P R O T O C O L № 38-1/26.05.2020

of virological testing of a medical mask

Article: A three-layer disposable medical mask DD02/20, 5 samples
Article material:
- first layer of 25 g nonwovens spunbond polypropylene with hydrophobic treatment;
- second layer 30 g filter non-woven textile meltbond polypropylene;
- third layer 25 g nonwovens spunbond polypropylene.

Manufacturer: DOR - DIS LTD., 1 Iskra Str., Pazardzhik 4400, Bulgaria

In the laboratory "Virology", Faculty of Biology at Sofia University "St. Cl. Ohridski" e is tested a three-layer medical mask, made of nonwovens spunbond and meltbond polypropylene of company DOR - DIS LTD. in accordance with the scope of EN 14683:2019+AC.

The mask is treated once in a sterile environment, in sterile vacuum apparatus with pre-placed plates with a specific coating to capture viral particles. The treatment is carried out in the form of an aerosol, which contains a human virus with a high concentration to moisten the surface of the studied objects. Viral particles are similar in size to coronaviruses. Subsequently, a suction with a capacity of 20 millibars is applied. The coating is treated with cell culture medium, after which the medium is inoculated into microplates with a cell monolayer.

After 48 hours of culturing at 37°C, no viral cytopathic effect was visually detected in the samples from the mask treatment which was also confirmed by the lack of viral titer. The amount of virus detected in the control sample corresponded to the baseline

P R O T O C O L № 38-2/26.05.2020

of Bacterial Filtration Efficiency and Differential Pressure testing of medical mask

Article: A three-layer disposable medical mask DD02/20, 5 samples
Article material:
- first layer of 25 g nonwovens spunbond polypropylene with hydrophobic treatment;
- second layer 30 g filter non-woven textile meltbond polypropylene;
- third layer 25 g nonwovens spunbond polypropylene.

Manufacturer: DOR - DIS LTD., 1 Iskra Str., Pazardzhik 4400, Bulgaria

The procedure was performed to determine the bacterial filtration efficiency (BFE) of the filtration materials, employing a ratio of the bacterial challenge counts to test article effluent counts to determine percent bacterial filtration efficiency (%BFE). This procedure provides a more severe challenge to most filtration materials than would be expected in normal use. This method complies with ASTM F2101/ EN 14683 Annex B.

The differential pressure (ΔP or Delta P) test determined the air exchange differential of porous materials. The technique involved a simple application of a basic physical principle employing a manometer differential upstream and downstream of the test material, at a constant flow rate. This method complies with EN 14683 Annex C.

Test side: Outside
Area tested: ~75 mm diameter
BFE Flow Rate: 28.3 L/min
Delta P Flow Rate: 8 L/min

Results:

Test Article	Percent BFE (%)	Delta P (Pa/cm^2)
01	>99.9*	37.26
02	>99.9*	38.25
03	>99.9*	35.30
04	>99.9*	40.00
05	>99.9*	38.25

* There were no detected colonies on any of the Andersen sampler plates for this test article.

Mean Positive Control Count: 2,552 colony forming units (CFU)
Negative Control Count: <1 CFU
Mean Particle Size: 3.0 µm

P R O T O C O L № 38-3/26.05.2020

of Microbial Cleanliness (Bioburden) testing of medical mask

Article: A three-layer disposable medical mask DD02/20, 5 samples
Article material:
- first layer of 25 g nonwovens spunbond polypropylene with hydrophobic treatment;
- second layer 30 g filter non-woven textile meltbond polypropylene;
- third layer 25 g nonwovens spunbond polypropylene.

Manufacturer: DOR - DIS LTD., 1 Iskra Str., Pazardzhik 4400, Bulgaria

The testing was conducted in accordance with EN 14683:2019+AC, with bottle size, approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a validated software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms.

Results:

Test Article	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
01	74.4	9*	15	14.8	0.2
02	74.6	9*	6	14.7	0.2
03	74.4	9*	15	20.1	0.3
04	75.3	12*	3	14.8	0.2
05	73.2	17*	3	23.7	0.3

Note: The results are reported as colony forming units (CPU) per mask.
Note: Sample positive testing was performed using Bacillus atrophaeus.
*Spreader. Count is considered a minimum estimate due to swarming of certain colonies on the membrane.

Procedure:

Positive Controls/Monitors: *Bacillus atrophaeus*
Extract Fluid: Peptone Tween® with Sodium Chloride
Extract Fluid Volume: ~600 mL
Extract Method: Orbital Shaking for 5 minutes at 250 rpm
Plating Method: Membrane Filtration
Agar Medium: Tryptic Soy Agar
Sabouraud Dextrose Agar with Chloramphenicol
Aerobic Bacteria: Plates were incubated 3 days at 30-35°C, then enumerated.
Fungal: Plates were incubated 7 days at 20-25°C, then enumerated.

CONCLUSION:

The provided three-layer medical mask protects 100% of viruses the size of SARS-Co-2 when inhaling aerosols containing them. Mask is for single-use.

26.05.2020 Signature:

/ Prof. Dr. St. Shishkov/

Acondicionamiento Tarrasense
C/ de la Innovació, 2 - 08225 Terrassa (Barcelona)
Tel. +34 93 788 23 00 – Fax +34 93 789 19 06
leitat@leitat.org - http://www.leitat.org

DOR-DIS LTD.
ISKRA 1
4400 - PAZARDZHIK
BULGARIA

INFORME TÉCNICO

Informe Nº: IN-01119/2020-1
Total páginas: 7

MUESTRA PRESENTADA

Descripción muestra:

De acuerdo a la información facilitada por el solicitante:

Descripción del producto: MASCARILLA QUIRÚRGICA 3 CAPAS; Referencia: 1ª CAPA 25g SEANBOND POLIPROPILENO NO TEJIDO, 2ª CAPA 30g TEXTIL POLIPROPILENO, 3ª CAPA 25g POLIPROPILENO NO TEJIDO

