



BARBARO  
**DEFENDER**  
MASK

# CERTIFICATO

*SU MATERIE PRIME UTILIZZATE  
E CICLO PRODUTTIVO*

*L'azienda Nutis s.r.l. autocertifica che per la produzione delle mascherine denominata Barbaro Defender Mask, vengono impiegati i seguenti materiali:*

*Corpo mascherina :  
PVC USO MEDICALE*

*Filtrini*

*POLIPROPILENE USO ALIMENTARE  
CARTA POLITENATA FILTRANTE USO ALIMENTARE*

*Per i suddetti materiali si garantisce  
che sono difficilmente infiammabili e non arrecano danni  
al contatto umano. Come dai certificati allegati.*

*All'interno del nostro Stabilimento di produzione sito in  
Via Sant Antonio Abate Traversa di Vittorio SNC Scafati (SA)  
si garantisce l'applicazione del sistema  
HAZARD ANALYSIS CRITICAL CONTROL POINTS,  
in ottemperanza del reg. (CE)852/04.*

*Firma e timbro*  
**NUTIS S.r.l.**  
**L'Amministratore**



**100%**  
**MADE IN ITALY**



## CITOTOSSICITÀ IN VITRO

Campione

Compound

- |                 |                 |                 |                 |                  |
|-----------------|-----------------|-----------------|-----------------|------------------|
| 1. RB1/DU DEHT  | 2. RB2 DEHT     | 3. RB2/M DEHT   | 4. RB1/T3M DEHT | 5. RB1/T3MS DEHT |
| 6. RB1 DEHT     | 7. RB3/D DEHT   | 8. RB3 DEHT     | 9. RB3/N DEHT   | 10. RB3/M DEHT   |
| 11. RB4 DEHT    | 12. RB/LL DEHT  | 13. RB6 DEHT    | 14. RB5/D DEHT  | 15. RB5 DEHT     |
| 16. RB5/N DEHT  | 17. RB5/M DEHT  | 18. RB1/S1 DEHT | 19. RB1/S2 DEHT | 20. RB1/S3 DEHT  |
| 21. RB1/S4 DEHT | 22. RB/SMR DEHT |                 |                 |                  |

Rapporto di Prova N°0808-1/15

Prova eseguita per

**MODENPLAST MEDICAL S.r.l.**  
Via Montegrappa, 24/26  
41040 UBERSETTO FIORANO MO

da

**BIOCHEM S.A.S.**  
Via Benini 13  
40069 ZOLA PREDOSA BO

### **Gestione Qualità**

Responsabile Gestione Qualità: Dr.ssa Alessandra Marchesi, PhD

### **Responsabile del Laboratorio**

Ing. Giovanni Bassini

### **Tempistica della Prova**

La Prova è stata iniziata il 08/06/2015 ed è stata terminata il 11/06/2015.

Rif. Vs. ordine N. 211 del 27/05/2015

### Descrizione campione

Denominazione: Compound

Codice: 1. RB1/DU DEHT 2. RB2 DEHT 3. RB2/M DEHT 4. RB1/T3M DEHT 5. RB1/T3MS DEHT 6. RB1 DEHT 7. RB3/D DEHT 8. RB3 DEHT 9. RB3/N DEHT 10. RB3/M DEHT 11. RB4 DEHT 12. RB/LL DEHT 13. RB6 DEHT 14. RB5/D DEHT 15. RB5 DEHT 16. RB5/N DEHT 17. RB5/M DEHT 18. RB1/S1 DEHT 19. RB1/S2 DEHT 20. RB1/S3 DEHT 21. RB1/S4 DEHT 22. RB/SMR DEHT

Lotto: n.r.

Sterilizzazione: NO

Numero di ricevimento: 0808-1

Data di ricevimento: 28/05/2015

Campionamento effettuato da: MODENPLAST MEDICAL S.r.l.

### Metodo di prova

ISO 10993-5: 2009

**Sommario del metodo:** Le cellule sono fatte crescere in piastre fino ad ottenere un monostrato quasi confluyente. Per ciascun campione vengono preparate tre piastre di coltura cellulare. Inoltre vengono preparate tre piastre per il controllo negativo, tre per il controllo positivo e tre per il controllo liquido di estrazione. Nelle piastre da trattare con il campione, il terreno viene aspirato e sostituito con l'estratto del campione. Le colture cellulari vengono esaminate microscopicamente dopo 24 e 48 ore di incubazione con l'estratto e viene valutata l'eventuale presenza di effetti citotossici prodotti dall'estratto del campione.

