Rexpiria®

BE SAFE, BREATH SAFE

PRODUCT INFORMATION

DISPOSABLE SURGICAL MASKS
IIR

For info and inquiries
Email: info@rexpiria.com

PRODUCT SPECIFICATIONS
DISPOSABLE SURGICAL MASK

PRODUCT:
DISPOSABLE SURGICAL FACE MASK IIR

PRODUCT MODEL: GS002 SURGICAL MASK TYPE IIR

NATIONAL STANDARD: GB 2626-2006
EN 14683:2019+AC2019

UNIVERSAL CERTIFICATIONS CE CERTIFICATION NR MDD-152
ISO 11737-1 UNIVERRSAL TURKEY REPORT NO. : 2011717E
EN ISO 10993-5:2009 TEST FOR VITRO CYTOTOXITY -
NPT REPORT NUMBER 20070212706/1

QUANTITY PER PACK: 25 PIECES

MANUFACTURER:
DONGYANG KIN-SHINE MEDICAL DEVICE CO., LTD
NO.1199,GUANGFU EAST STREET,CHANGSONGGANG FUNCTIONAL AREA,DONGYANG ECONOMIC
DEVELOPMENT ZONE,DONGYANG,ZHEJIANG,CHINA

IMPORTER / DISTRIBUTOR / MANUFACTURER:
GOLDEN SEASON SRL
VIA CORFU', 66 – 25124 BRESCIA – ITALY
N.TEL: +39030723777

COLOR: WHITE/BLUE

HELPS FILTER OUT DUST, BACTERIA, SMOKE & POLLEN

BACTERIAL FILTRATION AND PARTICULATE PROTECTION: ≥98%

ADDITIONAL DETAILS:
OUTER LAYER 25 GRMS SPUNBOND – CENTER LAYERS 50 G MELTBLOWN -
INNER FACE SITE LAYER
25GRMS SPUNBOND
CUSTOMIZED FACIAL MASK DESIGN
PROTECTION FROM DUST, SMOKE AND SOLID AND LIQUID AEROSOLS
HARMFUL TO HEALTH

PACKAGING - DISPOSABLE SURGICAL MASK

25 MASKS PACK

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Email: info@rexpiria.com

DOCUMENTATION - DISPOSABLE SURGICAL MASK

ORIGINAL DOCUMENTS

NPT
NATIONAL PROTECTIVE TESTING

NATIONAL PROTECTIVE TESTING LLC

TEST REPORT
EN ISO 10993-10:2009
Tests for Irritation

Client:	Dongyang Kin-Shine Medical Device So. Ltd
Address:	No.1199, Guangfu East Street, Changsonggang Zhejiang, CHINA
Brand name:	Golden Season
Model name:	GS002
Sample:	3ply Face Mask
Sample received on:	June 25, 2020
Report Number:	20070212706/6
Elaborated by:	Ashley Madison
Place and date of issue:	Sheridan, WY July 02, 2020

NATIONAL PROTECTIVE TESTING LLC · NPT · ACCREDITATED TESTING LABORATORY

Dr. Joseph Andrew, Ph.D.
Head of Testing Laboratory

Note: The results given in this Test Report apply only to the sample tested by our laboratory!
Without a written consent by National Protective Testing LLC, in WY, the Test Report may not be reproduced unless as a whole!

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

DOCUMENTATION - DISPOSABLE SURGICAL MASK

ORIGINAL DOCUMENTS

NPT
NATIONAL PROTECTIVE TESTING
DON'T STRESSING, NPT YOUR TESTING

NATIONAL PROTECTIVE TESTING LLC

Test Standard: EN ISO 10993-10:2009
Name of tests: Tests for Irritation
Reference no: IRT-001

Test Purpose:
The purpose of this study was to determine the potential of a test article to cause irritation

Sampling method:
Ten pieces samples material to be tested.

Testing methods used:
EN ISO 10993-10:2009 Biological evaluation of medical devices - Part 5: Test for Irritation

Test conditions:
Min. 24hr, temperature of (20 ± 2) °C and a relative humidity of air of (65 ± 5) %. Then incubate at 37°C in air with 5% CO2.

Test Procedure:
Test methods: ISO 10993-10:2010(E), Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization.

Test environment: Rabbit room of conventional condition. Certificate No.SYXK 2013-0086, Guangdong; Room temperature 21~23℃, Relative humidity 55~65%.

Test animal: New Zealand white albino rabbits, each weight between 2.2 kg and 2.3 kg, supplied by Guangdong Medical Experiment Animal Center (Sanshui Base) (Certificate No. SCXK 2014- 0035,Guangdong), animals certificate NO. 44411600002565
No. of animals/sex: 3/♀:♂=2:1

Preparation of Sample: took 20g sample and added 100ml 0.9% sodium chloride solution to make dilution ration as 0.2g/ml, bathed for 72h at 37°C, after returning to room temperature took the extract liquid as test substance.

