GEM 1

Mascherina Chirurgica Tipo IIR

Realizzata ai sensi dell'art. 15 comma 2 del D.L. 17 marzo 2020, n.18 convertito in Legge 24 Aprile 2020 n. 27

Produttore:

GEMINI PADANA SRL,Via Tibet 19, 21052 Busto Arsizio (Va) , Italy
Tel. 0331 342110 – Fax 0331 342080 - e-mail info@geminipadana.it

Descrizione:

Mascherina monouso realizzata con triplo strato di TNT 100% Polipropilene, con nasello stringinaso, non sterile, Made in Italy

Dati tecnici:

Composizione	100% PP , 3 strati di TNT Spunmelt idrofobo, grammatura 40 g/mq di cui 7 g/mq di Meltblown
Pressione differenziale ((Pa/cm2)	53
Efficienza di filtrazione particellare, PFE (%)	61%
Efficienza di filtrazione batterica, BFE (%)	99%
Bioburden con determinazione CFU/g	<6
Dimensioni mascherina disponibile anche nelle misure bambino e teenager	mm.175 x 95
Composizione nasello Stringinaso	Polipropilene
Composizione elastico	EA 27% PA 73%
Privo di lattice	
Conforme alle norme	UNI EN ISO 14683:2019 e 10993-1:2010

Confezionamento:

I dispositivi vengono confezionati all'interno di una busta termosaldata di Polietilene a bassa densità
Il materiale utilizzato per il confezionamento non contiene lattice
N° pezzi: confezionato in buste da 10 pezzi

Avvertenze e conservazione:

Prodotto monouso; deve essere conservato a temperatura ambiente compresa tra 15° e 30° gradi, al riparo da condizioni estreme di umidità, polvere, agenti inquinanti, ecc. Il periodo di validità è 5 anni a decorrere dalla data di produzione, purchè il prodotto sia correttamente conservato nella confezione di vendita originaria

Modalità di smaltimento:

Lo smaltimento del prodotto utilizzato deve essere effettuato in accordo alle normative vigenti relative a rifiuti sanitari

GEM 1

mascherina chirurgica IIR

MADE IN ITALY

GEMINI PADANA S.R.L

union

TECHNICAL DATASHEET

ART.NR.	D4007PHW
Description	SMS Thermobonded Nonwoven 100% PP Hydrophobic

PHYSICAL PROPERTIES	Unit	Target	Min or Max	Test method
Basis weight	g/m^2	40	± 7,5%	*WSP 130.1 (15)
Tensile strength MD	N/5cm	95	> 71,5	*WSP 110.4 (15) Option B Jaws distance 100 mm Rate of extension 200mm/min Without pretension
Tensile strength CD	N/5cm	45	> 34	
Elongation MD	%	60	> 45	
Elongation CD	%	60	> 45	
Waterproof	mm	560	> 420	*WSP 80.6 (15)
Air permeability - 1 layer	$l/m^2/s$	410	-	WSP 70.1 (15)
Air permeability - 2 layers	$l/m^2/s$	200	-	
Air permeability - 3 layers	$l/m^2/s$	135	-	
PFE**	%	61	-	UNI EN 14683:2019 - UNI EN 149:2019 -UNI EN 13274
BFE**	%	99		UNI EN 14683:2019
Differential Pressure**	Pa/cm^2	53	-	UNI EN 14683
Splash resistance**	Valuation	Pass	-	UNI EN 14683
Nonwovens sampling				*WSP 5.0 (15)
Quality Certification	-	ISO 9001 - 2015		

*WSP: Worldwide Strategic Partners [Edana & Inda]
** Test performed on 3 layers by Politecnico di Milano and reported on dated document 22 th April 2020

Union Signature *Luca Fantini*
Customer Signature

TD;LAB/COM;05-11-96,01;15-04-97;P16

TDS ID	Issue Date	Last Revision Date	Revision Number
D4007PHW	01/04/2020	22/04/2020	3

Union Industries SpA Nonwovens
Via 2 Giugno, 80 13866 Masserano (Bi) Italia
tel. +39 015 95153 fax +39 015 927240 telegr. Union Masserano e-mail: info@unionindustries.it
P. IVA e C. F. 01484660020 Cod. CEE IT 01484660020 CCIAA Biella n. 141972 meccanografico BI 000330
Capitale Sociale € 10.500.000 int. versato Registro Imprese CCIAA di Biella n. 10246

POLITECNICO
MILANO 1863

MATERIALE PROVATO

Produttore: **Union Industries**
Tipologia: **SMS 40 g/mq (MB 7 g/mq)**
Campioni: **3 strati: SMS + SMS + SMS (D4007-PHW)**

PROVE, METODI, RISULTATI

Ispezione visiva e microscopica preliminare:

Sono considerati accettabili esclusivamente materiali a trama fitta, privi di visibili interstizi nella trama anche sotto trazione, dotati di sufficiente traspirabilità e di adeguato comportamento idrofobico/idrorepellente. Il superamento di questa prova costituisce condizione necessaria per accedere alle prove successive.

Differenza di pressione:

Prova di permeabilità all'aria del materiale filtrante, valutata determinando la differenza di pressione attraverso il provino in condizioni di portata dell'aria specificate dalle normative. Le modalità di prova si basano per tutti i provini sulla UNI EN 14683. Modalità di prova: corrente di azoto o aria attraverso campione afferrato tra flange in alluminio/teflon. Portata di gas: 46.2 ± 5% litri/min su sezione di passaggio circolare con diametro di 60 mm, corrispondenti a 8 litri/min su sezione di 25 mm. Strumento di misura: GE DRUCK LPM9381 range −10/+10 mbar, 1/1000 FS, uscita 5V. Incertezza della misura ± 10%.