Fecha de entrada: 08/07/2020

DETERMINACIONES SOLICITADAS

- Ensayo(s) según EN 14683:2019+AC:2019, apartado 5.2.4
  - ROPA PARA LA PROTECCIÓN CONTRA AGENTES INFECCIOSOS. MÁSCARAS FACIALES MÉDICAS. MÉTODO DE ENSAYO DE RESISTENCIA A LA PENETRACIÓN DE SANGRE SINTÉTICA (VOLUMEN FIJO, PROYECTADO HORIZONTALMENTE). Norma: ISO 22609:2004-12

Firmado digitalmente por Albert Briz Aguilar
Nombre de reconocimiento (DN): c=ES, cn=Albert Briz Aguilar, email=legal@leitat.org, serialNumber=46237530D, sn=Briz Aguilar, givenName=Albert, 1.3.6.1.4.1.17326.30.3=G08360232, o=ACONDICIONAMIENTO TARRASENSE, ou=STA, title=RESPONSABLE TÉCNICO MATERIALES, 2.5.4.13=Qualified Certificate: CAM-PF-SW-KPSC
Fecha: 2020.07.16 17:16:55 +02'00'
Versión de Adobe Acrobat Reader: 2020.009.20074

Responsable Técnico STA – Área de Materiales
Albert Briz

Firmado digitalmente por 52397104E JORGE JAMILENA (C:G08360232)
Nombre de reconocimiento (DN): cn=52397104E JORGE JAMILENA (C:G08360232), givenName=JORGE, sn=JAMILENA CARRASCO, serialNumber=IDCES-52397104E, title=DIRECTOR LABORATORIO STA, 2.5.4.97=VATES-G08360232, ou=STA, o=ACONDICIONAMIENTO TARRASENSE, c=ES
Fecha: 2020.07.16 17:24:30 +02'00'

Director de Laboratorio STA
Jordi Jamilena

Terrassa, 16 de julio, 2020

El/los ensayo/s que recoge/n el presente informe ha/n sido realizado/s bajo criterios de Buenas Prácticas Medioambientales, considerando la minimización del consumo de recursos naturales, la reducción en la generación de residuos y emisión de contaminantes a agua y aire, así como la utilización de las mejores técnicas disponibles al alcance de nuestro laboratorio.

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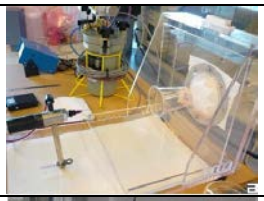
ROPA PARA LA PROTECCIÓN CONTRA AGENTES INFECCIOSOS. MÁSCARAS FACIALES MÉDICAS. MÉTODO DE ENSAYO DE RESISTENCIA A LA PENETRACIÓN DE SANGRE SINTÉTICA (VOLUMEN FIJO, PROYECTADO HORIZONTALMENTE).

Norma: ISO 22609:2004-12
Según: EN 14683:2019+AC:2019, apartado 5.2.4 (“Resistencia a las salpicaduras”)

Alcance: Esta Norma describe un método de ensayo para medir la resistencia de las máscaras faciales médicas a la penetración de una salpicadura de sangre sintética a una velocidad y a un volumen correspondientes a una cierta presión arterial. Se evalúa la parte de atrás de la máscara por medio de inspección visual y valorando si ha habido penetración de líquidos en la misma.

Equipos de ensayo:

	Equipo de salpicaduras de sangre sintética NORDSON EFD, nº EQ2572
	Cámara climática CTS C+10/350, nº EQ209

Acondicionamiento de las muestras: ≥ 4 horas a (21 ± 5) ºC y (85 ± 10) % h.r.

Condiciones de ensayo:

Identificación del material de ensayo: De acuerdo a la información facilitada por el solicitante
- *Descripción del producto: MASCARILLA QUIRÚRGICA 3 CAPAS; Referencia: 1ª CAPA 25g SEANBOND POLIPROPILENO NO TEJIDO, 2ª CAPA 30g TEXTIL POLIPROPILENO, 3ª CAPA 25g POLIPROPILENO NO TEJIDO*

Atmósfera de ensayo: 20ºC ± 2ºC y 65% h.r. ± 4% h.r.

Número de mascarillas ensayadas: 32 (AQL = 4%)

Tensión superficial de la sangre sintética: 42,75 mN/m

Presión de ensayo*:* 16 kPa (120mm de Hg)

Velocidad salpicadura: 550 cm/s

Volumen de sangre sintética recogido*:* 2 ml

Procedimiento:
1) Acondicionar las muestras a (21 ± 5)ºC y (85 ± 5)% h.r. durante un mínimo de 4 horas.
2) Extraer de la cámara climática la máscara a ensayar y, en menos de 60 segundos, realizar la salpicadura en las condiciones indicadas.
3) Valoración visual de la capa interior.
4) Anotar si ha habido penetración de sangre sintética después de (10 ± 1) segundos de la salpicadura.
5) Repetir proceso con el resto de las muestras.

Fecha de realización: 13 – 15 de julio, 2020

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Resultados:

Muestra	Evaluación visual tras la salpicadura (presión 16 kPa)	
	OK	NO OK
1	X	
2	X	
3	X	
4	X	
5	X	
6	X	
7	X	
8	X	
9	X	
10	X	
11	X	
12	X	
13	X	
14	X	
15	X	
16	X	
17	X	
18	X	
19	X	
20	X	
21	X	
22	X	
23	X	
24	X	
25	X	
26	X	
27	X	
28	X	
29	X	
30	X	
31	X	
32	X	
Para que el ensayo sea considerado como conforme no pueden fallar más de 3 muestras para cada presión aplicada.		

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Fotografías tras el ensayo:

Descripción del producto: MASCARILLA QUIRÚRGICA 3 CAPAS; Referencia: 1ª CAPA 25g SEANBOND POLIPROPILENO NO TEJIDO, 2ª CAPA 30g TEXTIL POLIPROPILENO, 3ª CAPA 25g POLIPROPILENO NO TEJIDO

Cara exterior: Salpicadura de sangre sintética visible.

Cara interior: No se observa coloración de sangre sintética u otro tipo de penetración líquida.