Observation period: 1,24,48 and 72 hours following removal the test substance, use only 24h,48h and 72h observations for calculations.

Test procedures: (1) Preparation of test animals. Selected three healthy young adult New Zealand white albino rabbits. Fur was shaved 24h before the test (approximately 10 cm×15 cm). (2) Procedures for testing: Applied 0.5mL test substance on the test skin site as shown in Figure 1 of ISO 10993- 10:2010(E) with a gauze patch.

Applied the control patch of gauze(moistened with 0.9% sodium chloride solution) on the control site indicated in Figure 1 of ISO 10993-10:2010(E). Wrapped with non-irritating tape and bandage for 4 hours. At the end of the contact time, removed the dressings and marked the sites, Removed residual test material and washed with lukewarm water. Examined for signs of erythema and edema, recorded the dermal reactions at each observation period according to table 1 and table 2 of ISO 10993-10:2010(E).

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Description and identification of samples:

Table I - Description and identification of samples

Sample lot number	Designation of the sample by the client	Description of the given sample
NP/LT/0857354/6	Made from Spunbound Polypropylene (SPP) with adjustable nose strip and round elastic ear loop to give basic protection to the user.	Figure 1

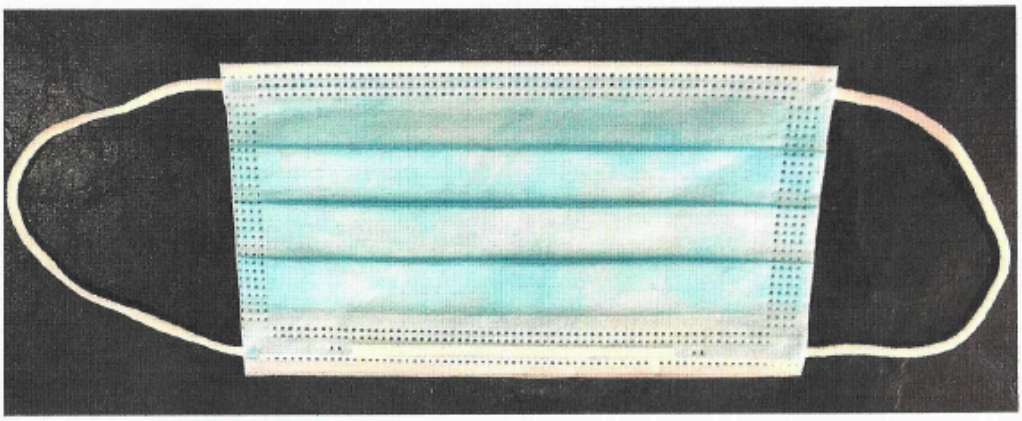

Fig. 1 - Sample Lot No. NP/LT/0857354/6

Test results:
The test results obtained are given in the tables as follows

The Primary Irritation Index (PII) of the test substance is 0.

Observation period	1h								24h							
Skin reaction	Erythema-eschar				Edema				Erythema-eschar				Edema			
Skin application site / Rabbit Number	Test Site		Control Site		Test Site		Control Site		Test Site		Control Site		Test Site		Control Site	
	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Note: The results given in this Test Report apply only to the sample tested by our laboratory!
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NPT NATIONAL PROTECTIVE TESTING

NATIONAL PROTECTIVE TESTING LLC

Observation period	48h								72h							
Skin reaction	Erythema-eschar				Edema				Erythema-eschar				Edema			
Skin application site / Rabbit Number	Test Site		Control Site		Test Site		Control Site		Test Site		Control Site		Test Site		Control Site	
	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Note 1. L= Left, R = Right

Reference information:

ISO 10993-10:2010 Table2- Primary or cumulative irritation index categories in a rabbit

Mean score	Response category
0~0.4	Negligible
0.5~1.9	Slight
2~4.9	Moderate
5~8	Severe

Conclusion:
According to "Table 2-Primary or cumulative irritation index categories in a rabbit" in ISO 10993- 10:2010(E), the irritation of the sample is **negligible** in rabbits' skins.

NATIONAL PROTECTIVE TESTING LLC NPT ACCREDITED TESTING LABORATORY

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UNIVERSAL CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate Nr: MDD-05/IT

In conformance to the European Economic Commission 93/42/EEC Medical Devices Directive on harmonization of laws, regulations and administrative documentation of Member States on Medical Devices and European Economic Commission directive 93/68/EE amending Medical Devices Directive dated 22 July 1993,

the products manufactured for

GOLDEN SEASON SRL

at the following address

VIA CORFU' 66 – 25124 BRESCIA - ITALY

Manufactured at

Dongyang Kin-Shine Medical Device Co. Ltd

No.1199, Guangfu East Street, Changsonggang Zhejiang, China

EN 14683:2019+AC:2019 Medical Face Masks

Brand Name: Golden Season - Model: GS002 Surgical Mask

type IIR

are tested according to the following initial type tests by the manufacturer

Technical standard EN 14683:2019+AC:2019 - Medical face masks - Requirements and test methods