**Cellule:** BSCL 56 /L 929 (tessuto connettivo di topo).

**Condizioni di estrazione:** 0,2 grammi del campione in esame sono stati sottoposti ad estrazione con 1,0 ml di terreno di coltura cellulare MEM con 5 % di siero a 37°C per 24 ore.

**Reagenti:** MEM con sali di earle's addizionato di siero bovino fetale, l-glutamina e antibiotici.

**Controllo positivo:** Lattice.

**Controllo negativo:** 4 g di policarbonato trattato come il campione.

**Incubazione:** le piastre trattate con l'estratto del campione in esame, quelle con i controlli positivi e negativi e quelle con il controllo liquido di estrazione vengono incubate per 48 ore a  $37 \pm 1^\circ\text{C}$  in atmosfera al 5% di  $\text{CO}_2$ .

### Apparecchiature

Termostato a  $\text{CO}_2$  (5%), mantenuto a  $37 \pm 1^\circ\text{C}$ ;  
Microscopio ottico a fase inversa;  
Cappa a flusso laminare sterile;  
Materiali monouso sterili;  
Piastrine per colture cellulari.

**Valutazione degli effetti e interpretazione dei risultati:** La citotossicità viene valutata per via qualitativa mediante esame microscopico delle cellule dopo 24 e 48 ore di incubazione. Vengono valutate la morfologia generale, la presenza di vacuolizzazione, distacchi, lisi cellulare, integrità delle membrane. Agli scostamenti rispetto alla morfologia normale evidenziata dal controllo negativo viene attribuito un punteggio da 0 a 4 (vedi sistema di punteggio). Inoltre per le piastre trattate con gli estratti del campione viene valutata la confluenza del monostrato e viene confrontata la colorazione del terreno di coltura con quella del terreno delle piastre del controllo negativo.

### Sistema di punteggio

Grado	Reattività	Descrizione reattività
0	nessuna	discreta quantità di granulazioni intracellulari; nessuna lisi cellulare
1	lieve	non più del 20% delle cellule sono rotondeggianti, approssimativamente attaccate e senza granulazioni intracellulari; occasionale presenza di lisi cellulare
2	leggera	non più del 50% delle cellule sono rotondeggianti e senza granulazioni intracellulari; non estesa presenza di lisi cellulare e aree vuote fra le cellule
3	moderata	non più del 70% dello strato cellulare contiene cellule rotondeggianti o lise
4	severa	quasi completa distruzione dello strato cellulare

**Risultati dopo 24 h di incubazione****Punteggio**

Controllo positivo	4
Controllo positivo	4
Controllo positivo	4
Controllo negativo	0
Controllo negativo	0
Controllo negativo	0
Controllo MEM	0
Controllo MEM	0
Controllo MEM	0
Estratto del campione	0
Estratto del campione	0
Estratto del campione	0
Confluenza del monostrato	Confluente
Colore del terreno di coltura	Comparabile al terreno del controllo negativo

**Risultati dopo 48 h di incubazione****Punteggio**

Controllo positivo	4
Controllo positivo	4
Controllo positivo	4
Controllo negativo	0
Controllo negativo	0
Controllo negativo	0
Controllo MEM	0
Controllo MEM	0
Controllo MEM	0
Estratto del campione	0
Estratto del campione	0
Estratto del campione	0
Confluenza del monostrato	Confluente
Colore del terreno di coltura	Comparabile al terreno del controllo negativo

## PARERI ED INTERPRETAZIONI – Non oggetto dell'accREDITAMENTO ACCREDIA

All'esame microscopico le cellule trattate con l'estratto del campione dopo 24 e 48 ore di incubazione non hanno mostrato scostamenti rispetto alla morfologia normale evidenziata dal controllo negativo. L'estratto del campione in esame non mostra nessuna reattività.

Il presente Rapporto di Prova è riferito esclusivamente al campione esaminato.  
Il presente Rapporto di Prova non può essere riprodotto parzialmente, salvo approvazione scritta di Biochem.

