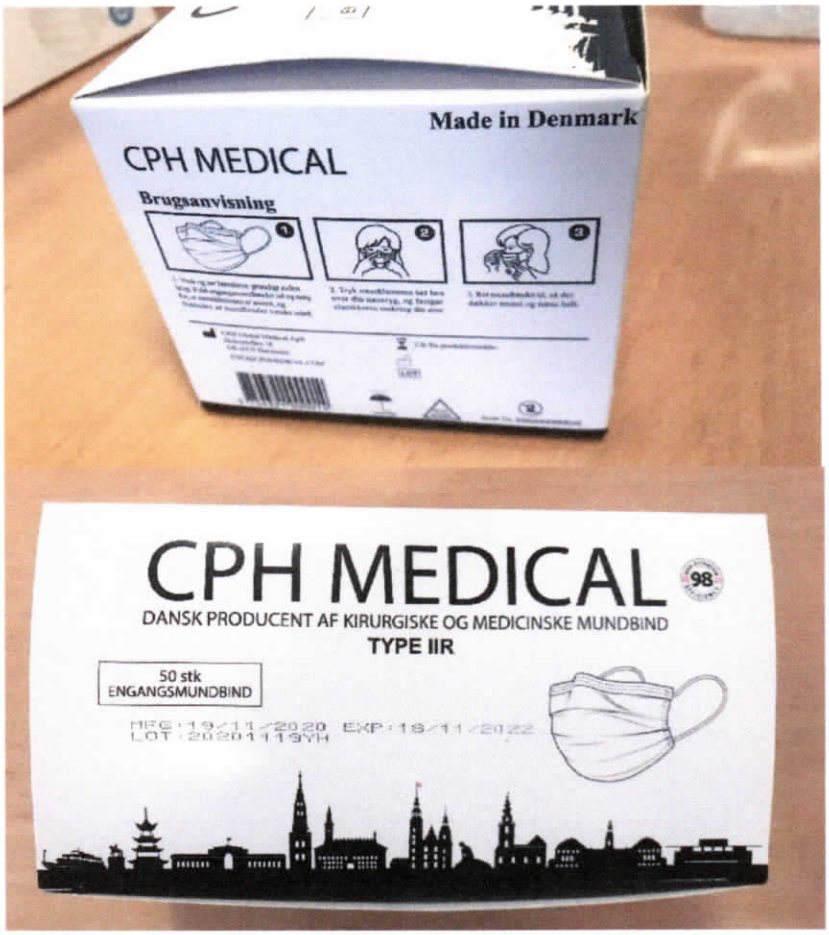

Figure 2 Pictures of the packaging, showing the Lot-number.

Test-setup and Equipment
A setup capable of affixing a mask, with pleats unfolded, was made using a convex geometry and an elastic cuff to hold the mask firmly in place. The pressure was provided using compressed air with a pressure range of 1 to 1.8 Bar. The pressure was fed to a bottle with a dip tube which ended in a magnetic valve (Bürkert 6013A). The valve was activated using a relay controlled by Labview.
At the end of the valve was a cannula with an inner diameter of 0.84 mm. The distance between mask and tip of cannula was kept at 30 ± 1 cm. The setup showed consistency of delivering the same sample volume at opening times of 0.40 s and 0.80 within 2%.

Synthetic blood
Synthetic blood was mixed with inspiration from Annex B in ISO22609. The synthetic blood is made of 40 g PVA (as thickener) and 6.052 g Direct Red 81 (dye). This was mixed in 1000 ml deionized water. Then it was stirred on a magnetic stirrer for at least 1 hour. The solution was then vacuum filtered to remove any particles and reduce clogging in the system. The surface tension was determined to be 43.2± 0.7 mN/m, with a Sigma Force Tensiometer 702. This is within a value of 42 ± 2 mN/m described in the standard. The density was determined to be 1.004 g/cm^3.

Test methods
The test was carried out in accordance with: "Clothing for projection against infectious agents- medical face masks -Test method for resistance against penetration by synthetic blood (fixed volume horizontally projected)" ISO 22609:2004(E). According to criteria in EN14683 requiring a valve time of 0.66 s yielding a velocity of 550 cm/s. The optional target plate described in 22609 was not used in these measurements.

The mask was pre-conditioning at 85% humidity at 23 °C for minimum 4 hours. The test was carried out within 60 seconds of removing the mask from the climate chamber. The room temperature was 23 °C with a humidity of 50%. Before use, the setup was flushed with water, and a new cannula was installed.

The valve time for this measurement was then set to 0.66 s. Then the pressure of the reservoir bottles was adjusted so the amount of synthetic blood leaving the cannula was 2.01 g, giving a volume of 2 ml. The applied reservoir pressure was 1.49 bar. When 2 ml fluids exit an orifice with a diameter of 0.084 cm in 0.66 s, the corresponding average velocity is 550 cm/s, which corresponds to a blood pressure of 16 kPa. This flowrate was tested, and confirmed to be within accuracy, more than each 16th measurement.

A mask is considered failed if the synthetic blood is present on the back side after the squirt. As the synthetic blood is clearly visible on the back side, only a visual identification is carried out. The squirt is aimed at the centre of the face mask, when the squirt was done, the mask was tested for penetration within 10 ± 1 s.

Test results
Table 1 consists of the measurements performed, Fig. 3 and Fig. 4 show the front and backside of a mask after the test – see enclosure 1.

Table 1, results of each measurement

Mask	CPH Medical	
	passed	failed
mask 1	X	
mask 2	X	
mask 3	X	
mask 4	X	
mask 5	X	
mask 6	X	
mask 7	X	
mask 8	X	
mask 9	X	
mask 10	X	
mask 11	X	
mask 12	X	
mask 13	X	
mask 14	X	
mask 15		X
mask 16		X
mask 17	X	
mask 18	X	
mask 19	X	
mask 20	X	
mask 21	X	
mask 22	X	
mask 23	X	
mask 24	X	
mask 25	X	
mask 26		X
mask 27	X	
mask 28	X	
mask 29	X	
mask 30	X	
mask 31	X	
mask 32	X	

3 out of 32 masks failed. At valve times of 0.66 s and velocities of 550 cm/s. Hence, an acceptable quality limit of 4% can be met, and the samples have passed.