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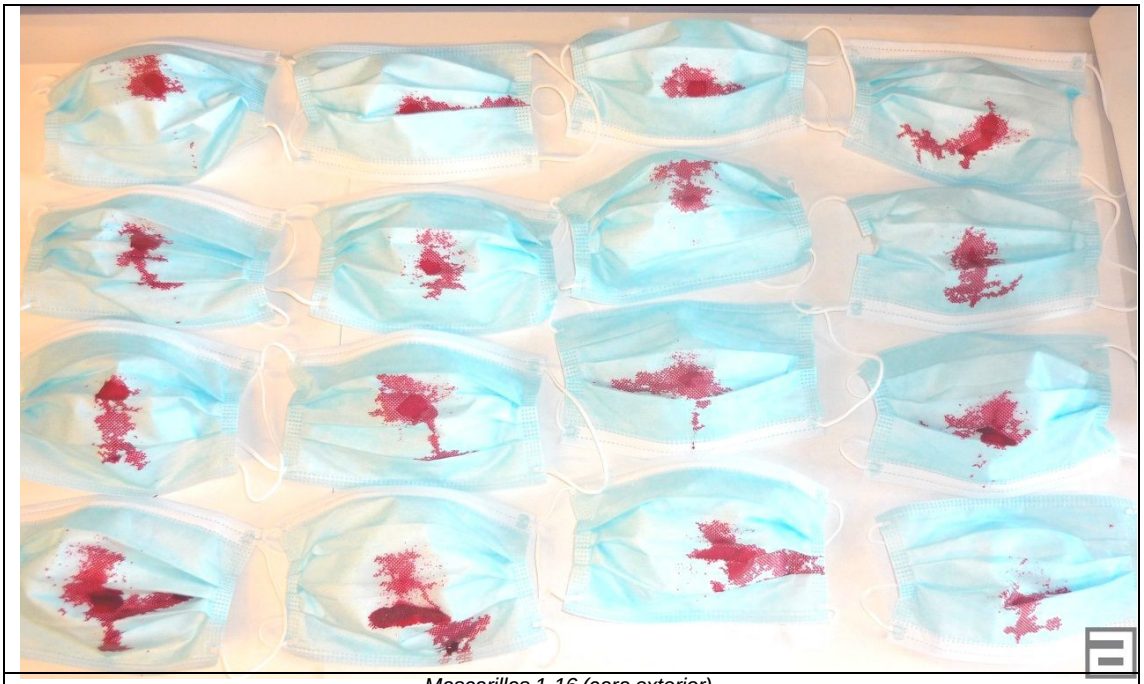
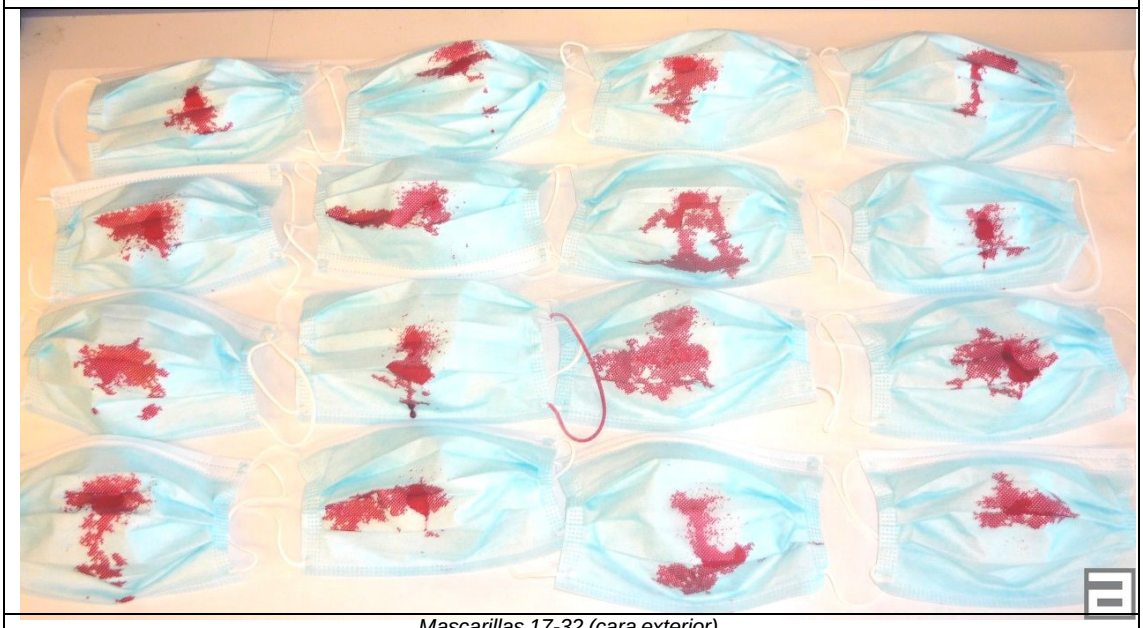


Mascarillas 1-16 (cara exterior).



Mascarillas 17-32 (cara exterior).

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Mascarillas 1-16 (cara interior)

Mascarillas 17-32 (cara interior)

IMPORTANTE: En las fotografías de las mascarillas OK puede parecer que existan manchas en la cara interna de las mismas, y no es el caso. No hay penetración. Se producen transparencias, y se pueden observar las manchas producidas tras ensayar en la capa externa.

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Conclusiones:

Resistencia a las salpicaduras según EN 14683:2019+AC:2019, apartado 5.2.7, tabla nº1

Requisitos:

Ensayo	Tipo I	Tipo II	Tipo IIR
Presión de resistencia a las salpicaduras (kPa)	---	---	≥ 16

CUMPLE Tipo IIR

DOR-DIS Ltd

EC DECLARATION OF CONFORMITY

The declaration of conformity is issued solely under the responsibility of the manufacturer.

The undersigned, representing the manufacturer

Dor-Dis LTD, Bulgaria, Pazardzhik 4400, 1 Iskra Str.

Hereby declares that the product covered by this Declaration,

A THREE-LAYER DISPOSABLE MEDICAL MASK

DD02/20, UMDNS код 12447, Category 10 – Single-use devices, Class I, type IIR

complies with relevant harmonized legislation of the European Union:
DIRECTIVE 93/42/EEC of 14 June 1993;
STANDARD EN 14683:2019+AC:2019.