Prova eseguita da: Dr.ssa Bongiovanni Lorena

Prova verificata da: Dr.ssa Guardiani Silvia

Emissione autorizzata da:  
Responsabile del Laboratorio Ing. Giovanni Bassini (La firma può trovarsi a fondo pagina)

Zola Predosa, 17/06/2015





ISO 9001

# The Certification Certificate Of Quality Management System

Certificate No. : 04916Q10278R0M

According to your organization's application, our centre carried out audit and certification in accordance with the requirements for *Quality Management System* (GB/T19001-2008/ISO9001:2008), it accords with the requirements through assessment.

The scope of the certified QMS is:

**The production and service of teabag filter paper, desiccant paper**

*Initial date: 2016-3-10*

*Term of validity of this certificate: 2016-3-10 to 2019-3-9*

The certified organization shall be subject to annual supervision of CTC during the validity period.  
The Certificate is only valid with the annual surveillance labels. The certificate information can be found at the CNCA's official website ([www.cnca.gov.cn](http://www.cnca.gov.cn)).

The first  
surveillance

The second  
surveillance

The third  
surveillance



Chairman

MANAGEMENT SYSTEM  
CNAS C049-Q

**Guangdong Quality Testing CTC Certification Co., Ltd.**

Address: 3<sup>rd</sup> Floor, Haicheng Xi Street, Xingangdong Road, Haizhu District,  
Guangzhou, Guangdong, P.R.C.

Tel.: 86-020-89232333 Fax: 86-020-89232078

Website: [www.qtctc.org](http://www.qtctc.org) P.C.:510330



The following sample(s) was/were submitted and identified on behalf of the clients as : FILTER PAPER

SGS Job No. : SP19-007316 - SH  
Date of Sample Received : 12 Mar 2019  
Testing Period : 12 Mar 2019 - 14 Mar 2019  
Test Requested : Selected test(s) as requested by client.  
Test Method : Please refer to next page(s).  
Test Results : Please refer to next page(s).

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

Helen Liu  
Approved Signatory



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: [CN.Doccheck@sgs.com](mailto:CN.Doccheck@sgs.com)  
3<sup>rd</sup> Building, No. 889 Yishan Road Xuhui District, Shanghai, China 200233 1 E&E (86-21) 61402553 1 E&E (86-21) 64953679 [www.sgs.com.cn](http://www.sgs.com.cn)  
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 1 HL (86-21) 61402594 1 HL (86-21) 61156899 e [sgs.china@sgs.com](mailto:sgs.china@sgs.com)

Member of the SGS Group (SGS SA)

## Test Report

No. SHAEC1904364101

Date: 14 Mar 2019

Page 2 of 5

Test Results :

### Test Part Description :

Specimen No.	SGS Sample ID	Description
SN1	SHA19-043641.001	White paper

Remarks :

- (1) 1 mg/kg = 0.0001%
- (2) MDL = Method Detection Limit
- (3) ND = Not Detected ( < MDL )
- (4) "-" = Not Regulated

### RoHS Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU

Test Method : With reference to IEC 62321-4:2013+AMD1:2017, IEC62321-5:2013, IEC62321-7-2:2017 and IEC 62321-6:2015, analyzed by ICP-OES, UV-Vis and GC-MS.

Test Item(s)	Limit	Unit	MDL	001
Cadmium (Cd)	100	mg/kg	2	ND
Lead (Pb)	1000	mg/kg	2	ND
Mercury (Hg)	1000	mg/kg	2	ND
Hexavalent Chromium (Cr(VI))	1000	mg/kg	8	ND
Sum of PBBs	1000	mg/kg	-	ND
Monobromobiphenyl	-	mg/kg	5	ND
Dibromobiphenyl	-	mg/kg	5	ND
Tribromobiphenyl	-	mg/kg	5	ND
Tetrabromobiphenyl	-	mg/kg	5	ND
Pentabromobiphenyl	-	mg/kg	5	ND
Hexabromobiphenyl	-	mg/kg	5	ND
Heptabromobiphenyl	-	mg/kg	5	ND
Octabromobiphenyl	-	mg/kg	5	ND
Nonabromobiphenyl	-	mg/kg	5	ND
Decabromobiphenyl	-	mg/kg	5	ND
Sum of PBDEs	1000	mg/kg	-	ND
Monobromodiphenyl ether	-	mg/kg	5	ND
Dibromodiphenyl ether	-	mg/kg	5	ND
Tribromodiphenyl ether	-	mg/kg	5	ND
Tetrabromodiphenyl ether	-	mg/kg	5	ND