Test di efficienza di filtrazione particellare (PFE):

Il test del medium filtrante viene effettuato attraverso il metodo misura del particolato (aerosol) a monte e a valle del campione di sezione circolare. L'aerosol campione (goccioline d'olio) è polidisperso; ne viene misurata la concentrazione mediante fotometro e con contatore ottico di particelle si rileva la distribuzione dimensionale (diametro mediano 0,6 µm).
Il risultato della prova è l'Efficacia di Filtrazione del Particolato (PFE): PFE = 1 - P con P = penetrazione. $P = C_2/C_1$, con C_1, C_2 = Concentrazione a monte, Concentrazione a valle.
Nella prova si controllano portata di aria e differenza di pressione. Diametro della sezione del provino filtrante 114 mm. Misura con fotometro ottico. Portata 102 l/min. Aerosol di olio paraffinico. Il risultato è calcolato come media di 3 misure. Le modalità di test tengono conto e adeguano al contesto le norme UNI EN 14683:2019, UNI EN 149:2009, UNI EN13274

Valutazione in vitro dell'efficacia di filtrazione batterica (BFE)

Le modalità di test per la valutazione in vitro dell'Efficacia di Filtrazione Batterica (BFE) sono derivate dalla normativa UNI EN 14683:2019 "Medical face masks – Requirements and test methods".
Il test è condotto su un provino di media filtrante (Ø = 46 mm). A monte del provino viene generato un aerosol batterico (batteri: *Escherichia coli*), A valle del provino viene fatto un campionamento microbiologico per raccogliere, all'interno di un impattore a tre stadi, i batteri eventualmente presenti. Dopo incubazione (37°C; 24 – 48 ore) si proceda al conteggio di CFU. Nella sperimentazione si fanno controlli positivi per valutare il numero di batteri (CFU) raccolti nell'impattore in assenza del campione di test.
La BFE viene calcolata come segue: BFE (%) = (C – T)/C x 100, dove: C = valore medio di conteggio di CFU nei controlli positivi (senza provino di test) e T = valore medio di conteggio di CFU nei campionamenti a valle del provino (media filtrante) soggetto a test.
La normativa EN 14683:2019 Annex B prevede la generazione di un nebulizzato batterico di Staphylococcus aureus (S. aureus, numero di catalogo ATCC: 6538) da utilizzarsi come generico microorganismo modello per la valutazione della BFE nella metodica di test sopraindicata. S. aureus è un noto agente patogeno umano, agente eziologico di varie patologie tra cui la polmonite batterica. Il Politecnico ritiene che il ceppo batterico Escherichia coli (E. coli, numero di catalogo ATCC: 53323) sia, con buona approssimazione, analogo a S. aureus (ATCC 6538), ovvero batterio modello di simili dimensioni, ai fini della suddetta sperimentazione per la determinazione della BFE, in considerazione del fatto che esso ha dimensioni confrontabili con quelle del batterio S. aureus.

POLITECNICO
MILANO 1863

Legenda risultati e classi**

TIPO DI PROVA	MISURA	CLASSE*
Ispezione visiva e microscopica	N/A	Passato / Non Passato
Pressione differenziale	DP (Pa/cm2) ± 5%	A (R < 40 Pa/cm2) B (R < 60 Pa/cm2) C (R > 60 Pa/cm2)
Efficienza di filtrazione particellare (PFE)	PFE (%) ± 5%	A (PFE > 65%) B (50% < PFE < 65%) C (PFE < 50%)
Efficienza di filtrazione batterica (BFE)	BFE (%) ± 10% ***	A (BFE > 90%) B (70% < BFE < 90%) C (BFE < 70%)

* Il materiale è ritenuto idoneo alla funzione filtrante se ogni test ha dato esito "**Passato**" oppure se risulta in classe **A o B**. Viceversa è da ritenersi non idoneo.
** Si veda anche la "Nota Tecnica 4.3" del 11/04/2020 o versioni successive.
*** Per valori di BFE ≥ 95% le prove sono state eseguite su una base statistica sufficientemente ampia da garantire una tolleranza del ± 1%. Per valori di BFE < 95%, la base statistica è più ristretta e dunque, in via cautelativa, deve essere mantenuto il valore di tolleranza indicato in tabella.

ESITI

Campione 3xSMS D4007-PHW

TIPO DI PROVA	MISURA	CLASSE*
Ispezione visiva e microscopica	N/A	Passato
Pressione differenziale (Pa/cm^2)	53	B
Efficienza di filtrazione particellare, PFE (%)	61	B
Efficienza di filtrazione batterica, BFE (%)	99	A

Data: 04/04/2020

POLITECNICO
MILANO 1863

MATERIALE PROVATO

Produttore: **Union Industries**
Tipologia: **SMS 40 g/mq (MB 7 g/mq)**
Campioni: **3 strati: SMS + SMS + SMS (D4007-PHW)**

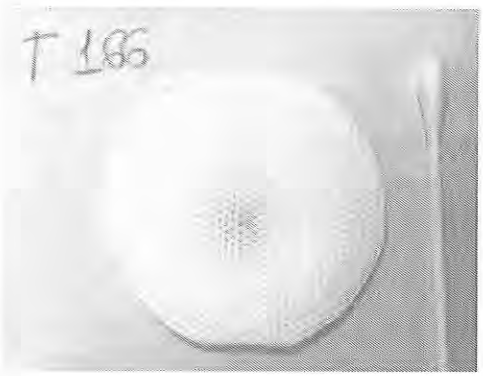
PROVE, METODI, RISULTATI

Impatto con getto liquido – splashing:

Il test verifica se i campioni sono in grado di proteggere l'operatore a seguito di uno schizzo di liquido biologico (per es. sangue) derivante dalla rottura di un tubo o simili.
L'impianto di test si basa sulla normativa EN 22609:2001 ed è stato testato il livello di resistenza allo "splash" secondo norma EN 14683:2019 per maschere ad uso medicale di tipo IIR (ossia 16 kPa).
Metodo di prova: i campioni – condizionati per almeno 4 ore in atmosfera controllata – vengono impattati da uno spruzzo proiettato da un ago 18 Gauge, dopo che questo ha attraversato un target con un foro di 5 mm di diametro. Dopo 10 secondi, viene valutato se il liquido ha attraversato il campione. In assenza di attraversamento, la prova si intende superata. Si documenta la prova fotografando il lato non esposto allo spruzzo.
Il sangue artificiale rispetta i requisiti richiesti di densità e tensione superficiale ed è stato sviluppato dallo spin-off ReActive – Powder Technology S.r.l.