Figure 3 Front side of a mask after the test

Figure 4 Back side of a mask after the test. The penetration is clearly visible as a red spot

CPH Global Medical ApS Biocompatibility Support

Biological Evaluation Report

Disposable Medical Mask Type IIR

CPH Global Medical ApS

Report

March 2021

This report has been prepared under the DHI Business Management System certified by Bureau Veritas to comply with ISO 9001 (Quality Management)

Approved by

Dorthe Nørgaard Andersen
Head of Projects
Environment and Toxicology

CPH Global Medical ApS Biocompatibility Support

Biological Evaluation Report

Disposable Medical Mask Type IIR

Prepared for CPH Global Medical ApS

Project manager	Astrid Skovmand, PhD, Toxicologist
Quality supervisor	Poul Bo Larsen MSc, Principal Toxicologist

Project number	11826128
Approval date	1 March 2021
Revision	Final
Classification	**Confidential:** This document is only accessible to the project team members and sharing it outside the project team is subject to the client's prior approval.

CONTENTS

FIGURES

TABLES

APPENDICES

ABBREVIATIONS

BBP	Benzyl butyl phthalate
DBP	Dibutuyl Phthalate
DEHP	Bis-(2-ethyl hexyl)-phthalate
DIBP	Diisobutyl phthalate
FDA	Food and Drug Administration
MDD	Medical device directive
MDR	Medical device regulation
PBBs	Polybrominated biphenyls
PBDEs	Polybrominated diphenyl ethers
PE	Polyethylene
PP	Polypropylene
SMS	spunbond/melt blown/spunbond
WHO	World Health Organization

1 Executive Summary

The purpose of this biological evaluation is to examine and document the biocompatibility and toxicological safety of the disposable medical mask type IIR manufactured by CPH Global Medical ApS in accordance with the requirements laid out in harmonized standard *ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,* and the updated version of this standard *ISO 10993-1:2018*, as well as other relevant parts of the ISO 10993-series. In addition, the evaluation is conducted to comply with requirements for the use of ISO 10993-1 described in US FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* (2020).

According to the definition and classifications described in ISO 10993-1:2009 and 2018, the masks are surface contacting medical devices with permanent contact (> 30 days) to intact skin. The categorisation is based on the cumulative use under current COVID-19 requirements on the use of masks to prevent the spread of the virus SARS-CoV-2. The following endpoints should be considered according to the categorisation given:

- Physical/chemical information
- Cytotoxicity
- Sensitisation
- Irritation or intracutaneous reactivity

The fabric material used for the manufacturing of the masks is polypropylene (PP) SMS fabric in blue and white; the metal nose strip is made of a single iron core coated with PP; and the ear loops are made of polyamide material.

The masks, in their final form, have been tested for cytotoxicity, skin irritation and skin sensitisation. The masks were shown to be non-cytotoxic, non-sensitising, and non-irritating.

Based on the available material characterisation information and biological test data it can be concluded that the materials used for the masks are safe with regards to the relevant endpoints determined by the ISO 10993 categorisation i.e., cytotoxicity, irritation and skin sensitisation. Thus, the masks are biocompatible according to their intended use.

2 Introduction

The intended use of a disposable medical face mask is to cover the mouth and nose in order to provide a barrier that minimizes the direct transmission of infective agents between hospital staff and patients; and in certain circumstances to protect the wearer against splashes of potentially contaminated liquids. Medical masks may also be intended to be worn by the general public to reduce the risk of spread of infections in an epidemic or pandemic situation (EN14683:2019 2019).

Medical masks are products falling within the scope of the EU legal framework on medical devices – Directive 93/42/EEC (MDD), to be replaced by Regulation (EU) 2017/745 (MDR) as of 26 May 2021 (Commission 2020).

3 Scope and methodology

The purpose of this report is to document the biocompatibility and toxicological safety of the disposable medical mask type IIR manufactured by CPH Global Medical ApS. This was performed in accordance with the requirements in harmonized standard *ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,* and the updated version of this standard *ISO 10993-1:2018*, as well as other relevant parts of the ISO 10993-series (see section 0, The scope of work included:

- Characterisation of the device including a description of the intended purpose, the device design, composition, and categorisation according to ISO 10993-1:2018.
- Identification of biological hazards or risks as aligned with the product risk assessment, and in accordance with the endpoints identified for evaluation in ISO 10993-1:2018 and FDA Guidance *Use of International Standard ISO 10993-1* (2020).
- Systematic review of existing data including:

  Information on material characterisation which cover the requirement in ISO 10993-18:2018, including physical and chemical information.

  Information on manufacturing, sterilisation, and shelf life.

  Existing nonclinical data, including previous biocompatibility testing and/or chemical analyses.

  Updated literature search, serving to evaluate the safety of the device.

  Toxicological exposure and risk assessment of critical substances or residuals, as relevant.
- Overall evaluation of the available data and documentation, including evaluation whether there are any data gaps, leading to a need to perform additional testing.
- Final biological risk assessment, including input for the product risk analysis.

- Conclusion.

The biological evaluation according to ISO 10993-1:2009 and 2018 is part of the risk management process according to *ISO 14971:2012 Medical Devices – Application of Risk Management to medical devices*. Any hazard or risk related to biocompatibility identified in the biological evaluation must be subject to risk assessment. Hence, the conclusion of the biological evaluation also provides input for the device specific product risk assessment.

The evaluation included gathering and reviewing relevant data, including information on materials, manufacturing, biological and chemical test data, and literature information that was relevant to cover toxicological and biological aspects of the risk assessment. The literature review was conducted in accordance with ISO 10993-1:2018 Annex C. The detailed description of the literature review and search log tables are described in Annex A of this report.

