TEST REPORT N°

ITAT20009093 of 02/07/2020

START DATE 23/06/2020
END DATE 02/07/2020

Total Quality. Assured.

APPLICANT

Opharm Sp. z o.o.
POKRZYWNICA 62
99-120 Piatek .

SAMPLE DESCRIPTION	Sample Received 23/06/2020 Reference: SANI - DM - 01 Colour: BLUE Batch number: S001 Fiber composition POLYPROPYLENE Buyer's Name: Opharm Sp. z o.o.

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intertek
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TEST METHOD	SAMPLE DESCRIPTION	PARAMETERS	RESULT	U.M.	LIMITS	NOTES	LAB
Biocompatibility Iso 10993-1	01	Result	See test report C.201096 attacched				33

Test performed by:
33: CEQ Laboratorio Prove e Tarature
Via Trieste
51039 Quarrata (PT)

The content of the present document refers exclusively to the submitted samples and not to the batch that they want to represent.
A representative portion of the sample is kept for 60 days. Specimen are kept for 30 days.
Samples are drawn by customer.
UM: unit of measurement
Limits are based on Customer's Manual in force available at Intertek Italia S.p.a. - Via di Stagno 17 F/G - 50055 Lastra a Signa (FI)
Uncertainty is the extended uncertainty calculated using a coverage factor of 2 which gives a level of confidence of approximately 95%.
All the results are reported without considering the uncertainty.
LQ: Quantification Limit

RESULTS MARKED IN RED EXCEED LIMITS

END OF TEST REPORT

Laboratory Manager
Ilenia Francioni
ilenia.francioni@intertek.com

TEST REPORT C.201096.04 Rev.0

Date of issue: 25/06/2020

Customer: **INTERTEK ITALIA SPA - Cernusco sul Naviglio (MI)**

Sample No. 201096

Sample type: Face mask for medical use
Description: ART. ITAT20009093; No. of layers: 3 ; PP

Arrival date: 24/06/2020 Testing date(s): 24/05/2020 until 25/06/2020
Testing site: CEQ Laboratory - Monsummano Terme

This Test Report is issued within the Quality Management System of Next Technology Tecnotessile Soc.Naz. di Ricerca rl and of its CEQ Laboratory, documented by the Quality Manual and related Procedures. The Quality Management System assures the traceability of the measurements to the national and international standards of the International System (SI) measurement units, through a metrology chain originating from first line samples provided with calibration certificates proving the traceability to the SI system standards, as required in ISO 9001: 2015 (par.7.1.5.1).

The results reported were obtained by applying the standards and / or technical procedures indicated on the following pages, and refer only to the tested samples, in the state in which they were at the time of the test itself.

Any measurement uncertainty declared in this Test Report is expressed as expanded uncertainty obtained by multiplying the standard uncertainty for a coverage factor k = 2, corresponding - in the case of normal distribution - to a confidence level of approximately 95%.

Operator: G. Gori Head of Laboratory: G. Gori

This Report has been issued after internal electronic approval and authorization

Company with quality system certified ISO 9001: 2015 by TÜV Italia (Cert. No. 50 100 14364) for:

- Design and provision of applied research and development services and technology transfer services ☐
- Design and provision of training services☐
- Design and provision of consultancy services on management systems☐
- Chemical, physical, mechanical, electrical and non-destructive laboratory tests☐
- Calibration of measuring and testing equipment

TEST REPORT C.201096.04 Rev.0

MASCHERE FACCIALI (AD USO MEDICO O NON PROFESSIONALE)	
Description:	Medical face masks - Requirements and test methods - Biocompatibility: assessment according to EN ISO 10993-1
Norme di riferimento:	UNI EN 14683:2019; UNI EN ISO 10993-1:2010; UNI EN ISO 10993-10:2013; UNI EN ISO 10993-18:2009
Procedura di prova:	PT-LAB-3101-A14

SAMPLING
Sampling: Carried out by the customer

SPECIMENS CHARACTERISTICS		
Device name and ID code:	#	ART. ITAT20009093; No. of layers: 3 ; PP-PP-COTTON
Device dimensions:		170x160 mm
No. of layers:		3
Materials adopted:		non-woven
Fiber composition:		Polypropylene; Polyamide (only in elastic bands)