"ДОР-ДИС" ЕООД
DOR-DIS Ltd
EIC: BG 200141210
Bulgaria

Pazardzhik
16.07.2020

Signature and stamp:
Zhana Aleksandrova, Manager

РЕПУБЛИКА БЪЛГАРИЯ
Изпълнителна агенция по лекарствата
REPUBLIC OF BULGARIA
Bulgarian Drug Agency

УДОСТОВЕРЕНИЕ ЗА РЕГИСТРАЦИЯ

№ *BG/CA01/MD* ..0018...../..03.06.....2020 *г.*

На основание чл. 6, т. 1 от ЗМИ, във връзка с чл. 27, ал. 1 от ЗМИ и подадено заявление вх. № ИАЛ-21323/29.05.2020 г.

РЕГИСТРИРАМ

Медицинско изделие:
Трислойна медицинска маска за еднократна употреба
A three-layer medical mask

UMDNS код: ***12447***

Категория и код на категорията: ***Изделия за еднократна употреба - 10***

Клас: ***I***

Производител:
„ДОР- ДИС" ЕООД
ЕИК: 200141210
област София (столица), община Столична
гр. София 1582
район Искър
ж.к. Дружба 2, бл. 322, вх. В, ет. 4, ап. 10

Място на производство:
област Пазарджик, община Пазарджик
гр. Пазарджик 4400
ул. Искра № 1

Производителят е отговорен за проектирането, производството и контрола на регистрираното медицинско изделие/я и оценката му в съответствие със съществените изисквания на Закона за медицинските изделия и актовете по неговото прилагане, които въвеждат Директиви 93/42/ЕЕС, 90/385/ЕЕС и 98/79/ЕС.

Медицинското изделие е вписано в регистъра по чл. 31 от Закона за медицинските изделия, при Изпълнителната агенция по лекарствата.

МАГ. - ФАРМ. БОГДАН КИРИЛОВ
Изпълнителен директор

София 1303, ул. Дамян Груев № 8, тел.: (02) 8903 555, факс: (02) 8903434
8, Damyan Gruev Str., 1303, Sofia, Bulgaria, tel: + 359 2 8903555, fax: + 359 2 8903434,
e-mail: bda@bda.bg

ЕТ "ПИНО-РОЛАНДО МАРТИНЕС"
PINO - ROLANDO MARTINEZ Co.

MEGAHIM TRADE CENTRE
12 K. Velichkov Str, Office 12
Pazardzhik 4400
Bulgaria

TRANSLATION AGENCY

☎ 359 34 443 054, 359 888 430 580, 359 896 789 776, E-mail: pino@cybcom.net

Translation from Bulgarian

REPUBLIC OF BULGARIA
Bulgarian Drug Agency

REGISTRATION CERTIFICATE

No. *BG/CA01/MD-0018* of 03-06-2020

Pursuant to Art. 6 Para 1 of the Medical Devices Act and to Application Ref. No. ИАЛ – 21323 submitted on 29-05-2020,

I REGISTER

The medical device:
Disposable three-layer medical mask

UMDNS Code: ***12447***

Category and Category Code: ***Disposable products – 10***

Class: ***I***

Manufacturer:
DOR-DIS EOOD
Unified Identification Code: 200141210
Sofia (Capital City) Region, Stolichna Municipality
Sofia 1582
Iskar District
Druzhba 2, Block 322, Entrance B, 4th Floor, Apt 10

Manufacturing location:
Pazardzhik Region, Pazardzhik Municipality
Pazardzhik 4400
1 Iskra St

The manufacturer is liable for the design, manufacturing and control over the registered medical device and its compatibility with the fundamental requirements of the Medical Devices Act as well as the regulations for its implementation which introduce Directives 93/42/EEC, 90/385/EEC, and 98/79/EC.

The medical device is registered with the Bulgarian Drug Agency in the register under Art. 31 of the Medical Devices Act.

BOGDAN KIRILOV, MPharm
Executive Director

Signature (illegible)

Stamp of the Bulgarian Drug Agency, Republic of Bulgaria

Sofia 1303, 8 Damyan Gruev St, Tel. (02) 8903 555, Fax (02) 8903434, E-mail: bda@bda.bg

I, the undersigned Albena Rolando Pino, certify the accuracy of my translation from Bulgarian into English of the attached Registration Certificate No. BG/CA01/MD-0018 of 3 June 2020. The translation consists of one (1) page.

Translator: *Albena Rolando Pino*

ЕТ "РОЛАНДО МАРТИНЕС" -ПИНО" BULGARIA ПАЗАРДЖИК

ЕТ "ПИНО-РОЛАНДО МАРТИНЕС"
PINO - ROLANDO MARTINEZ Co.
TRANSLATION AGENCY

MEGAHIM TRADE CENTRE
12 K. Velichkov Str, Office 12
Pazardzhik 4400
Bulgaria

☎ 359 34 443 054, 359 888 430 580, 359 896 789 776, E-mail: pino@cybcom.net

Traducción del idioma búlgaro

REPÚBLICA DE BULGARIA
AGENCIA EJECUTIVA DE MEDICAMENTOS

CERTIFICACIÓN DE REGISTRO
№BG/CA01/MD-0018/ 03.06.2020

En virtud del art.6, pto.1 de la Ley de Productos Médicos (LPM), en relación con el art.27, aptdo.1 de la LPM y la solicitud registrada con el №ИАЛ-21323/ 29.05.2020

REGISTRO,

El producto médico:

Mascarilla médica de tres capas para uso único.

Código UMDNS: **12447**

Categoría y código de la categoría: **Producto de uso único - 10**

Clase: I

Productor:

"DOR DIS" EOOD (SURL)

Código Único de Identificación (EIK): 200141210

Región de Sofia (Capital), Municipalidad Stolichna

Ciudad de Sofía 1582

Distrito Iskar

Urbanización Druzhba 2, Edif.322, Entrada B, Piso 4, Apto 10

Lugar de producción:

Región de Pazardzhik, Municipalidad de Pazardzhik

Ciudad de Pazardzhik 4400

c/Iskra №1

El Productor se hace responsable del diseño, producción y control del producto médico registrado y su valoración en correspondencia con los requerimientos esenciales de la Ley para Productos Médicos y las actas para su aplicación, las cuales han sido presentadas en las Directivas 93/42/EEC, 90/385/EEC y 98/79/EC.