Requirements given in ISO 18562-1:2017*; Biocompatibility evaluation of breathing gas pathways in healthcare applications. Part 1: Evaluation and testing within a risk management process, are ***not*** considered relevant for face masks as this standard excludes biological evaluation of the surfaces of medical devices that are in direct contact with the patient as the requirements for direct contact surfaces are found in the ISO 10993 series.

*ISO 18562-1:2017 more specifically addresses medical devices such as : ventilators, anaesthesia workstations (including gas mixers), breathing systems, oxygen conserving equipment, oxygen concentrators, nebulizers, low-pressure hose assemblies, humidifiers, heat and moisture exchangers, respiratory gas monitors, respiration monitors, masks, mouth pieces, resuscitators, breathing tubes, breathing system filters and Y-pieces as well as any breathing accessories intended to be used with such medical devices.

List of Applied Standards). In addition, the evaluation was conducted to comply with requirements for the use of ISO 10993-1 described in US FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* (2020).

This evaluation does not include assessments regarding requirements for technical properties and functioning according to EN14683:2019 2019.

The scope of work included:

- Characterisation of the device including a description of the intended purpose, the device design, composition, and categorisation according to ISO 10993-1:2018.
- Identification of biological hazards or risks as aligned with the product risk assessment, and in accordance with the endpoints identified for evaluation in ISO 10993-1:2018 and FDA Guidance *Use of International Standard ISO 10993-1* (2020).
- Systematic review of existing data including:

  Information on material characterisation which cover the requirement in ISO 10993-18:2018, including physical and chemical information.

  Information on manufacturing, sterilisation, and shelf life.

  Existing nonclinical data, including previous biocompatibility testing and/or chemical analyses.

  Updated literature search, serving to evaluate the safety of the device.

  Toxicological exposure and risk assessment of critical substances or residuals, as relevant.
- Overall evaluation of the available data and documentation, including evaluation whether there are any data gaps, leading to a need to perform additional testing.
- Final biological risk assessment, including input for the product risk analysis.
- Conclusion.

The biological evaluation according to ISO 10993-1:2009 and 2018 is part of the risk management process according to *ISO 14971:2012 Medical Devices – Application of Risk Management to medical devices*. Any hazard or risk related to biocompatibility identified in the biological evaluation must be subject to risk assessment. Hence, the conclusion of the biological evaluation also provides input for the device specific product risk assessment.

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4 List of Applied Standards

ISO 10993-1 (2009). DS/EN ISO 10993-1:2009 Biological evaluation of medical devices, Part 1: Evaluation and testing within a risk management process

ISO 10993-1 (2018). DS/EN ISO 10993-1:2018 Biological evaluation of medical devices, Part 1: Evaluation and testing within a risk management process

ISO 10993-5 (2009). DS/EN ISO 10993-5:2009 Biological evaluation of medical devices, Part 5: Tests for in vitro cytotoxicity

ISO 10993-10 (2010). DS/EN ISO 10993-10 Biological evaluation of medical devices, Part 10: Tests for irritation and skin sensitization

ISO 10993-11 (2018). DS/EN ISO 10993-11:2018 Biological Evaluation of medical devices, Part 11: Tests for systemic toxicity

ISO 10993-17 (2009). DS/EN ISO 10993-17:2009 Biological evaluation of medical devices, Part 17: Establishment of allowable limits for leachable substances

ISO 10993-18 (2009). DS/EN ISO 10993-18:2009 Biological evaluation of medical devices, Part 18: Chemical characterization of materials

ISO 10993-18 (2020). DS/EN ISO 10993-18:2020 Biological Evaluation of medical devices, Part 18: Chemical characterization of medical device materials within a risk management process

ISO 14971 (2012). DS/EN ISO 14971:2012 Medical Devices – Application of Risk Management to medical devices

US FDA Guidance “Use of International Standard ISO 10993-1” (2020): U.S. Food and Drug Administration: Guidance for Industry and Food and Drug Administration Staff: “Use of International Standard ISO-10993, “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process”. Document issued September 2020

ISO/TS 21726:2019 Biological evaluation of medical devices — Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents

5 Characterization of device

5.1 Overall product description and intended use scenario

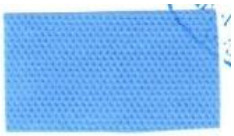
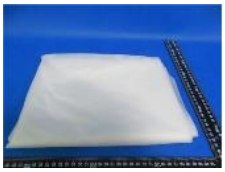
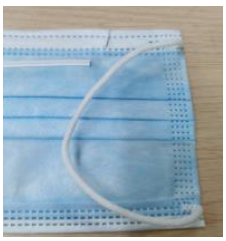
CPH Global Medical ApS is the manufacturer of the disposable medical face mask, hereinafter referred to as 'mask', product model no. CPH MED001 (Figure 1). The masks are classified as a medical device Class I (non-sterile) according to MDD 93/42/EEC and MDR(EU) 2017/746. As well as a medical mask type IIR (splash resistance) according to the harmonised standard DS/EN 14683:2019-AC:2019 (Medical 2020).

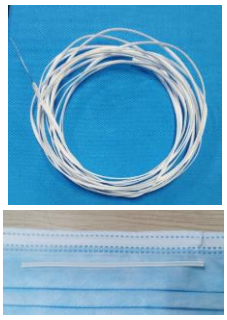
Medical masks are intended to be used by healthcare professionals, hospital staff, and patients as a means to reduce the spread of respiratory droplets produced by coughing or sneezing. However, under special conditions, such as the COVID-19 pandemic, the use of masks has been extended to the public. In Denmark, as well as other EU countries, wearing a face mask during the COVID-19 pandemic is obligatory on all public transport; in establishments selling food, drinks, or tobacco for consumption on-site; in retail shops, including supermarkets, shopping centres, department stores, etc; indoors premises for cultural, sports and recreational activities; indoors in churches or other places of worship; at institutions of learning; and in public and private hospitals and clinics.