ESITI

Campione

<table>
<tr><td> 
</td><td> 
</td></tr>
<tr><td>Fronte</td><td>Retro</td></tr>
<tr><td colspan="2">Evidenza sperimentale.
Si riscontra una direzionalità del risultato.
Comunque, il liquido NON passa da entrambi i lati. Prova SUPERATA</td></tr>
</table>

Data: 22/04/2020

chem S.r.l.

ANALISI CHIMICO-FISICHE
MICROBIOLOGICHE
BIOCOMPATIBILITA'
CONSULENZA TECNICA
BIOTECNOLOGIE

Spettabile
GEMINI PADANA S.R.L.
Via Tibet, 19
21052 BUSTO ARSIZIO VA

Zola Predosa, 05/06/2020

Rif. Vs. ordine del 2020

Rapporto di Prova N° 20-0600-01

VALUTAZIONE DELLA POPOLAZIONE DI MICRORGANISMI – CONVALIDA DEL METODO

Descrizione campione

Denominazione: MASCHERINA CHIRURGICA
Codice: GEM1
Lotto: 1
Sterilizzazione: Gamma Ray Steriliz.
N° unità analizzate: 5
Numero di ricevimento: 16059
Data di ricevimento: 18/05/2020
Campionamento effettuato da: GEMINI PADANA S.R.L.

Analisi iniziata il 03/06/2020 e terminata il 05/06/2020.

Metodo di prova

ISO 11737-1:2018

Sommario del metodo

Campioni sterili sono stati contaminati con una concentrazione nota di Staphylococcus aureus ATCC 6538 e Candida albicans ATCC 10231. I microrganismi sono stati estratti dai campioni utilizzando una soluzione di fisiologica sterile contenente lo 0,05% di Tween 80 in agitazione meccanica. L'estratto ottenuto da ogni campione è stato filtrato con un filtro da 0,45 µm. Ciascun filtro è stato tagliato a metà, una metà è stata posta su una piastra di Tryptone Soya Agar (TSA) e incubata per 72 ore a 32 ± 2℃ per effettuare il conteggio dei microrganismi mesofili recuperati, l'altra metà è stata incubata su Potato Dextrose Agar (POT) per 5 giorni a 22℃ ± 2℃ per e ffettuare il conteggio dei miceti recuperati. Al termine si è effettuato il conteggio dei microrganismi recuperati e si è calcolato il fattore di correzione.

VIA BENINI 13– 40069 ZOLA PREDOSA BO – TEL +39-051755295 – FAX +39-051754622
www.biochem-bcm.com E-mail: info@biochem-bcm.com - C.F. e P.IVA IT 03531810376 – R.E.A. BO-297535

Risultati

Staphylococcus aureus ATCC 6538

N°campione	Contaminazione (ufc/campione)	Microrganismi recuperati (ufc/campione)	Recupero (%)
1	32	15	46,9
2	32	18	56,3
3	32	10	31,3
4	32	22	68,8
5	32	24	75,0
Valore medio		**17,8**	**55,7**
Fattore di correzione		**1,80**	

Candida albicans ATCC 10231

N°campione	Contaminazione (ufc/campione)	Microrganismi recuperati (ufc/campione)	Recupero (%)
1	43	26	60,5
2	43	20	46,5
3	43	28	65,1
4	43	18	41,9
5	43	26	60,5
Valore medio		**23,6**	**54,9**
Fattore di correzione		**1,82**	

Il presente Rapporto di Prova è riferito esclusivamente al campione esaminato.
Nel caso in cui il campione sia stato fornito dal Cliente, i risultati si applicano al campione così come ricevuto.
Il presente Rapporto di Prova non può essere riprodotto parzialmente, salvo approvazione scritta di Biochem.

(#) Dati forniti dal Cliente. Il laboratorio declina la responsabilità di tali dati.

Prova verificata da: Buriani Giampaolo, PhD.

Emissione autorizzata da:
Responsabile del Laboratorio Ing. Giovanni Bassini

FINE RAPPORTO DI PROVA

VIA BENINI 13– 40069 ZOLA PREDOSA BO – TEL +39-051755295 – FAX +39-051754622
www.biochem-bcm.com E-mail: info@biochem-bcm.com - C.F. e P.IVA IT 03531810376 – R.E.A. BO-297535

chem S.r.l.

ANALISI CHIMICO-FISICHE
MICROBIOLOGICHE
BIOCOMPATIBILITA'
CONSULENZA TECNICA
BIOTECNOLOGIE

Spettabile
GEMINI PADANA S.R.L.
Via Tibet, 19
21052 BUSTO ARSIZIO VA

Zola Predosa, 05/06/2020

Rif. Vs. ordine del 2020

Rapporto di Prova N° 20-0600-02

VALUTAZIONE DELLA POPOLAZIONE DI MICRORGANISMI

Descrizione campione

Denominazione: MASCHERINA CHIRURGICA
Codice: GEM1
Lotto: 1
Sterilizzazione: Gamma Ray Steriliz.
N° unità analizzate: 5
Numero di ricevimento: 16060
Data di ricevimento: 18/05/2020
Campionamento effettuato da: GEMINI PADANA S.R.L.

Analisi iniziata il 25/05/2020 e terminata il 01/06/2020.