El Producto Médico está inscrito por el art.31 de la Ley de Productos Médicos, ante la Agencia Ejecutiva de Medicamentos

MÁSTER EN FARMACIA BOGDAN KIRILOV (firmado)
Director Ejecutivo Sello de la Agencia Ejecutiva de Medicamentos

Sofia 1303, c/Damyan Gruev №8, tel: (02) 8903 555; fax: (02)8903 434
e-mail: bda@bda.bg

El firmante, Rolando Pino Martínez, certifico la veracidad de la traducción realizada por mi del idioma búlgaro al español del documento adjunto. /Certificado de Registro № BG/CA01/MD-0018/ 03.06.2020. La traducción consta de una (1) página.

Traductor: Rolando Pino Martínez

ЕТ "РОЛАНДО МАРТИНЕС - ПИНО" BULGARIA ПАЗАРДЖИК

РЕПУБЛИКА БЪЛГАРИЯ
Изпълнителна агенция по лекарствата
REPUBLIC OF BULGARIA
Bulgarian Drug Agency

РАЗРЕШЕНИЕ
ЗА ТЪРГОВИЯ НА ЕДРО С МЕДИЦИНСКИ ИЗДЕЛИЯ

Рег.№ BG/WDA/MD-0258/04.05.2020 г.

На основание чл. 79, ал.2 от Закона за медицинските изделия и заявление с вх. № ИАЛ – 15685 / 22.04.2020 г.

Р А З Р Е Ш А В А М

на : **"ДОР-ДИС" ЕООД**
/наименование на физическо или юридическо лице/

със седалище и адрес на управление: **гр. София 1582, район Искър, ж.к. „Дружба 2", бл. 322, вх. В, ет. 4, ап. 10**

представлявано от: **Жана Симеонова Александрова**

ДА ИЗВЪРШВА
ТЪРГОВИЯ НА ЕДРО С МЕДИЦИНСКИ ИЗДЕЛИЯ

от видове (категории) съгласно Приложението

АДРЕС НА СКЛАДОВОТО ПОМЕЩЕНИЕ ЗА СЪХРАНЕНИЕ И ТЪРГОВИЯ НА ЕДРО С МЕДИЦИНСКИ ИЗДЕЛИЯ:

гр. Пазарджик 4400, ул. „Искра" № 1

РЪКОВОДИТЕЛ НА СКЛАДА СЪГЛАСНО чл. 78, ал. 2, т.2 от ЗМИ:

Жана Симеонова Александрова
/име, презиме, фамилия/

Разрешението за търговия на едро с медицински изделия е безсрочно.

МАГ.-ФАРМ. БОГДАН КИРИЛОВ
/ИЗПЪЛНИТЕЛЕН ДИРЕКТОР/

София 1303, ул. Дамян Груев № 8, тел.: (02) 8903 555, факс: (02) 8903434
8, Damyan Gruev Str., 1303, Sofia, Bulgaria, tel: + 359 2 8903555, fax: + 359 2 8903434,
e-mail: bda@bda.bg

П Р И Л О Ж Е Н И Е
КЪМ РАЗРЕШЕНИЕ

ЗА ТЪРГОВИЯ НА ЕДРО С МЕДИЦИНСКИ ИЗДЕЛИЯ

с рег.№ BG/WDA/MD-0258/07.05.2020г.

на: **„ДОР-ДИС" ЕООД**

/наименование на физическо или юридическо лице/

Списък на видове (категории) медицински изделия с които се търгува:

код на категория 1: Активни имплантируеми изделия/ Active implantable devices

код на категория 2: Изделия за анестезия и респирация/ Anesthetic and respiratory devices

код на категория 3: Стоматологични изделия/ Dental devices

код на категория 4: Електро-механични медицински изделия/ Electro mechanical medical devices

код на категория 5: Болнично оборудване/ Hospital hardware

код на категория 6: Ин витро диагностични изделия/ In Vitro diagnostic Devices

код на категория 7: Неактивни имплантируеми изделия/ Non-active implantable Devices

код на категория 8: Изделия за офталмология и оптика/ Ophtalmic and optical Devices

код на категория 9: Инструменти за многократна употреба/ Reusable Instruments

код на категория 10: Изделия за еднократна употреба/ Single-use Devices

код на категория 11: Помощни средства за лица с увреждания/ Assistive products for persons with disability

код на категория 12: Изделия за диагностична и терапевтична радиация/ Diagnostic and therapeutic radiation Devices

код на категория 13: Изделия за допълнителна терапия/ Complementary therapy Devices

код на категория 14: Изделия с биологичен произход/ Biologically-derived Devices

код на категория 15: Продукти и приспособления за лечебни и здравни заведения/ Healthcare facility products and adaptations

код на категория 16: Лабораторно оборудване / Laboratory equipment

МАГ.-ФАРМ. БОГДАН КИРИЛОВ
/ИЗПЪЛНИТЕЛЕН ДИРЕКТОР/

София 1303, ул. Дамян Груев № 8, тел.: (02) 8903 555, факс: (02) 8903434
8, Damyan Gruev Str., 1303, Sofia, Bulgaria, tel: + 359 2 8903555, fax: + 359 2 8903434,e-mail: bda@bda.bg

ЕТ "ПИНО-РОЛАНДО МАРТИНЕС"
PINO - ROLANDO MARTINEZ Co.