SGS-CTI (Technical Services) (Shanghai) Co., Ltd.  
Inspection & Testing Services  
Testing Center-CHINA

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephones: (86-755) 8307 1443, or email: [CN\\_Doccheck@sgs.com](mailto:CN_Doccheck@sgs.com)

3<sup>rd</sup> Building, No. 889 Yachen Road, Xuhui District, Shanghai, China 200233 | E&E (86-21) 61402553 | F&E (86-21) 64953679 | [www.sgs.com.cn](http://www.sgs.com.cn)  
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 | T HL (86-21) 61402594 | F HL (86-21) 61156899 | e [sgs.china@sgs.com](mailto:sgs.china@sgs.com)

## Test Report

No. SHAEC1904364101

Date: 14 Mar 2019

Page 3 of 5

Test Item(s)	Limit	Unit	MDL	001
Pentabromodiphenyl ether	-	mg/kg	5	ND
Hexabromodiphenyl ether	-	mg/kg	5	ND
Heptabromodiphenyl ether	-	mg/kg	5	ND
Octabromodiphenyl ether	-	mg/kg	5	ND
Nonabromodiphenyl ether	-	mg/kg	5	ND
Decabromodiphenyl ether	-	mg/kg	5	ND

### Notes :

- (1)The maximum permissible limit is quoted from RoHS Directive (EU) 2015/863. IEC 62321 series is equivalent to EN 62321 series  
[http://www.cenelec.eu/dyn/www/f?p=104:30:1742232870351101:::FSP\\_ORG\\_ID,FSP\\_LANG\\_ID:1258637,25](http://www.cenelec.eu/dyn/www/f?p=104:30:1742232870351101:::FSP_ORG_ID,FSP_LANG_ID:1258637,25)
- (2)On 4 June 2015, Commission Directive (EU) 2015/863 was published in the Official Journal of the European Union (OJEU) to include the phthalates BBP, DBP, DEHP and DIBP into ANNEX II of the Rohs Recast Directive. The new law restricts each phthalate to no more than 0.1% in each homogeneous material of an electrical product.
- (3)The restriction of DEHP, BBP, DBP and DIBP shall apply to medical devices, including in vitro medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, from 22 July 2021.
- (4)The restriction of DEHP, BBP, DBP and DIBP shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of EEE placed on the market before 22 July 2019, and of medical devices, including in vitro medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, placed on the market before 22 July 2021.
- (5)The restriction of DEHP, BBP and DBP shall not apply to toys which are already subject to the restriction of DEHP, BBP and DBP through entry 51 of Annex XVII to Regulation (EC) No 1907/2006.