\# *Datum is customer-provided*

SYNTHESIS OF THE ASSESSMENT METHODOLOGY ADOPTED

A. Methodologic approach

On the basis of the categorization proposed by the UNI EN ISO 10993-1: 2009 standard (appendix A), the object of the evaluation is classified as a device in contact with the skin with a limited duration (not exceeding 24 hours).
From this categorization it is clear, again from the aforementioned standard, that the biological effects to be
a. cytotoxicity
b. sensitivization
c. irritation or skin reactivity
The aforementioned effects are assessed with a risk-based approach (R), intended as a combination of potential damage (Severity) and probability (Occurrency), according to the R = SxO model, where Severity and Occurrency are estimated at a low (1), medium (2) or high (3) level based on the information collected.
The R risk is rated "Very low" if R <3; "Low" if 3 <= R <6; "High" if 6 <= R <7; "Very high" if R> = 7

B. Cytotoxicity risk assessment

This risk is estimated taking into account the information collected, as indicated below:

1. The Laboratory verified the correctness of the composition declared by the customer by infrared spectroscopic analysis (ATR / FT-IR)
2. Based on the fibrous composition, the Laboratory has verified that the type of polymers present did not present elements of cytotoxic risk based on the scientific literature and / or previous experience of use in similar or more critical applications.
3. The Laboratory acquired from the technical data sheets of the materials and from the data acquired by the customer the information on any treatments present on the material (e.g. for antibacteriality, bacteriostaticity, water repellency, etc.) and in the presence of one or more chemical treatments it verified through the Safety Data Sheets (SDS) the presence of any compounds with potential cellular

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MASCHERE FACCIALI (AD USO MEDICO O NON PROFESSIONALE) (following)

C. Risk assessment for sensitivization or skin irritation(reactivity

For these risks, in addition to the consideration based on the information collected (as for the risk of cytotoxicity), as indicated below: the pH of the aqueous extract was measured, a practical test of use and in vivo tests (patch test) according to ISO 10993-10 by voluntary operators who previously showed skin reactivity), who were asked to document any effects encountered during or as a result of the test, characterized as:

- skin redness
- skin abrasion / excoriation
- itch
- upper respiratory tract irritation (nose / throat)
- respiratory difficulties
- annoying smell

The absence of findings relating to these effects iss interpreted as a demonstration of adequacy, given the short duration of use of these devices, which normally exhaust their function in a short period of time.

ASSESSMENT RESULTS

A. Materials cytotoxicity assessment

a1. Fiber/Material: Polipropylene

Evaluation: Polypropylene is a synthetic polymer which does not normally require organic or inorganic additive treatments to achieve the characteristics required for efficient filtration.
It has been used for decades as a first selection material not only for facial masks for medical use but also for internal prostheses (containment nets for hernia, endovascular stents) thanks to its non-toxicity.
Recent in vitro dcito-toxicity tests conducted according to a method derived from ISO 10993-5 by researchers for the development of special improvement treatments have shown that PP in its original state (untreated) already has an excellent degree of cellular non-toxicity.

Bibliographic Ref. : P.Ekabutr, P. Chuysinuan, et al. "Development of antiturbercolisis met-blown polyprolylrnr filters coated with mangosteen extracts for medical face mask applications", Polymer Bulletin (2019) 76:1985-2004
P.Madsen, et al. "A study of disposable surgical masks" Americal Journal of Surgery, Vol. 114, Sept. 1967
M.Kelly, et al. "In vivo response to polypropylene following implantation in animal models: a review of biocompatibility" Int.Urogynecol J 2017; 28(2): 171–180.

Antecedents: Polypropylene facial masks for medical use are already registered in the MD Health Ministry Directory (e.g. BD / RDM N. 1161755, 1405007, 30713, etc.). Other registered devices: Implantable hernia nets) BD / RDM 1892795, 1892802

Risk evaluation: Severity: 2 Occurrency: 1 Risk level: 2 (Very low)

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Materials cytotoxicity assessment (following)

a2. Fibra/Mater.: Polyamide

Evaluation: Polyester is a synthetic polymer widely used in the realization of medical devices, including implantable ones, such as containment nets for inguinal hernias, endovascular plastics, etc. Polyester textile matrices are used both as a reabsorbable tissue patch and as a support for collagen and albumin for tissue reconstruction.