MEGAHIM TRADE CENTRE
12 K. Velichkov Str, Office 12
Pazardzhik 4400
Bulgaria

TRANSLATION AGENCY

☎ 359 34 443 054, 359 888 430 580, 359 896 789 776, E-mail: pino@cybcom.net

Translation from Bulgarian

REPUBLIC OF BULGARIA
Bulgarian Drug Agency

PERMIT
FOR WHOLESALE OF MEDICAL DEVICES

Reg. No. BG/WDA/MD-0258 of 04-05-2020

Pursuant to Art. 79 Para 2 of the Medical Devices Act and to Application Ref. No. ИАЛ – 15685 of 22-04-2020,

I GRANT PERMIT TO

DOR-DIS EOOD
(name of natural or legal person)

Head office and administration address: **Sofia 1582, Iskar District, Druzhba 2, Block 322, Entrance B, 4th Floor, Apt. 10,**
Represented by: **Zhana Simeonova Aleksandrova**

TO CARRY OUT
WHOLESALE OF MEDICAL DEVICES

types (categories) in the Appendix

ADDRESS OF WAREHOUSE FOR STORAGE AND WHOLESALE OF MEDICAL DEVICES:
Pazardzhik 4400, 1 Iskra Street

WAREHOUSE MANAGER ACCORDING TO Art. Para 2(2) of the Medical Devices Act:
Zhana Simeonova Aleksandrova
(first, middle and last name)

This Permit on the wholesale of medical devices is valid for an unlimited period of time.

Signature (illegible)
BOGDAN KIRILOV, MPharm
EXECUTIVE DIRECTOR
Stamp of the Bulgarian Drug Agency,
Republic of Bulgaria

I, the undersigned Albena Rolando Pino, certify the accuracy of my translation from Bulgarian into English of the attached Permit BG/WDA/MD-0258 of 4 May 2020. The translation consists of one (1) page.

Translator: *Albena Rolando Pino*

ЕТ "РОЛАНДО МАРТИНЕС" - ПИНО" BULGARIA ПАЗАРДЖИК

ЕТ "ПИНО-РОЛАНДО МАРТИНЕС"
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Traducción del idioma búlgaro

REPÚBLICA DE BULGARIA
Agencia Ejecutiva de Medicamentos

AUTORIZACIÓN

PARA LA COMERCIALIZACIÓN MAYORISTA DE PRODUCTOS MÉDICOS

№ de registro BG/WDA/MD-0258 / 04.05.2020

En virtud del art. 79, apartado 2 de la Ley de Productos Médicos (LPM) y solicitud con

№ ИАЛ – 15685 / 22.04.2020

AUTORIZO

a: **"DOR-DIS" EOOD**
/Nombre de la persona física o jurídica/

Con sede y dirección social:
Ciudad de Sofía 1582, distrito de Iskar, urbanización Druzhba 2, edif. 322, entr. B, piso 4, apto. 10
representada por: ZHANA SIMEONOVA ALEKSANDROVA

A REALIZAR COMERCIALIZACIÓN MAYORISTA CON PRODUCTOS MÉDICOS de los tipos (categorías) acordes al Anexo.

DIRECCIÓN DEL ALMACÉN PARA LA GUARDA Y COMERCIALIZACIÓN MAYORISTA CON PRODUCTOS MÉDICOS:
Ciudad de Pazardzhik, c/ Iskra No. 1

JEFE DE ALMACÉN EN VIRTUD del art.78, aptdo. 2, pto. 2 de la LPM:

ZHANA SIMEONOVA ALEKSANDROVA
/Nombre propio, patronímico y apellido/

La autorización de comercialización mayorista con productos médicos es por tiempo indefinido.

MÁSTER EN FARMACIA BOGDAN KIRILOV (firmado)
/DIRECTOR EJECUTIVO/
Sello de la Agencia Ejecutiva de Medicamentos

Sofia 1303,c/Damyan Gruev No. 8, tel: (02)8903 555; fax: (02) 8903434

El firmante, Rolando Pino Martínez, certifico la veracidad de la traducción realizada por mi del idioma búlgaro al español del documento adjunto/ Autorización № de registro BG/WDA/MD-0258/ 04.05.2020. La traducción consta de una /1/ página.

Traductor: Rolando Pino Martínez

ЕТ "РОЛАНДО МАРТИНЕС - ПИНО" BULGARIA ПАЗАРДЖИК

MATERIALS

HOHENSTEIN Textile Testing Institute GmbH & Co. KG
Schlosssteige 1, 74357 Bönnigheim, Germany

OEKO-TEX®
INSPIRING CONFIDENCE

CERTIFICATE

The company

Extrapack OOD
Kozludzha Str. 1A
5000 Veliko Tarnovo, BULGARIA

is granted authorisation according to STANDARD 100 by OEKO-TEX® to use the STANDARD 100 by OEKO-TEX® mark, based on our test report
19.0.83271

OEKO-TEX®
CONFIDENCE IN TEXTILES
STANDARD 100
16.HBG.89637 HOHENSTEIN HTTI
Tested for harmful substances
www.oeko-tex.com/standard100

for the following articles:

Non-woven fabric made of 100 % polypropylene in colours white, beige, light blue and black.

The results of the inspection made according to STANDARD 100 by OEKO-TEX®, Appendix 4, **product class I** have shown that the above mentioned goods meet the human-ecological requirements of the STANDARD 100 by OEKO-TEX® presently established in Appendix 4 for baby articles.

The certified articles fulfil requirements of Annex XVII of REACH (incl. the use of azo colourants, nickel release, etc.), the American requirement regarding total content of lead in children's articles (CPSIA; with the exception of accessories made from glass) and of the Chinese standard GB 18401:2010 (labelling requirements were not verified).

The holder of the certificate, who has issued a conformity declaration according to ISO 17050-1, is under an obligation to use the STANDARD 100 by OEKO-TEX® mark only in conjunction with products that conform with the sample initially tested. The conformity is verified by audits.

The certificate 16.HBG.89637 is valid until 30.09.2020

Boennigheim, 19.08.2019

Dipl.-Ing. (FH) Ivonne Schramm
Leiterin Zertifizierungsstelle OEKO-TEX®

191020340175

中国认可
国际互认
检测
TESTING
CNAS L13034

In Vitro Cytotoxicity Test

MTT Method

Final Report

Article Name: Meltblown cloth (for masks only)

Report Number: CSTBB20050131

Method Standard: ISO 10993-5：2009

Sponsor

XUZHOU GUOHONG PACKING CO., LTD.