The masks are manufactured with spunbond/melt blown/spunbond (SMS) fabric in blue and white. The mask is held in place to the user's face by round elastic ear loops and a metal nose bar. The mask components, function, and user contact are detailed in Table 1.

Figure 1 CPH Medical, disposable medical mask product no. CPH MED001

Table 1 Overview of the disposable medical mask components in scope for the biological evaluation

Component name	Illustration	Material and Dimensions	Short description of functionality	User contact
Fabric inner layer	 	SMS non-woven fabric in blue 17.5 x 9.6 cm	SMS fabrics have excellent physical properties and barrier qualities. Features include high tensile strength, softness, comfort, breathability, wearability, and is also lightweight. It acts as a water-repellent, and a barrier against bacteria, blood, and other liquids as well as gas/steam perspiration.	No direct user contact with SMS blue fabric
Fabric mid layer		Meltblown nonwoven fabric in white 17.5 x 9.6 cm		No direct user contact with mid layer of meltblown nonwoven fabric in white
Fabric outer layer	 	SMS non-woven fabric in white 17.5 x 9.6 cm		During use the white SMS fabric will be in contact with skin around the mouth, nose, and chin. When handling and placing the mask on there will be contact to with hands
Ear loops	 	Polyamide white 3mm thickness	Elastic ear loops are placed over the ears to hold the mask in place	During use the mask will be in contact with skin around the mouth, nose, and chin. When handling and placing the mask on there will be contact with hands

Nose strip		Single iron core Polypropylene 3mm width	The metal nose strip is 'bent' over the users nose to hold the mask in place.	No direct contact to the user´s skin

5.2 Categorisation of device

According to the definition and classifications described in ISO 10993-1:2009 and 2018, the masks are surface contacting medical devices, and since masks may be used every day over a long period, permanent contact (> 30 days) to intact skin is to be considered (Table 1). Thus, the categorisation is based on the cumulative use under current COVID-19 requirements on the use of face masks to prevent the spread of the virus. The following endpoints should be considered according to the categorisation given:

- Physical/chemical information
- Cytotoxicity
- Sensitisation
- Irritation or intracutaneous reactivity

Table 2 Categorisation and biological effects for initial consideration according to ISO 10993-1

Device categories			**Biological effect**															
Category	**Contact**	**Contact duration** **A- Limited (24 h)** **B – Prolonged (24 hours to 30 days)** **C – Permanent (> 30 days)**	**Physical and/or Chemical information**	**Cytotoxicity**	**Sensitisation**	**Irritation or intracutaneous reactivity**	**Material mediated Pyrogenicity**	**Acute Systemic toxicity**	**Sub-acute toxicity**	**Sub-chronic toxicity**	**Chronic toxicity**	**Implantation effects**	**Haemocompatibility**	**Genotoxicity**	**Carcinogenicity**	**Reproductive/Developmental**	**Biodegradation / degradation**
Surface medical device	Intact skin	A	X	X E	X E	X E											
		B	X	X E	X E	X E											
		C	X	X E	X E	X E											

Legend: Yellow highlight indicates categorisation and endpoints for the device
X: ISO 10993-1:2009 (Annex A)
E (and X): ISO 10993-1:2018 (Annex A)
X: Means prerequisite information needed for risk assessment.
E: Means endpoints to be evaluated by existing data or by testing.

6 Review of existing data

6.1 Material characterisation

The fabric material used for the manufacturing of the masks is polypropylene (PP) SMS fabric in blue and white; the metal nose strip is made of a single iron core coated with PP; and the ear loops are made of polyamide material (Table 3). PP is generally considered a safe material and is authorised for use as an additive or production aid according to Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (EU 2011). The fabric material and the nose strip are considered to be compliant with RoHS Directive 2011/65/EU and (EU) 2015/863 (CCIC 2020). Chemical testing of the materials is described in the following sections.

Table 3. Material characterisation of the disposable medical mask

Component	Supplier	Material information	References
Fabric outer layer white SMS fabric	Hunan Xinlong Nonwovens Material Co., Ltd.	Xinlong Polypropylene	(GTT 2008)
Fabric mid layer white meltblown nonwoven fabric	Tangsiang Dinor Textile co., Ltd	Polypropylene	(ZLIPIRI 2020)
Fabric inner layer blue SMS fabric	Hunan Xinlong Nonwovens Material Co., Ltd.	Xinlong Polypropylene	(GTT 2018)
Ear loops	Pingyang Xiulian Knitting Co., Ltd	Polyamide	("GBT32610 Earloop Report Chinese," n.d.)
Nose strip	TechAdhesion System Ltd.	Single iron core Polypropylene	(CPRT 2020)

6.1.1 Chemical analysis of white non-woven polypropylene fabric

The white non-woven PP fabric was submitted for chemical analysis to determine the levels of Lead (Pb), Cadmium (Cd), Mercury (Hg), Hexavalent Chromium (Cr (VI)), Polybrominated biphenyls (PBBs), Polybrominated diphenyl ethers (PBDEs), Dibutuyl Phthalate (DBP), Benzyl butyl phthalate (BBP), Bis-(2-ethyl hexyl)-phthalate (DEHP) and Diisobutyl phthalate (DIBP). Pb, Cd, and Hg were analysed using ICP-OES; Cr (VI) was analysed using UV-VIS; and PBBs, PBDEs, DBP, BBP, DEHP, and DIBP were analysed using GC-MS. The results of the chemicals analysis are shown in Figure 2. None of the analytes were found above the detection limit (CCIC 2020).