Polyester fibers have been used extensively for some time for the construction of suture structures (category H0102010102 of the CNDM).

Bibliografic ref: P.Madsen, et al. "A study of disposable surgical masks" Americal Journal of Surgery, Vol. 114, Sept. 1967
H. Shadpour et al. "Physiochemical properties of various polymer substrates and theri effects on microchip epectrophoressi performance" J. Chromatogr. A, 1111:238:251 (2006)

Antecedens: Polyester medical face masks are already registered on the MD Health Ministry Directory by Sintenex with BD / RDM 52158

Risk evaluation: Severity: 2 Occurrency: 1 Risk level: 2 (Very low)

a3. Fibra/Mater.:
Evaluation: //

Rif. Bibliografici: //

Antecedents: //

Risk evaluation: Severity: // Occurrency: // Risk level: //

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Materials cytotoxicity assessment (following)

a4. Latex: Absent

Evaluation: No risk of latex-inducted allergy

Risk Assessment: Low

General considerations on materials:
The non-woven textile is 100% polypropilene non-woven, widely used for medical devices, even implantable, for its high biocompatibility

B. **Treatments cytotoxicity**
Surface treatments declared or found:

Treatment type	Active principle(s)	Relevant risks	Assessment

General considerations about treatments:
No treatment applied

Risk Evaluation: Severity: Occurrency: 0 Risk level: // (None)

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Materials cytotoxicity assessment (following)

C Biocompatibility risks from pH, proof of use and "in vivo" test

c.1 Determination of pH of aqueous extract(COMPLIANT) [min 3; max 11]: pH: 6,4

c.2 Proof of use and "in vivo" test

Assessed aspects: sensitivization, skin irritation, skin reactivity

No.of involved people: 3 Proof duration: 4 hrs

Biological effects	Reaction level	Notes
Skin redness	0 - None	In vivo test according to UNI EN ISO 10993-10 §6.5 and Annex C with 3 operators
Itch	0 - None	
Scratches	0 - None	The proof of use has been carried out by 3 operators in parallel
Nose/throai irritation	0 - None	
Respiratory difficulties	0 - None	
Annoying smell	0 - None	

Evaluation scale (see ISO 10993-10 Annex C):

0 = No reaction (optimal)
1 = Weakly positive reaction (acceptable)
2 = Moderately reaction (unacceptable)
3 = Strongly positive reaction (absolutely unacceptable)

For each effect, the worst reaction among operators is reported and considered

General considerations on the proof of use: The proof of use has not been carried out since the sample is not a mask. The "in vivo" test has not even provided a minimal reaction on operators

Other considerations: The material (100% Polypropylene) has been widely used for decades for the realization of phlebolinfological, compressive or orthopedic bandages, and therefore with wide and prolonged contact with the skin even in areas with high sensitivity. Devices made of this material have long been present in the medical devices directory of the Italian Ministry of Health (eg. Bandages in PP Ref. BD / RDM 1921677-1921678-1921679-1774655-1774656-1774657 etc.).

Other references and/or Bibliography: C.I. Foo, et al. "Adverse skin reactions to personal protective equipment against SARS - A descriptive study in Singapore" . Publ. On Contact Dermatitis 2006: 55: 291-294. The study reports the effects of N95 masks and gloves used during the SARS epidemic; the paper refers that "All those who had skin reactions developed them while using N95 masks for an average duration of 8 hr a day and over a mean period of 8.4 months. Staff who only used surgical masks or paper masks did not report any skin reactions", and in the conclusions it states that "most reactions were of mild to moderate severity as most staff continued to use the equipment and few sought formal treatment with a physician". Furthermore, it is observed that most of the reactions were caused by the presence of latex and the high pressure typical of N95 masks but not of medical face masks.

Risk evaluation: Severity: 1 Occurrency: 1 Risk level: 1 (Very low)

Final notes: The non-woven material is biocompatible on the basis of the documentary and bibliographic evaluation of cytotoxicity and in vivo tests (skin reactions).

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