SOUTH OF XIAOHE ROAD, PEIXIAN ECONOMIC DEVELOPMENT ZONE, XUZHOU CITY, JIANGSU PROVINCE

Test Facility

CCIC Huatongwei international inspection (Suzhou) Co., Ltd

Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

CONTENTS

Notices

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The report is only responsible for the test results of the tested samples.
5. The report shall not be reproduced except in full without the written approval of the company.

Abstract

In this study, mammalian L-929 cells were cultured in vitro according to ISO 10993-5:2009 to test the potential cytotoxicity of the test article.

The test articles and the control material were separately placed in MEM medium containing 10% fetal bovine serum, and extracted in a 37 ℃ incubator for 24 hours. After the end of the extraction, the cell culture medium in the 96-well plate (10^4 cells/well) cultured for 24 hours was removed and replaced with the corresponding extract, cultured in 37 ℃, 5% CO_2, >90% humidity for 24 hours. After the culture, the morphology and cell lysis of the cells were observed under the microscope, and the cytotoxicity of the test samples was determined by MTT assay.

The results showed that the cells in the blank control group and the negative control group (high density polyethylene) were well-formed throughout the experiment and showed no cytotoxic reaction. A severe cytotoxic response was shown in the positive control group (ZDEC). The 100% concentration of the test extract retained a normal appearance after 24 hours of incubation, and the cell viability was 81.1%. The data of each group met the acceptance criteria, and the results of this test were valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article Meltblown cloth (for masks only) have no potential toxicity to L-929 in the MTT method.

Study Verification and Signature

Protocol Number	SST2004042005BB
Protocol Effective Date	2020-05-01
Technical Initiation Date	2020-05-06
Technical Completion Date	2020-05-08
Final Report Completion Date	2020-05-09

Personnel _____ Yang

).2 l? - ?f - i
Date Completed

Approved _____ Xiang Wang
rector

2020-05-09
Date Complete

Supervisory _____ Suxiang Li

2020-05-09
Date Completed

Huatongwei international inspection (Suzhou) Co., Ltd.

1.0 Purpose

The purpose of the test is to determine the potential cytotoxicity toxicity of a mammalian cell culture (mouse fibroblast L-929 cells) in response to the test article.

2.0 Reference

Biological evaluation of medical devices-Part 5: Tests for In Vitro Cytotoxicity (ISO 10993-5：2009)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12：2012)

3.0 Test and control articles

Groups	Test article	Negative Control Article	Positive Control Article	Blank Control
Name	Meltblown cloth (for masks only)	High Density Polyethylene Film	ZDEC	MEM medium, with addition 10% FBS
Manufacture	XUZHOU GUOHONG PACKING CO., LTD.	Hatano Research Institute. FDSC	Sigma-Aldrich.	Hyclone
Size	25 g	3 cm×10 cm (5 sheets)	25 g	500 ml
Model	19.5	/	/	/
Lot Batch#	GHRPB2020	C-161	BCBQ6847V	AE29441978
Test Article Material	Not provided	/	/	/
Physical State	Solid	Solid	Solid	Liquid
Color	White	White	White	Pink
Packaging Material	Not provided	/	/	/
Sterilized or Not	Not provided	No	No	Yes
Concentration	/	/	0.1%	/
Total Surface or weight	Not provided	/	/	/
Storage Condition	Room Tep.	Room Tep.	Room Tep.	4℃
Note：The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification and justification of test system

L-929 mouse fibroblast cells obtained from American Type Culture Collection (ATCC).

L-929 cells have been used for cytotoxicity studies because they demonstrate sensitivity to extractable cytotoxic articles. Also, the test article is extracted and administered in vitro to mouse fibroblast L929 cells through a solvent compatible with the test system, which is the optimal route of administration available in this test system as recommended in ISO 10993-5.

5.0 Equipment and reagents

5.1 Instruments

Vertical pressure steam sterilizer (SHB026), CO_2 Incubator (SHB002), Steel Straight Scale (SHB076), Electronic Balance (SHB016), Clean bench (SHB014), Multiskan Spectrum Microplate Spectrophotometer (SHB003), Bench type low speed centrifuge (SHB022), Inverted microscope (SHB005)

5.2 Reagents

MEM (Hyclone, AE29441978), FBS (Clark, JC65116), Penicillin-Streptomycin (Gibco, 2145453), Trypsin (Gibco, 2048080), PBS (Hyclone, AE29451445), MTT (3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyletrazolium bromide) (Sigma, MKBG2038V), Isopropyl alcohol (Macklin, C10394867)

6.0 Experiment design and dose

6.1 Sample preparation

According to the table below, aseptic extraction of the test article sealed and incubated in MEM medium (10% FBS) at 37 ℃, 5% CO_2 and 60 rpm for 24 hours.

Groups	Sampling		Sterilization	Aseptic Extraction In Inert Container				Final Extract
	Sampling Manner	Actually sampling	Method	Ratio	Extracts	Condition	pH	Clear or Not
Test article	Random	120.0 cm^2	EO	6 cm^2: 1 ml	20.0 ml	37 ℃ 24 h	7.4	Clear
Negative Control	Random	60.0 cm^2	UV	3 cm^2: 1 ml	20.0 ml	37 ℃ 24 h	7.4	Clear
Positive Control	Random	0.02 g	Filter	0.1 g: 100 ml	20.0 ml	37 ℃ 24 h	7.4	Clear
Blank Control	/	/	/	/	20.0 ml	37 ℃ 24 h	7.4	Clear

The changes of the leaching solution was observed after extraction. No particulates or color changes were observed in pre- and post-extraction, and immediately be used in the follow-up experiment. The color and pH of the extraction solution did not change before and after use, and the pH value was 7.4 after leaching.

6.2 Test method

Aseptic procedures were used for handling cell cultures. L-929 cells were cultured in MEM medium (10% FBS, 1% Penicillin-Streptomycin solution) at 37 ℃ in a humidified atmosphere of 5% CO_2, then digested by 0.25% trypsin containing EDTA to get single cell suspension. 1×10^5 cells/ml suspension were obtained by centrifuging (1000 rpm, 5 min) and re-dispersing in MEM medium.