Metodo di prova

ISO 11737-1:2018

Sommario del metodo

I campioni sono stati trattati asetticamente. I microrganismi sono stati estratti dai campioni utilizzando una soluzione di fisiologica sterile contenente lo 0,05% di Tween 80 in agitazione. L'estratto ottenuto da ogni campione è stato raccolto e filtrato su un filtro sterile da 0,45 µm. Ciascun filtro è stato tagliato a metà, una metà è stata posta su una piastra di Tryptone Soya Agar (TSA) e incubata per 72 ore a 32 ± 2℃ per la ricerca dei batteri mesofili aerobi, l'altra metà su una piastra di Potato Dextrose Agar (POT) e incubata a 22 ± 2℃ per 5 giorni per la ricerca di muffe e lieviti . I risultati ottenuti sono stati moltiplicati per il fattore di correzione (1,8 – 1,82) ricavato dalla validazione del metodo (vedi Rapporto di Prova N° 20-0600-01).

VIA BENINI 13– 40069 ZOLA PREDOSA BO – TEL +39-051755295 – FAX +39-051754622
www.biochem-bcm.com E-mail: info@biochem-bcm.com - C.F. e P.IVA IT 03531810376 – R.E.A. BO-297535

Risultati

Unità campione	Batteri mesofili aerobi (ufc/campione)	Muffe (ufc/campione)	Lieviti (ufc/campione)
1	<2	<2	<2
2	<2	<2	<2
3	<2	<2	<2
4	<2	<2	<2
5	<2	<2	<2
Valore medio	**<2,0**	**<2,0**	**<2,0**
Fattore di correzione	1,8	1,82	1,82
Valore corretto	**<3,6**	**<3,6**	**<3,6**
Valore per grammo	**<2**	**<2**	**<2**

SOMMA DEI MICROORGANISMI: <6 ufc\grammo

PARERI ED INTERPRETAZIONI – Non oggetto dell'accreditamento ACCREDIA

Conformità alla EN 14683:2019 5.2.5 Microbial cleanliness (Bioburden): In conformità

Il presente Rapporto di Prova è riferito esclusivamente al campione esaminato.
Nel caso in cui il campione sia stato fornito dal Cliente, i risultati si applicano al campione così come ricevuto.
Il presente Rapporto di Prova non può essere riprodotto parzialmente, salvo approvazione scritta di Biochem.

(#) Dati forniti dal Cliente. Il laboratorio declina la responsabilità di tali dati.

Prova verificata da: Buriani Giampaolo, PhD.

Emissione autorizzata da:
Responsabile del Laboratorio Ing. Giovanni Bassini

FINE RAPPORTO DI PROVA

VIA BENINI 13– 40069 ZOLA PREDOSA BO – TEL +39-051755295 – FAX +39-051754622
www.biochem-bcm.com E-mail: info@biochem-bcm.com - C.F. e P.IVA IT 03531810376 – R.E.A. BO-297535

Final Report 2012/2325 SAMi

CYTOTOXICITY - DIRECT CONTACT ON "SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE"

Study Program: 2012/2325 SAM

Contract n.: PCSA2012019701

Sponsor: UNION INDUSTRIES SPA
VIA 2 GIUGNO, 80
13866 – MASSERANO (BI)
ITALIA

Test item: SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE

Study Director: Cristina Giarei (Dr. C. Giarei)

Released on: Jan 10th 2013

Eurofins Biolab S.r.l.
Società con Socio unico sottoposta
a direzione e coordinamento della società
Eurofins Scientific Italia S.r.l.
parte di Eurofins Scientific Group
http://pharma.eurofins.com/

Via Bruno Buozzi, 2
20090 Vimodrone (MI) - Italia
Tel. + 39-022507151
Fax + 39-0225071599
biolab@eurofins.com
www.eurofins.it www.biolab.it

C.SOC. € 100.000 i.v.
P. IVA 00762140960
C.F. 03765750157
REA MI 966696
D-U-N-S 429117112
CIT005 4-385

INDEX

SUMMARY

On the test item "SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE" was carried out a toxicological study aimed to evaluate any cytotoxic effects.
The following test was performed:

- cytotoxicity direct contact according to ISO 10993-5:2009

For the **cytotoxicity test by direct contact**, a confluent BalbC 3T3 cell culture in exponential phase of growth was used.
A qualitative evaluation was performed observing cell culture by an inverted microscope, while a quantitative evaluation was performed using the Neutral Red Uptake method (NRU).
The NRU is a method that allow to measure cell vitality using their capacity to incorporate and to bind a cellular vitality dye, the Neutral Red.

The test item was applied to the monolayer of BalbC 3T3 and was incubated at 37°C ±1°C in CO_2 atmosphere for 24 hours.
After 24 hours of incubation the cells were observed to microscope (qualitative evaluation) to evaluate the biological reaction.

After 24 hours of contact, in the cells treated with test product no detectable zone around or under specimen was observed (reactivity grade 0).

After the qualitative evaluation cells were treated for 3 hours with the Medium containing the cell vitality dye and then with a Desorb Solution that allows to obtain a cell lysate. The optic density was than calculated after a 540nm spectrophotometric reading.

Cells treated with test sample have shown a cell vitality reduction of 8.07%.

On the basis of the results, interpreted according to ISO 10993-5:2009, the test item "SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE" must be considered **NOT CYTOTOXIC.**

INTRODUCTION

This study has been carried out on behalf of the Sponsor UNION INDUSTRIES SPA on the item "SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE".

The study was performed at the Test Facility Eurofins Biolab S.r.l. of Vimodrone (MI) – via B. Buozzi n. 2 (Italy).

TEST	*START*	*END*	*RESEARCHER*
Cytotoxicity	02/01/2013	04/01/2013	G. Bizzaro

BIBLIOGRAPHY

ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity

FILING

The study program, all raw data are filed in the archives of Eurofins Biolab S.r.l. for ten years after the issuing of the final report.
No retained sample has been kept.