For the assessment of conformity, the following documents were also applied to: Results of laboratory tests by NPT Testing for Laboratory BFE, Microbial Cleanliness and Differential Pressure

UNIVERSAL has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components (if exists) and product technical drawings of the medical face masks manufactured and designed for use during the medical operations or similar medical situations with same requirements which require restriction of infectious materials to be spread to patients. With this certificate, it is approved that the product fulfils all essential requirements and the related rules of 93/42/EEC Medical Devices Directive (MDD) Class I are applied. The information on the packaging for the above listed products covers the necessary information stated in Annex I, § 13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745. This information includes; reference to EN 14683 standard, type of mask (as indicated in Table I) and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It is considered to be suitable to attach a CE mark as seen below, on your products in accordance with the information given in this certificate with publishing an EU Declaration of Conformity.

This certificate is issued on 07/07/2020 and valid until 06/07/2021 with the conditions that no change has been made with the product references and no change in the production processor not suspended or withdrawn for any reason.

CE

Verify the validity with the QR code

ROME 07/07/2020

UNIVERSAL CERTIFICATION

Italy Manager

This certificate will be in the absence of any changes in standard and legal terms and with the surveillance audits to be conducted annually following the surveillance audit updating the publication date without changing the certificate number.

DOCUMENTATION - DISPOSABLE SURGICAL MASK

ORIGINAL DOCUMENTS

ZERTIFIKAT • CERTIFICATE • CERTIFICADO • CERTIFICAT

UNICERT

UNIVERSAL UNICERT QUALITÄT

MEDICAL QUALITY MANAGEMENT SYSTEM CERTIFICATE

Universal GmbH

This certificate is granted to the organization,

Dongyang Kin-Shine Medical Device Co. Ltd

No.1199, Guangfu East Street, Changsonggang Zhejiang, CHINA

by review of IA2-10459 numbered report for the scope

Production and wholesale of medical devices and personal protective equipment

to certify that a management system in accordance with standard's clauses is established and being implemented

ISO 13485:2016

Certificate No : MDMS 0620 006960
Original Certification Date : 01.07.2020
Issue / Revised Date : 01.07.2020
Expiry Date : 30.06.2021
Certification Period : 3 years (1st year)

UNIVERSAL UNICERT QUALITÄT

Universal GmbH

The authenticity of this certificate can be confirmed online or by e-mail to the Head Office via:
UNIVERSAL GmbH • Wilfried Diekmann Str., 20b, 44536 Lünen Germany • T : +49 (0) 231 9931 9960 • info@uni-cert.de • www.uni-cert.de

DICHIARAZIONE DI CONFORMITA'

GOLDEN SEASON SRL

VIA CORFU' 66 25124 BRESCIA ITALY

PRODOTTO: Dongyang Kin-Shine Medical Device Co. Ltd

No, 1199, Guangfu East Street, Changsonggang Zhejiang, China

Brand: Golden Season

Sulla base del fascicolo tecnico approntato in conformità alla Direttiva Europea 93/42/CEE per la mascherina chirurgica Modello: GS002 Surgical Mask EN 14683:2019+AC:2019 Medical Face Masks e degli ulteriori attestati:

- Attestato di conformità allo standard armonizzato Europeo UNI EN 14683: Nr:. MDD-05/IT rilasciato da Universal Certification
- Rapporto di prova in conformità allo standard EN ISO 10993-5 (non citotossicità) ed EN ISO 10993- 10 (non irritabilità della cute) rilasciati da National Protective Testing LLC nptesting.com
- Certificato: Medical Quality Management System Certificate ISO 13485:2016 No. MDMS 0620 006960 rilasciato da Universal GmbH - www.uni-cert.de

La Golden Season srl dichiara sotto la propria responsabilità che il dispositivo medico di classe I tipo IIR sopra designato è conforme ai requisiti essenziali della seguente direttiva dell'Unione Europea:

Direttiva: Europea 93/42/CEE e s.m.i.

La Golden Season srl si impegna a conservare e a tenere a disposizione delle autorità competenti presso la propria sede la documentazione tecnica, come da allegato VII della direttiva citata, per un periodo di 5 anni (cinque) dalla messa in commercio di questo dispositivo medico e dichiara che:

Il prodotto Mascherina Chirurgica è un Dispositivo Medico, appartenente alla Classe I di tipo ITR

La Golden Season srl ha istituito una procedura sistematica per valutare l'esperienza acquisita nell'uso del dispositivo nella fase successiva alla produzione, nonché a mantenere un sistema appropriato cui ricorrere per applicare le misure correttive eventualmente necessarie.

Luogo: Via Corfù, 66 25124 BRESCIA, ITALY
Data 07-07-2020

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C.F. / P. IVA 03233670987

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