Test Results (Unit: mg/kg):

Test Item(s)	Results	MDL
Cadmium (Cd)	ND	2
Lead (Pb)	ND	2
Mercury (Hg)	ND	2
Hexavalent Chromium (Cr (VI))	ND	8
Sum of PBBs	ND	—
Monobromo biphenyl	ND	5
Dibromo biphenyl	ND	5
Tribromo biphenyl	ND	5
Tetrabromo biphenyl	ND	5
Pentabromo biphenyl	ND	5
Hexabromo biphenyl	ND	5
Heptabromo biphenyl	ND	5
Octabromo biphenyl	ND	5
Nonabromo biphenyl	ND	5
Decabromo biphenyl	ND	5
Sum of PBDEs	ND	—
Monobromobiphenyl ether	ND	5
Dibromobiphenyl ether	ND	5
Tribromobiphenyl ether	ND	5
Tetrabromobiphenyl ether	ND	5
Pentabromobiphenyl ether	ND	5
Hexabromobiphenyl ether	ND	5
Heptabromobiphenyl ether	ND	5
Octabromobiphenyl ether	ND	5
Nonabromobiphenyl ether	ND	5
Decabromobiphenyl ether	ND	5
Dibutyl Phthalate (DBP)	ND	50
Benzyl butyl phthalate (BBP)	ND	50
Bis-(2-ethylhexyl)-Phthalate (DEHP)	ND	50
Diisobutyl Phthalate (DIBP)	ND	50

Note:

(1) mg/kg = milligram per kilogram
(2) ND = Not Detected (<MDL)
(3) MDL = Method Detection Limit
(4) "—" = Not regulated

Figure 2. Excerpt from chemical testing report QHJ20120206/EN. Chemical analysis results of the white polypropylene non-woven fabric.

6.1.2 Chemical analysis of blue non-woven polypropylene fabric

The blue PP SMS fabric was submitted for chemical analysis to determine the content of formaldehyde and banned Azo colourants listed in Appendix 8 of REACH regulation (EC) No 1907/2006. Formaldehyde was not detected in the blue PP fabric. Results of the chemical analysis of azo colourants are shown in Figure 3. None of the azo colourants were found above the detection limit of 5 mg/kg (GTT 2018).

FORBIDDEN AMINE	CAS NO.	REQUIREMENT (mg/kg)	RESULT (mg/kg)
4-aminobiphenyl	[92-67-1]	≤20	N
benzidine	[92-87-5]	≤20	N
4-chloro-o-toluidine	[95-69-2]	≤20	N
2-naphthylamine	[91-59-8]	≤20	N
o-aminoazotoluene	[97-56-3]	≤20	N
5-nitro-o-toluidine	[99-55-8]	≤20	N
p-chloroaniline	[106-47-8]	≤20	N
2,4-diaminoanisole	[615-05-4]	≤20	N
4,4' -diaminobiphenymethane	[101-77-9]	≤20	N
3,3' -dichlorobenzidine	[91-94-1]	≤20	N
3,3' -dimethoxybenzidine	[119-90-4]	≤20	N
3,3' -dimethylbenzidine	[119-93-7]	≤20	N
3,3' -dimethyl-4,4' -diaminobiphenylmthane	[838-88-0]	≤20	N
p-cresidine	[120-71-8]	≤20	N
4,4' -methylene-bis-(2-chloroaniline)	[101-14-4]	≤20	N
4,4' -oxydianiline	[101-80-4]	≤20	N
4,4' -thiodianiline	[139-65-1]	≤20	N
o-toluidine	[95-53-4]	≤20	N
2,4-toluylendiamine	[95-80-7]	≤20	N
2,4,5-trimethylaniline	[137-17-7]	≤20	N
o-anisidine	[90-04-0]	≤20	N
2,4-xylidine	[95-68-1]	≤20	N
2,6-xylidine	[87-62-7]	≤20	N
4-aminoazobenzene	[60-09-3]	≤20	N

"N" MEANS LESS THAN THE DETECTION LIMIT OF 5mg/kg

RATING ACCORDING TO GB 18401-2010.

Figure 3 Excerpt from report No. 180329790. Chemical analysis results of the blue polypropylene non-woven fabric.

6.1.3 Chemical analysis of metal nose strip

The metal nose strip was submitted for chemical analysis to determine the levels of Pb, Cd, Hg, Cr(VI), PBBs, PBDEs, and phthalates. Metals were analysed using ICP-OES; and PBBs, PBDEs and phthalates were analysed using GC-MS. The results of the chemicals analysis are showed in Figure 4. None of the analytes were found above the detection limit.

Test Items 测试项目	Unit 单位	Test Method 测试方法	Result 结果	MDL 检出限	Limit 限值
Lead (Pb)/铅	mg/kg	IEC 62321-5:2013, ICP-OES	N.D.	2	1000
Mercury (Hg)/汞	mg/kg	IEC 62321-4:2013+A1:2017, ICP-OES	N.D.	2	1000
Cadmium(Cd)/镉	mg/kg	IEC 62321-5:2013, ICP-OES	N.D.	2	100
Hexavalent Chromium (CrVI)/六价铬	mg/kg	IEC 62321-7-2:2017, UV-VIS	N.D.	2	1000
Monobromobiphenyl/一溴联苯	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Dibromobiphenyl/二溴联苯	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Tribromobiphenyl/三溴联苯	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Tetrabromobiphenyl/四溴联苯	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Pentabromobiphenyl/五溴联苯	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Hexabromobiphenyl/六溴联苯	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Heptabromobiphenyl/七溴联苯	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Octabromobiphenyl/八溴联苯	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Nonabromobiphenyl/九溴联苯	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Decabromobiphenyl/十溴联苯	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Sum of PBBs/多溴联苯总和	mg/kg	-	N.D.	-	1000
Monobromodiphenyl ether/一溴联苯醚	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Dibromodiphenyl ether/二溴联苯醚	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Tribromodiphenyl ether/三溴联苯醚	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Tetrabromodiphenyl ether/四溴联苯醚	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Pentabromodiphenyl ether/五溴联苯醚	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Hexabromodiphenyl ether/六溴联苯醚	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Heptabromodiphenyl ether/七溴联苯醚	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Octabromodiphenyl ether/八溴联苯醚	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Nonabromodiphenyl ether/九溴联苯醚	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Decabromodiphenyl ether/十溴联苯醚	mg/kg	IEC 62321-6:2015, GC-MS	N.D.	5	-
Sum of PBDEs/多溴联苯醚总和	mg/kg	-	N.D.	-	1000