SGS-CTI (Technical Services) (Shanghai) Co., Ltd.  
 Testing Center-China

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

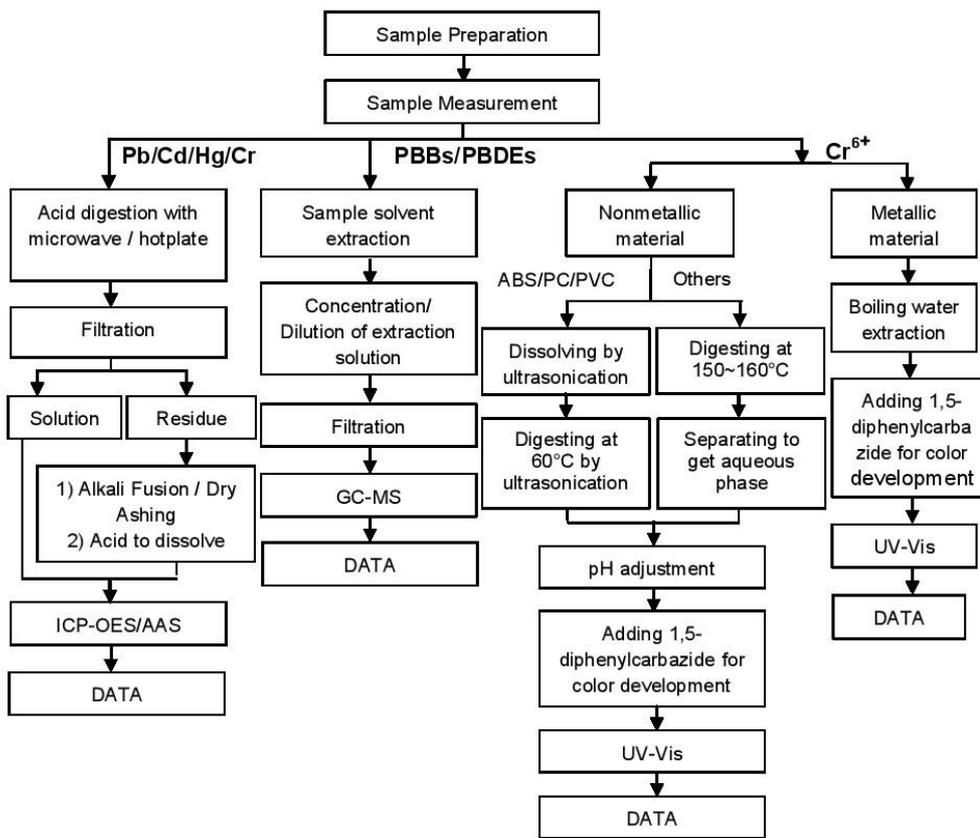
Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephones: (86-755) 8307 1443, or email: [CN.Doccheck@sgs.com](mailto:CN.Doccheck@sgs.com)  
 3<sup>rd</sup> Building, No. 889 Yatan Road, Xuhui District, Shanghai, China 200233 1 E&E (86-21) 61402553 f E&E (86-21) 64953679 www.sgs.com.cn  
 中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t HL (86-21) 61402594 f HL (86-21) 61156899 e sgs.china@sgs.com

Member of the SGS Group (SGS SA)

ATTACHMENTS

Pb/Cd/Hg/Cr<sup>6+</sup>/PBBs/PBDEs Testing Flow Chart

1) These samples were dissolved totally by pre-conditioning method according to below flow chart. (Cr<sup>6+</sup> and PBBs/PBDEs test method excluded)



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

SGS CST (China) Technical Services (Shanghai) Co. Ltd.  
Testing Center - China

Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com  
3<sup>rd</sup> Building, No. 889 Yishan Road Xuhui District Shanghai China 200233 t E&E (86-21) 61402553 f E&E (86-21) 64953679 www.sgs.com.cn  
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t HL (86-21) 61402594 f HL (86-21) 61156899 e sgs.china@sgs.com



**Test Report**

No. SHAEC1904364101

Date: 14 Mar 2019

Page 5 of 5

Sample photo:



SGS authenticate the photo on original report only

\*\*\* End of Report \*\*\*



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

Attention: To check the authenticity of testing / inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: [CN.Doccheck@sgs.com](mailto:CN.Doccheck@sgs.com)

SGS CSTC (Shanghai) Technical Services (China) Co. Ltd.  
Testing Center-Client Technical Services

3<sup>rd</sup> Building, No. 889 Yishan Road Xuhui District Shanghai China 200233 f E&E (86-21) 61402553 f E&E (86-21) 64953679 www.sgs.com.cn  
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t HL (86-21) 61402594 f HL (86-21) 61156899 e [sgs.china@sgs.com](mailto:sgs.china@sgs.com)

Member of the SGS Group (SGS SA)

ROLLS ,ATHER PRODUCTION TEST

筒号 MATHER ROLL	127 上	127 下	128	126	121	123
定量 g/m <sup>2</sup> weight	27,2	27,6	26,6	26,8	24,8	27,5
厚度 thickness µm	86,7	101	70	66	77	78,2
紧度 Tightness g/m <sup>3</sup>	0,388	0,348	0,38	0,406	0,322	0,352
抗张强度 tensile strength (干) KN/m	纵向 MD 0,822	0,893	1,125	1,013	0,793	1,062
	横向 CD 0,472	0,487	0,437	0,527	0,368	0,6
热封强度- Heat seal strength KN/m	0,198	0,197	0,194	0,188	0,188	0,22
透气度- Air permeability L/m <sup>2</sup> .S	761	852	788	805	1220	733
水分 MOISTURE	5,70%	4,90%	5,40%	5,70%	5,80%	5,50%