At the end of the conservation period, the Sponsor may request an extension of the conservation of all or part of the substances for a further period, or their restitution. A suitable agreement shall be drafted in this case.

PROCEDURES

All procedures used during this study are recorded in the Biolab Procedures Manual.

TEST ITEM

The test item consists of a medical device.

Item	SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE
Code	D2508PIW
Stability	Not provided
Sterilization	None
Composition declared by Sponsor	Not provided
Storage	Room temperature, protected from light

TESTED SAMPLE

The specimen analysed, representative of the test item, consists of a white nonwoven sheet.

Batch	70064
Manufacturing date	27/11/2012
Expiry date	Not provided
Receiving	EUITVI-31804
Date	December 13th 2012
#ID	12.3153-S

The characterisation of the test item is under Sponsor responsibility

Experimental Report 2012/2325.A1 – Cytotoxicity direct contact

TEST METHOD

Characterisation
Mammal fibroblasts ATCC BalbC 3T3.

Materials and equipment

Culture medium BalbC 3T3.	
Dulbecco's Modification of Eagle's Medium (DMEM)	(Lonza)
Calf Bovine Serum (CBS)	(ATCC)
Penicillin	(Lonza)
Streptomycin	(Lonza)
Neutral Red dye	(Sigma)
Glacial acetic acid	(Sigma)
Ethanol (ETOH)	(Sigma)
Plastic material for cell culture	(PBI)
Inverted Microscope Diavert	(Lux octica)
Laminar flow filtered work area	(Flow)
CO_2 incubator	(Flow)
USP reference standard	(Nova chimica)
Latex from glove	(Artsana)
Microplate reader Mod EI800-Pc	(Bio-Tek)

Media

Routine culture medium:	DMEM 10% CBS 100 IU/ml penicilin 100 µg/ml streptomycin
Stock Neutral Red solution:	0,4 g NR Dye 100 ml H_2O
Neutral Red Medium:	1 ml NR Stock 79 ml DMEM
Ethanol/acetic acid solution (NRdesorb):	1% Glacial Acetic acid 50% Ethanol 49% H_2O

EXPERIMENTAL DESIGN

The experimental design included a 12 wells plate containing a subconfluent cell monolayer, subdivided in the following groups:

REPLY	GROUP			
1	Blank	Test Sample	Negative control	Positive control
2	Blank	Test Sample	Negative control	Positive control
3	Blank	Test Sample	Negative control	Positive control

PLATE PREPARATION

Samples preparation
Test item was used neat, 30 mm^2 are deposed in the middle of each well.

Negative control preparation
The negative control was represented by 30 mm^2 USP reference standard in the middle of each well.

Positive control preparation
The positive control was represented by 30 mm^2 of latex placed in the middle of each well.

TREATMENT

1 ml of cell suspension were placed from a confluent culture to a plate having 22 mm diameter wells. The plate was incubated at 37°C ±1°C in a 5% CO_2 atmosphere, allowing cell sedimentation and the constitution of a subconfluent monolayer.
Subsequently Medium was replaced and the test sample was added through direct deposition.
The plate was incubated in a thermostat at 37°C ±1°C in a 5% CO_2 atmosphere for 24 hours.
After the 24 hours the plate was observed to an inverted microscope and biological reactions were evaluated following a 1 to 4 scale according to ISO10993-5:2009.
Each well is than treated with 2 ml of Neutral Red Medium for 3 hours. After that each well was washed with PBS and treated with 2 ml of Desorb Solution, the plate was put in a stirring for 10 minutes to homogenize the solution.
The optic density was than calculated after a 540nm spectrophotometric reading.

OBSERVATIONS

Qualitative evaluation

After 24 hours of incubation the plates were observed with an inverted microscope.
The biological reactivity (cell degeneration and malformations) were evaluated after 24 hours of incubation with a scale ranging from 0 to 4, according to ISO 10993-5 as shown in the following table:

GRADE	REACTIVITY	DESCRIPTION OF REACTIVITY ZONE
0	None	No detectable zone around or under specimen
1	Slight	Some malformed or degenerated cells under specimen
2	Mild	Zone limited to area under specimen
3	Moderate	Zone extending specimen size up to 1,0 cm
4	Severe	Zone extending farther than 1,0 cm beyond specimen

Quantitative evaluation

Optical density was measured at 540nm by Gen5 software (Biotek).

$$\%\ \text{of cell viability} = \frac{OD_{\text{test product}} - OD_{\text{blank}}}{OD_{\text{negative control}} - OD_{\text{blank}}} \cdot 100$$

INTERPRETATION OF RESULTS

The achievement of a numerical grade greater than 2 is considered a **cytotoxic** effect.
A cellular vitality reduction more than 30% is considered a **cytotoxic** effect.

ACCEPTABILITY CRITERIA

Qualitative evaluation

Negative control ≤ 1
Positive control ≥ 3

Quantitative evaluation

Standard deviation of each group must be ≤ 18%.
The positive control % cellular vitality must be < 70%

RESULTS

Qualitative evaluation

The Acceptability criteria were satisfied.

REPLICATE	*QUALITATIVE EVALUATION*		
	Test sample	*Negative control*	*Positive control*
1	0	0	4
2	0	0	4
3	0	0	4

After 24 hours of contact, in the cells treated with test product no detectable zone around or under specimen was observed (reactivity grade 0).

Quantitative evaluation

The Acceptability criteria were satisfied.
Cells treated with the positive control have shown a cell vitality of 20.87%.
Cells treated with the assay sample have shown a cell vitality of 91.93%.