Test Items 测试项目	Unit 单位	Result 结果	MDL 检出限	Limit 限值
Di-(2-ethylhexyl) phthalate (DEHP) 邻苯二甲酸二(2-乙基己基)酯(DEHP)	mg/kg	N.D.	50	1000
Benzylbutyl phthalate (BBP) 邻苯二甲酸苯基丁酯(BBP)	mg/kg	N.D.	50	1000
Dibutyl phthalate (DBP) 邻苯二甲酸二丁酯(DBP)	mg/kg	N.D.	50	1000
Diisobutyl phthalate(DIBP) 邻苯二甲酸二异丁酯(DIBP)	mg/kg	N.D.	50	1000

Note:
1. mg/kg = milligram per kilogram= ppm
2. N.D. = Not Detected (<MDL)
3. MDL = Method detection limit

注释：
1. mg/kg =毫克每千克= ppm
2. N.D. = 未检出 (< MDL)
3. MDL = 方法检测限

Figure 4 Excerpt from Report No. C200312014001. Chemical analysis results of the metal nose strip.

6.2 Sterilisation, packaging, and manufacturing

6.2.1 Sterilisation

The masks are non-sterilised, therefore testing for sterilization residuals is not necessary.

6.2.2 Packaging

The masks are packaged in polyethylene (PE) bags. PE is generally considered a safe plastic material and is authorised for use as an additive or production aid according to Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (EU 2011).

6.2.3 Manufacturing

The masks are manufactured in Denmark. The materials are welded together by ultrasonic welding.

Materials are stored and marked in batches referring to the incoming invoices for batch traceability. Machines and cleaned and services in the morning before the first run and in the evening after the final run. All personnel use hand sanitiser before entering the machine area. Personnel are wearing gloves, face masks, gowns, and special shoes during daily operations. Materials are loaded onto the machine in rolls and/or ear loop cartons. From there it is a 100% mechanical process until the masks are packed.

No intended additives, process contaminants and residues are used or expected to come into contact with the masks during manufacturing.

6.3 Existing nonclinical data

Biological tests have been performed for the masks. The test sample used for the biological tests were representative samples of the final product. The testing methods and the results of the biological test are summarised in the following sections. The mask was shown to be non-cytotoxic, non-sensitising, and non-irritating and met the requirements of the following standards:

- ISO 10993-5:2009 *Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity*
- ISO 10993-10:2010 *Biological evaluation of medical devices – part 10: test for irritation and skin sensitization*

6.3.1 Cytotoxicity

The disposable medical mask was subjected to testing in accordance with ISO 10993-5:2009 *Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity* and ISO 10993-12:2012 *Biological evaluation of medical devices -part 12: sample preparations and references materials*. The study is GLP compliant. In short, the potential cytotoxicity of extracts from the disposable medical mask were evaluated using the MTT assay. Mouse fibroblasts L929 cultured cells were exposed to 100% test extracts from the disposable medical masks. The results showed 96.1% cell viability, thus it is concluded that the

disposable medical mask extracts did not show potential for cytotoxicity of L929 cells (SETI 2020a).

The SMS non-woven fabric in blue was subjected to testing under the same protocol as described above. The results showed 88.94% cell viability, thus it is concluded that the non-woven blue fabric extracts did not show potential for cytotoxicity of L929 cells (GTT 2008)

6.3.2 Sensitisation

The disposable medical mask was subjected to testing on two separate studies using two different extraction vehicles (polar and non-polar) in accordance with ISO 10993-10:2010 *Biological evaluation of medical devices – part 10: test for irritation and skin sensitization;* ISO 10993-12:2012 *Biological evaluation of medical devices -part 12: sample preparations and references materials;* and ISO 10993-2:2006 *Biological evaluation of medical devices – Part 2: Animal welfare requirements.* The study is GLP compliant. In short, the potential for extracts from the disposable medical mask to cause skin sensitisation was evaluated using the guinea pig maximization test using 0.9% sodium chloride injection extract (polar extraction vehicle) (SETI 2020b), and sesame oil extract (non-polar extraction vehicle) (SETI 2020c). The positive rate of sensitisation in both studies was 0%, thus it is concluded that there is no evidence that extracts from the disposable medical mask have the potential to induce sensitisation in the test animal.

The SMS non-woven fabric in blue was subjected to testing under the same protocol as described above. The results showed the delayed hypersensitivity in guinea pigs was negative, thus it is concluded that the non-woven blue fabric did not have the potential for sensitisations in the test animal (GTT 2008).

6.3.3 Irritation or intracutaneous reactivity

The disposable medical mask was subjected to testing on two separate studies using two different extraction vehicles (polar and non-polar) in accordance with ISO 10993-10:2010 *Biological evaluation of medical devices – part 10: test for irritation and skin sensitization;* ISO 10993-12:2012 *Biological evaluation of medical devices -part 12: sample preparations and references materials;* and ISO 10993-2:2006 *Biological evaluation of medical devices – Part 2: Animal welfare requirements.* The study is GLP compliant. In short, the potential for extracts from the disposable medical mask to cause skin irritation on New Zealand white rabbits using 0.9% sodium chloride injection extract (polar extraction vehicle) (SETI 2020d), and sesame oil extract (non-polar extraction vehicle) (SETI 2020e). The results showed a mean value of 0 for the primary irritation index at 24h, 48h, and 72hr on New Zealand white rabbits. Thus, it is was concluded that the irritation induced on the test animal is negligible.

The SMS non-woven fabric in blue was subjected to testing under the same protocol as described above. The results showed a mean value of 0 for the primary irritation index at 1h, 24h, 48h, and 72hr on New Zealand white rabbits. Thus, it is was concluded that the irritation induced on the test animal is negligible (GTT 2008).