The suspended cells were dispensed at 100 µl per well in 96-well plate, and cultured in cell incubator (5% CO_2, 37 ℃, >90% humidity). Cell morphology was evaluated to verify that the monolayer was satisfactory.

After the cells grew to about 70% and form a monolayer, original culture medium was discarded. The 96-well plates were then treated with 100 µl of extract of test article (100%、75%、50%、25%), control article, negative article and positive article respectively. The 96-well plate was incubated at 37 ℃ in cell incubator of 5% CO_2 for 24 h. Six replicates of each test were tested.

After incubation, observe the cell morphology first and then discard the culture medium. Add 50 µl MTT (1mg/ml) to each well and then incubated at 37 ℃ in a humidified atmosphere of 5% CO_2 for 2 hours. The liquid in

each well was tipped out and 100 µl Isopropyl alcohol was added to each well to suspend the cell layer.

Evaluate the suspension above with a dual-wavelength spectrophotometer with the measurement wavelength at 570 nm.

7.0 Statistical method

Mean±standard deviation ($\bar{x} \pm s$)

The cell cytotoxicity ratio = OD_{570} of test (or positive or negative) article group/ OD_{570} of blank control group×100%.

8.0 Evaluation criteria

8.1 The 50% extract of the test article should have at least the same or a higher viability than the 100% extract. Otherwise the test should be repeated.

8.2 The lower the Viab.% value, the higher the cytotoxic potential of the test article is.

8.3 If viability is reduced to < 70% of the blank, it has a cytotoxic potential.

8.4 The Viab.% of the 100% extract of the test article is the final result.

9.0 Results of the test

9.1 Results of the cell morphology

Table 1 Observation of the cell morphology

Group	Before inoculation	Before treated with extract	24 h after treatment
Blank control	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
Negative control			Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth.
Positive control			Nearly complete or complete destruction of the cell layers.
100% Test article extract			The cells showed a round shape and a change in cell morphology occasionally, and there were particles in the cytoplasm, occasionally cell lysis and slight growth inhibition.
75% Test article extract			The cells showed a round shape and a change in cell morphology occasionally, and there were particles in the cytoplasm, occasionally cell lysis and slight growth inhibition.
50% Test article extract			The cells showed a round shape and a change in cell morphology occasionally, and there were particles in the cytoplasm, occasionally cell lysis and slight growth inhibition.
25% Test article			Discrete intracytoplasmatic granules, no cell

extract			lysis, no reduction of cell growth.

9.2 Results of the cell vitality

Table2 Results of the cell vitality

Group	OD value								Viab. (%)
	1	2	3	4	5	6	$\bar{x}$	s	
Blank control	0.629	0.630	0.623	0.621	0.632	0.630	0.628	0.004	100.0
Negative control	0.603	0.603	0.609	0.619	0.632	0.624	0.615	0.012	98.0
Positive control	0.056	0.052	0.054	0.056	0.058	0.051	0.054	0.002	8.7
100% test article extract	0.516	0.503	0.506	0.518	0.506	0.507	0.509	0.006	81.1
75% test article extract	0.530	0.531	0.534	0.535	0.531	0.527	0.531	0.003	84.7
50% test article extract	0.575	0.568	0.570	0.553	0.557	0.549	0.562	0.011	89.5
25% test article extract	0.570	0.585	0.580	0.584	0.581	0.583	0.581	0.005	92.5

10.0 Conclusion

Under the conditions of this study, the test article have no potential toxicity to L-929 cells.

11.0 Record

All raw data pertaining to this study and a copy of the final report are to be stored in the designated archive files at Huatongwei.

12.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

TEST REPORT

(Electronic version)

扫码下载报告

VERIFICATION WEBSITE: www.gttc.net.cn

VERIFICATION CODE: ILEC-1369-54

No:200122213

ISSUE DATE:2020-05-20

APPLICANT: XUZHOU GUOHONG PACKAGING CO., LTD
ADDRESS: SOUTH SIDE OF XIAOHE ROAD, PEIXIAN ECONOMIC DEVELOPMENT ZONE, XUZHOU CITY

INFORMATION CONFIRMED BY APPLICANT:

MELTBLOWN NONWOVEN FABRIC

QUANTITY: ONE PIECE

MANUFACTURE'S NAME: XUZHOU GUOHONG PACKAGING CO., LTD

DATE RECEIVED/DATE TEST STARTED: 2020-05-13

CONCLUSION:

BACTERIAL FILTRATION EFFICIENCY	M

NOTE: "M"-MEET THE STANDARD'S REQUIREMENT "F"-FAIL TO MEET THE STANDARD'S REQUIREMENT
"---"-NO COMMENT

REMARK:
TEST MATERIAL,TESTED AND JUDGED BY YY 0469-2011 AS PER CLIENT'S REQUIREMENT.
THIS REPORT IS THE ENGLISH TRANSLATION VERSION OF THE REPORT 200122212.
ALL THE TESTED ITEMS ARE TESTED UNDER THE STANDARD CONDITION (EXCEPT FOR INDICATION).
COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.
THE EXPERIMENT WAS CARRIED OUT AT No.1, ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P.R.CHINA.

APPROVED BY:

Nan Ma ENGINEER

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

总部：广州市番禺区珠江路1号
花都实验室：广州市花都区狮岭镇旗岭河滨西路1号
电话:020-61994598/61994599
电话:020-37721161

TEST REPORT

(Electronic version)

No:200122213

BACTERIAL FILTRATION EFFICIENCY(%)

(YY 0469-2011 ANNEX B, TEST BACTERIA: STAPHYLOCOCCUS AUREUS ATCC 6538, TEST AREA: 49cm , FLOW RATE: 28.3L/min, MEAN PARTICLE SIZE: 3.0μm, RESULT OF THE POSITIVE CONTROL: 1.9×10 CFU, RESULT OF THE NEGATIVE CONTROL: ＜1CFU)

		REQUIREMENT
BFE	99.6	≥95
BFE	99.4	(YY 0469-2011)
BFE	99.2	

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

———End of Report———

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