REPLICATE	*QUANTITATIVE EVALUATION*			
	Optic density (OD) 540 nm			
	Blank	*Test sample*	*Negative control*	*Positive control*
1	0,075	1,266	1,207	0,309
2	0,069	1,178	1,249	0,309
3	0,068	1,014	1,287	0,331
Average	0,071	1,153	1,248	0,316
S.D.	0,004	0,128	0,040	0,013
S.D. %	/	11,096	3,207	4,015

Cells treated with test sample have shown a cell vitality reduction of 8.07%.

DEVIATION

No deviation has been recorded during the study.

CONCLUSIONS

On the basis of the results, interpreted according to ISO 10993-5:2009, the test item "SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE" must be considered **NOT CYTOTOXIC.**

ADDENDA

//

Final Report 2012/2326 SAMi

SKIN IRRITATION TEST ON "SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE"

Study Program: 2012/2326 SAMi

Contract n.: PCSA2012019701

Sponsor: UNION INDUSTRIES SPA
VIA 2 GIUGNO, 80
13866 – MASSERANO (BI)
ITALY

Test item: SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE

Study Director Chiara Picotti
(Dr. C. Picotti)

Released on: January 22nd 2013

Eurofins Biolab S.r.l.
Società con Socio unico sottoposta
a direzione e coordinamento della società
Eurofins Scientific Italia S.r.l.
parte di Eurofins Scientific Group
http://pharma.eurofins.com/

Via Bruno Buozzi, 2
20090 Vimodrone (MI) - Italia
Tel. + 39-022507151
Fax + 39-0225071599
biolab@eurofins.com
www.eurofins.it www.biolab.it

C.SOC. € 100.000 i.v.
P. IVA 00762140960
C.F. 03765750157
REA MI 966696
D-U-N-S 429117112
CIT005 4-385

INDEX

SUMMARY

On the test item "SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE" was carried out a biological evaluation aimed to identify irritant effects by means of following test:

- Skin irritation according to ISO 10993-10:2010

The **skin irritation test** was carried out through a semi-occlusive application; the test item was applied on the intact skin of 3 rabbits, in the dorsal region both on the left and on the right side.
Each animal had the right caudal region and left cranial region treated with the test item. The right cranial region and the left caudal region were treated with a no irritant humidified gauze (25mm x 25 mm), used as control.

Reactions were evaluated 1 hour after the removal of the patches and were evaluated again at 24, 48 and 72 hours after exposure.

Nothing abnormal was detected in treated sites.

Nothing abnormal was detected in control sites.

PRIMARY SKIN IRRITATION INDEX: 0,00

On the basis of the results, interpreted according to ISO 10993-10:2010, the test item "SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE" must be considered **NOT IRRITANT** for skin.

INTRODUCTION

This study has been carried out on behalf of the Sponsor UNION INDUSTRIES SPA on the product "SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE".

The study was performed at the test Facility Eurofins Biolab S.r.l. of Vimodrone (MI) – via B. Buozzi n. 2 (Italy).

TEST	*START*	*END*	*RESEARCHER*
Skin irritation	14/01/13	17/01/13	A.Moschetti

BIBLIOGRAPHY

- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

FILING

The study program, all raw data are filed in the archives of Eurofins Biolab S.r.l. for ten years after the issuing of the final report.
Retained sample will not be kept.
At the end of the conservation period, the Sponsor may request an extension of the conservation of all or part of the substances for a further period, or their restitution. A suitable agreement shall be drafted in this case.

PROCEDURES
All procedures used during this study are recorded in the Eurofins Biolab Procedures Manual.

TEST ITEM
The test material consists of a medical device.

Item	SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE
Code	D2508PIW
Stability	Not provided
Sterilization	None
Composition declared by Sponsor	Not provided
Storage	Room temperature, protected from light

TESTED SAMPLE
The specimen analysed, representative of the test item, consists of a white nonwoven sheet.

Batch	70064
Manufacturing date	27/11/2012
Expiry date	Not provided
Receiving	EUITVI-31804
Date	December 13th 2012
#ID	12.3154-S

The characterisation of the test item is under Sponsor responsibility

Experimental Report 2012/2326 SAMi– Skin irritation

TEST METHOD

Characterization

Specie:	White rabbits
Strain:	New Zealand
No.:	3
Sex:	male
Weight:	2840-2985 g at the beginning of the test
Supplier:	Allevamento Bettinardi - Momo (NO) – Italy
Food:	Altromin MSK Batch: 1206

Caging

Each rabbit has been caged in NORYL cages (dimensions cm 48.2 x 63 x 37 h).
The housing room are lighted with fluorescent lamps 12 hours for day.
The room temperature and humidity have been regulated by an air conditioning unit and have been monitored continuously. Recordings of the housing conditions are retained in Eurofins Biolab S.r.l. files.

Cleaning and disinfection

The cages and the housing room were cleaned before the animals were accommodated, then cleaning and disinfecting were performed periodically.

Feeding

The animals were fed with standard pellet complete diet supplied by the authorised breeder.

Watering

Filtered tap water from local network was supplied ad libitum.

Animal identification

A numbered tag placed through the edge of the right ear identified the animals selected for the study.
A label identified the cages.

Quarantine

Before being used in this study, the animals were kept in quarantine for one week. During this period they were observed daily.
At the end of the quarantine week the animals were carefully examined in order to evaluate their suitability for the study.

Animal selection

The animals used for this study were selected randomly from those suitable, available at that time.

PREPARATION OF THE ASSAY SAMPLE

The test item was cut in order to obtain pieces of 25 mm x 25 mm.

EXPERIMENTAL DESIGN

Three male white rabbits were used.
Each animal had the right caudal region and left cranial region treated with the test item.
The right cranial region and the left caudal region was treated with a no irritant gauze (25 mm x 25 mm) humidified with physiological solution, used as control. The reactions could be present in the treated area were compared with those of the control area.

TREATMENT

Skin preparation
Approximately 24 hours before the test, the fur was removed from an area approximately 240 cm^2 wide by clipping and shaving the dorsal and flank zones of the animals.
An area of the back, about 6 cm^2 wide, was designed for the application of the test sample.