7 Biological evaluation

The masks are manufactured using PP which is biological inert and is generally considered a safe material. Non-woven materials, such as the ones used for the masks, are specifically created for personal hygiene and medical products that are in contact with skin, including medical gauze, surgical gowns, feminine hygiene products, diapers, etc (Ajmeri and Ajmeri 2011; Dey et al. 2014). The white SMS fabric has been tested to

determine the level of a range of potentially hazardous substances including the metals Pb, Cd, Hg and Cr (VI); polybrominated biphenyls and polybrominated diphenyl ethers; as well as a range of phthalate. The blue SMS fabric was tested to determine levels of azo colorant which may undergo reduction decomposition to form carcinogens. None of the analytes tested for were found above the detections limit. Therefore, it is concluded there is no risk to the user from the above-mentioned hazardous substances. The blue SMS fabric was tested to determine the levels of formaldehyde, which is a known skin sensitiser and may cause severe skin burns and eye damage (ECHA 2021a). Formaldehyde was not detected in the blue SMS fabric. Based on the chemical characterisation, it is concluded that there are no risks arising from the white and blue SMS fabrics. The mid layer of fabric is made of PP, no chemical testing was performed on this material, however, any risks to the user would have been detected in the biological testing.

The metal nose strip is composed of a single iron core covered with PP. Dermal contact with metallic iron has been a common feature of everyday life for humans in the domestic sphere and occupation. No reports exist in the literature of skin irritation or sensitisation in humans due to contact with metallic iron; furthermore, iron oxides are considered non-irritating and sensitising according to guidelines studies reported in the ECHA website (ECHA 2021b). The metal nose strip has been tested to determine levels of a range of potentially hazardous substances including Pb, Cd, Hg and Cr (VI); polybrominated biphenyls and polybrominated diphenyl ethers; as well as a range of phthalate. Based on the chemical characterisation, it is concluded there are no risks arising from the metal nose strip.

The ear loops are made of polyamide. Synthetic polyamide materials are commonly used for other consumer products such as clothing. The type of polyamide material is unknown and no chemical testing was performed on the ear loops. However, despite the limited material characterisation data, it is considered that any risks to the user would have been detected in the biological testing.

No intended additives, process contaminants and residues are used or expected to come into contact with the masks during manufacturing and are therefore not considered further in the evaluation.

The masks, in their final form, have been tested for cytotoxicity, skin irritation and skin sensitisation. The masks were shown to be non-cytotoxic, non-sensitising, and non-irritating.

8 Conclusion

Based on the available material characterisation information and biological test data it can be concluded that the materials used for the masks can be considered as safe with regards to the relevant endpoints determined by the ISO 10993 categorisation i.e., cytotoxicity, irritation and skin sensitisation. Thus, the masks are considered biocompatible according to their intended use.

9 References

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APPENDIX A – Toxicological literature and data search

Approach for toxicological literature and data search

In order to identify relevant toxicological data a literature review was conducted in accordance with ISO 10993-1(2018), Annex C. The literature and data search was conducted systematically, logged and documented in a table format (Table A1).

- In selection of the information, a preference is given to documents such as:
- Supplier/manufacturer information and relevant information on homepages of manufacturers of similar medical devices and/or similar products, which are on the market
- Information on the materials or similar materials in database on i.e., food contact materials, materials for pharmaceutical packaging or other medical applications
- Reviews and scientific opinions on the materials and/or ingredient substances in the components of the system
- Regulatory requirements, international guidelines, and standards for the type of materials. This could be guidelines or standards relevant for the area published or presented on for a or associations of health care professionals or authorities
- Scientific journal papers including original article and review articles

Table A 1 Literature search log table

Date of Search	Database	Search Terms	Selected references
10/2/2021	ECHA (europa.eu)	Polypropylene	(EU 2011)
10/2/2021	PubMed (nih.gov)	Polypropylene	(Dey et al. 2014) (Ajmeri and Ajmeri 2011)
22/2/2021	ECHA (europa.eu)	Formaldehyde	(ECHA 2021a)
22/2/2021	ECHA (europa.eu)	iron	(ECHA 2021b)

CPH MEDICAL

CPH Global Medical ApS, Lyngsø Alle 3, 2970 Hørsholm, Denmark

EU Declaration of Conformity

CPH Global Medical ApS

CPH/2021.2.0/EN

With Head Office and production facilities registered at Lyngsø Alle 3, DK2970 Hørsholm, Denmark, declares under sole responsibility as a manufacturer of:

CPH MEDICAL non-sterile disposable surgical medical face masks Type IIR. Product Model no. CPH MED001:

The products comply with essential requirements to meet the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR). We have consulted Annex VIII, Chapter III, 4.1. of the MDR and can confirm that our product - a non-invasive and non-sterile face mask - is correctly classified as Class I under Rule I.
The following (harmonized) norms has been applied**:**

- *DS/EN14683:2019+AC:2019 – Medical face masks – Requirements and test methods*
- *DS/EN ISO 11737-1:2018 – Biological evaluation*
- *ISO 22609:2004(E) Splash resistance against infectious agents and penetration by syntactic blood.*
- *EN 1041:2008+A1:2013 Information supplied by the Manufacturer of Medical devices.*
- *EN ISO 15223-1:2021 Medical devices – symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.*
- *SRN: DK-MF-000017573*
- *UDI-DI: 57000022462Mundbind3Q*

The CE marking is affixed on the packing of the face mask in a visible, legible and indelible way.
The CE marking format is in compliance with Annex V in the MDR
The intended purpose:
The non sterile disposable surgical face mask is used by covering the mouth and nose providing a barrier to minimize the direct transmission of infective agents between staff and patient. This intended purpose is normally used surgical procedures and other medical settings with similar requirements, but is today because of COVID 19 also used in public areas.

CE

Chairman Steen Berntsen
SIGNED BY CPH GLOBAL MEDICAL ApS
Date: December 2nd. 2021
Hørsholm, Denmark

Atelier

PAPYRUS

Folding boxboard (GC1), 100% virgin fibres, multilayered with a white top and a white back, double-coated top and pigmented rear side, superior whiteness, surface smoothness and print quality, with high bulk

Basis weight	**ISO 536**	**g/m²**	**220**	**240**	**260**	**280**	**300**	**325**	**350**
Thickness / Caliper	ISO 534	µm	320	360	405	445	495	535	595
Specific Volume / Bulk	ISO 534	cm^3/g	1,45	1,50	1,56	1,59	1,65	1,65	1,70
CIE Whiteness	ISO 11475	%	125	125	125	125	125	125	125
CIE Whiteness (reverse)	ISO 11475	%	116	116	116	116	116	116	116
ISO Brightness	ISO 2470-2	%	100	100	100	100	100	100	100
ISO Brightness (reverse)	ISO 2470-2	%	98,5	98,5	98,5	98,5	98,5	98,5	98,5
Gloss (Tappi 75°)	ISO 8254-1	%	50	50	50	50	50	50	50
Bending stiffness (DIN 5° MD)	ISO 5628	mNm	15,5	20,4	25,2	31,1	41,7	53,3	67,9
Bending stiffness (DIN 5° CD)	ISO 5628	mNm	8,3	10,2	13,5	16,5	22,5	29,5	36,5
Bending resistance (L&W 15° MD)	ISO 2493-1	m/N	174	233	301	379	465	582	720
Bending resistance (L&W 15° CD)	ISO 2493-1	m/N	85	115	145	190	250	300	375
Bending moment (Taber 15° MD)	ISO 2493-2	mNm	8,5	11,5	14,5	18,0	22,2	28,0	35,0
Bending moment (Taber 15° CD)	ISO 2493-2	mNm	4,0	5,5	7,5	9,5	12,0	14,5	18,0
Roughness (PPS)	ISO 8791-4	µm	1,2	1,2	1,2	1,3	1,3	1,4	1,4
Moisture (absolute)	ISO 287	%	6	6	6	6	6	6	6
Cobb value 60 sec. (Topside)	ISO 535	g/m^2	60	60	60	60	60	60	60
L* D65/10° (Topside)	ISO 5631-2		95,5	95,5	95,5	95,5	95,5	95,5	95,5
a* D65/10° (Topside)	ISO 5631-2		1,2	1,2	1,2	1,2	1,2	1,2	1,2
b* D65/10° (Topside)	ISO 5631-2		-8,6	-8,6	-8,6	-8,6	-8,6	-8,6	-8,6
L* D65/10° (Reverse side)	ISO 5631-2		95,5	95,5	95,5	95,5	95,5	95,5	95,5
a* D65/10° (Reverse side)	ISO 5631-2		1,3	1,3	1,3	1,3	1,3	1,3	1,3
b* D65/10° (Reverse side)	ISO 5631-2		-6,5	-6,5	-6,5	-6,5	-6,5	-6,5	-6,5

All properties are according to mill measurements that may be subject to fluctuations which are customary within the industry

Atelier

Applications

• Folding boxes, Food packaging, Luxury packaging, Tags, Covers for books and brochures, Folders, Desktop calendars, Desktop displays, Greeting cards

Technical product certificates and information

• Toy Safety (DIN EN 71/3)
• Food safety ISEGA (EN 45011)
• Food safety (EC 1935/2004)
• Food safety (BfR recommendation XXXVI)
• Free from heavy metals according to EU packaging directive (94/62/EC)

Environmental product certificates and information

• FSC®
• Elemental chlorine free (ECF)

The mark of responsible forestry
FSC® C004423

Supplier certificates

• FSC®
• PEFC™
• Environmental Management System (ISO 14001)
• Quality Management System (ISO 9001)
• Energy management (ISO 50001)
• Occupational Health and Safety Management System (OHSAS 18001)
• Eco-Management and Audit Scheme (EMAS)

Atelier

Technical capability

Printing technologies:	Absorbent substrate that is suitable for offset, UV-offset and screen printing. A sufficient quantity of printing powder with an appropriate particle size has to be considered.
Screen ruling:	All conventional screen rulings up to 80 l/cm (200 lpi) are applicable. When using other screen technologies, tests are recommended before print production.
Printing inks:	Suitable for inks that dry by absorption and oxidation (Offset), for UV-inks and screen printing inks.
Ink drying:	The drying process of the conventional offset ink is entirely completed within 24 to 48 hours, depending on the thickness of the ink film.
Printing pressure:	Standard pressure
Finishing:	All types of varnishing such as overprint-, water-based and UV varnishes, as well as cold foil transfer, hot foil stamping, embossing and die-cutting are possible.
Hot foil stamping:	suitable
Laminating:	suitable
Creasing & folding:	For the substances of 150 g/m² and higher, the folding process has to be prepared via creasing. In order to obtain the best possible folding results, the common standard values for creasing have to be considered.
Handling information:	The flatness of this paper is guaranteed at a relative humidity between 45 and 55% at a temperature between 20 and 23°C. It is recommended that the printing room has comparable climatic conditions. The paper should be kept as long as possible in the mill-wrapper before use. Extreme changes in temperature and humidity should be avoided.

For all printing and processing techniques, the recommendations of the manufacturers of machines, inks, adhesives, laminating and embossing foils, etc. are to be followed. For damages caused by faulty implementation of printing and processing, Papyrus cannot accept any liability.

Recommended by Asthma Allergy Nordic

This certificate confirms that a range of products from CPH Global Medical ApS has been certified by Asthma-Allergy Denmark and in this way helps people of all ages to take care of their skin and prevent skin allergy.
Asthma-Allergy Denmark is thankful for the cooperation.

Roskilde, 27 th September 2021

Rikke Bille
Head of the certification by Asthma-Allergy Denmark
The certificate is valid throughout 2021