Application
25 mm x 25 mm of the test product were applied with a gauze directly to the skin of each rabbit and covered with non-occlusive dressing, then the trunk will be protected with a semi-occlusive bandage.

Removal of the patches
The patches were removed 4 hours after the application.

OBSERVATIONS

General conditions of the animals were verified daily. Reactions were evaluated following the removal of the patches and were evaluated again at 24, 48 and 72 hours after exposure.
Skin irritation was scored and recorded according to the scores reported in the following table.

GRADING VALUES

Erythema and eschar formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet redness with slight eschar formation; injuries in depth)	4
Edema formation	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond the area of exposure)	4

INTERPRETATION OF RESULTS

For acute exposure, determine the Primary Irritation Index (PII) as follows.
For each animal, add together the Primary Irritation Scores for the test substance for both erythema and oedema at each time specified and divide by the total number of observations (two test/observation sites, three time points). When vehicle controls are used, calculate the Primary Irritation Score for the vehicle controls and subtract that score from the score for the test substance to obtain the Primary Irritation Score.
Only use 24 hours, 48 hours and 72 hours observations for calculations. Observations made prior to dosing or after 72 hours, to monitor recovery, are not used in the determination.
Add the scores for each animal and divide the total by number of animals. This value is the Primary Irritation Index.
Number and description in follow table characterise the Primary Irritation Index:

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

RESULTS

TIME AFTER REMOVAL OF PATCHES	REACTION	RABBIT N.											
		1254				1261				1265			
		Treated		Control		Treated		Control		Treated		Control	
		Ca dx	Cr sx	Ca sx	Cr dx	Ca dx	Cr sx	Ca sx	Cr dx	Ca dx	Cr sx	Ca sx	Cr dx
60 minutes	Erythema	0	0	0	0	0	0	0	0	0	0	0	0
	Oedema	0	0	0	0	0	0	0	0	0	0	0	0
24 hours	Erythema	0	0	0	0	0	0	0	0	0	0	0	0
	Oedema	0	0	0	0	0	0	0	0	0	0	0	0
48 hours	Erythema	0	0	0	0	0	0	0	0	0	0	0	0
	Oedema	0	0	0	0	0	0	0	0	0	0	0	0
72 hours	Erythema	0	0	0	0	0	0	0	0	0	0	0	0
	Oedema	0	0	0	0	0	0	0	0	0	0	0	0

Nothing abnormal was detected in treated sites.

Nothing abnormal was detected in control sites.

Primary skin irritation Index of the test substance: 0,00
Primary skin irritation Index of control: 0,00

PRIMARY SKIN IRRITATION INDEX: 0,00

DEVIATION

No deviation has been recorded from study program.

CONCLUSIONS

On the basis of the results, interpreted according to ISO 10993-10:2010, the test item "SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE" must be considered **NOT IRRITANT** for the skin.

ADDENDA

\\

Final Report 2012/2327 SAMi

DELAYED HYPERSENSITIVITY TEST
Closed patch Test (Buehler test)
ON SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE

Study Program: 2012/2327 SAM

Contract n.: PCSA2012019701

Sponsor: UNION INDUSTRIES SPA
VIA 2 GIUGNO, 80
13866 – MASSERANO (BI)
ITALY

Test product: SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE

Study Director Chiara Picotti Released on: February 27th 2013
(Dr. C. Picotti)

Eurofins Biolab S.r.l.
Società con Socio unico sottoposta
a direzione e coordinamento della società
Eurofins Scientific Italia S.r.l.
parte di Eurofins Scientific Group
http://pharma.eurofins.com/

Via Bruno Buozzi, 2
20090 Vimodrone (MI) - Italia
Tel. + 39-022507151
Fax + 39-0225071599
biolab@eurofins.com
www.eurofins.it www.biolab.it

C.SOC. € 100.000 i.v.
P. IVA 00762140960
C.F. 03765750157
REA MI 966696
D-U-N-S 429117112
CIT005 4-395

INDEX

SUMMARY

On the test product "SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE" a toxicological study was carried out to evaluate the possible sensitising effects, throughout the following test:

- closed-patch test (Buehler test) according to ISO 10993-10:2010

To perform the **closed-patch test (Buehler test)** 15 guinea pigs were used, 10 treated with the test product and 5 used as control.
The test consists of an induction phase and a challenge phase.
During the induction phase treated guinea pigs were topically treated with the test sample for three consecutive days for three weeks.
The control animals received the same treatment using water for injection (WFI).

28 days after the beginning of treatment, the challenge phase was performed by applying the test product on the untreated side of all the animals. The animals were bandaged and after 6 hours the bandages were removed.

24 and 48 hours after the removal of the bandage, the tested animals and the control animals were observed.

No abnormalities were observed in treated and control animals.

On the basis of the results, interpreted according to ISO 10993-10:2010, the test product "SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE" must be considered **NOT SENSITISING**.

INTRODUCTION

This study has been carried out on behalf of the Sponsor UNION INDUSTRIES SPA on the product "SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE".

The study was performed at the Test Facility Eurofins Biolab S.r.l. of Vimodrone (MI) – via B. Buozzi n. 2 (Italy).

TEST	*START*	*END*	*RESEARCHER*
Buehler test	21/01/13	22/02/13	A.Moschetti

BIBLIOGRAPHY

ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensivity

FILING

The study program, all raw data are filed in the archives of Eurofins Biolab S.r.l. for ten years after the issuing of the final report.
Retained sample has not be kept.
At the end of the conservation period, the Sponsor may request an extension of the conservation of all or part of the products for a further period, or their restitution. A suitable agreement shall be drafted in this case.

PROCEDURES

All procedures used during this study are recorded in the Biolab Procedures Manual.

TEST PRODUCT

The test material consists of a medical device.

Item	SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE
Code	D2508PIW
Stability	Not provided
Sterilization	None
Composition declared by Sponsor	99,5% Polypropylene + 0,5% Durable Hydrophilic Finish
Storage	Room temperature, protected from light

TESTED SAMPLE

The specimen analysed, representative of the test item, consists of a white nonwoven sheet.

Batch	70064
Manufacturing date	27/11/2012
Expiry date	Not provided
Receiving	EUITVI-31804
Date	December 13th 2012
#ID	12.3155-S

The characterisation of the test substance is under Sponsor responsibility

Experimental Report 2012/2327 – Delayed hypersensitivity test -Closed patch test-

TEST METHOD

Characterisation

Species:	Albino guinea pigs
Strain :	Dunkin-Hartley
N.:	15
Sex:	Male
Weight:	300 - 400 g at the arrival at the centre
Supplier:	Bettinardi - Momo (NO)
Food:	Altromin MSK Batch: 1210
Bedding:	Lignocell Batch: 03018121101

Caging

The animals were caged, in groups of five, in transparent polycarbonate cages (dimensions: 590x385x200h mm).
Stabling rooms have been lighted with fluorescent lamps and kept with cycles of 12 hours of light and 12 hours of darkness. Temperature and humidity, controlled by air conditioning system, have been continuously registered.

Cleaning and disinfection

The cages and the housing room were cleaned before the animals were accommodated, then disinfected periodically.

Feeding

Animals have been fed with standard pellet complete diet supplied by the authorised breeder.

Watering

Filtered tap water from local network was supplied ad libitum from an automatic watering system.

Quarantine

Before allocation to the study, the animals were kept in quarantine for five days. During this period they were observed daily.
At the end of the quarantine week the animals were carefully examined in order to evaluate their suitability for the study.

Animals' identification

The animals were identified with an indelible colouring in different areas of the body as:

No sign	(B)	1
Head	(T)	2
Tail	(C)	3
Head-tail	(TC)	4
Right forepaw	(ZAD)	5
Left forepaw	(ZAS)	6
Right hind leg	(ZPD)	7
Left hind leg	(ZPS)	8
Abdomen	(P)	9
Head-abdomen	(TP)	10

PREPARATION OF THE ASSAY SAMPLE

The test item was cut in order to obtain pieces of 25 mm x 25 mm.

EXPERIMENTAL DESIGN

Experimental design consisted of one group of 10 treated animals (group 1) and one group of 5 control animals (group 2). The animals were allocated into groups as follows:

GROUP	INDUCTION PHASE *Day 0, 1, 2* *Day 7, 8, 9* *Day 14, 15, 16*	CHALLENGE PHASE *Day 28*
1	Test product	Test product
2	WFI	Test product

The animals allocated to the study were selected randomly from those suitable, available at that time. At maximum 5 animals for each cage; cages have been identified via a tag.

TREATMENT

Skin preparation

24 hours before testing, fur was removed by shaving a 50 cm^2 wide area on the back of the animals.

Administration

The test sample was used neat.
25 x 25 mm of test sample were applied directly on back of the animals made humidify with sodium chloride injection.

Induction phase

The test sample was administered by topical application to the clipped left upper back region of each animal. Each site was covered by an occlusive dressing.
The dressing was removed after 6 h.
This procedure was performed on three days a week for three weeks.
The control animals were treated using WFI in the same way.

Challenge phase

Fourteen days after the last induction application, all test and control animals were challenged with the test sample.
The test sample was administered by a single topical application to a clipped untested area of each animal.
Each site was covered by an occlusive dressing.
The dressing was removed after 6 h.

OBSERVATIONS

24 hours after removal the patch, and 48 hours after removal the patch all the animals treated and controlled were evaluated for a skin reaction.
The intensity of erythema and/or edema were evaluated according to the following scale:

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

INTERPRETATION OF RESULTS

Magnusson and Kligman grades of 1 ore greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals. If grades of 1 or grater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization.
If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge. The outcome of the test is presented as the frequency of positive challenge results in the test and control animals.

RESULTS

SKIN REACTIONS IN ANIMALS TREATED WITH TEST SAMPLE

ANIMAL N.	TIME AFTER CHALLENGE	
	24 hours	48 hours
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0	0
8	0	0
9	0	0
10	0	0

SKIN REACTIONS IN CONTROL ANIMALS

ANIMAL N.	TIME AFTER CHALLENGE	
	24 hours	48 hours
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0

No abnormalities were observed in treated and control animals.

% sensitising guinea pigs treated: 0%

DEVIATIONS

No deviation has been detected during the study.

CONCLUSIONS

On the basis of the results, interpreted according to ISO 10993-10:2010, the test product "SMS THERMOBONDED NONWOVEN DURABLE HYDROPHILIC, WHITE" must be considered **NOT SENSITIZING**.

ADDENDA

//

union

To whom it may concern

Masserano, 21-04-2020

Biocompatibility Statement accordingly ISO10993-5-10

The Biocompatibility Reports attached n°**2325-2326-2327** of the year 2012 for Cytotoxicity, Skin Irritation, Skin Sensitizing of the article [White, Durable Hydrophilic Polypropylene Spunbond and Polypropylene Melt Blown Thermobonded Nonwoven] covers all the Raw Materials [Polypropylene Spunbond & Polypropylene Melt Blown] used for the production of the article **D4007PHW**.

Gianni Crappa

Quality Assurance Department

Union Industries SpA
Nonwovens

Via 2 Giugno 80
13866 Masserano (BI)
Italia

tel. +39 015 95153
fax +39 015 927240
telegr. Union Masserano
e-mail: info@unionindustries.it

P. IVA e C.F. 01484660020
Cod. CEE IT 01484660020
CCIAA Biella n. 141972
meccanografico BI 000330

Capitale Sociale
€ 10.500.000 int. versato
Registro Imprese
CCIAA di Biella n. 10246