Double One

Digitally signed by Volcovschi Mihai
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Location: Moldova
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—SINCE 1955—

GUANGZHOU DOUBLE ONE

GUANGZHOU DOUBLE ONE LATEX PRODUCTS CO., LTD.

Double One Company Profile

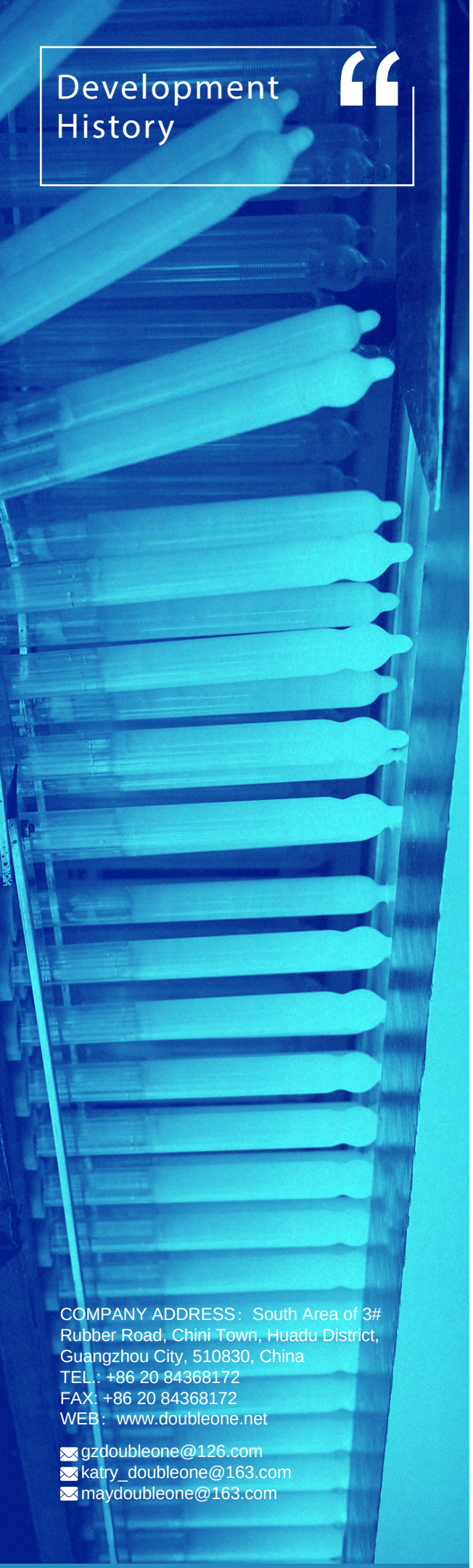
*** It belongs to the world's top 500 Guangzhou Industrial Investment Holdings Group**
***70 years manufacturing experience.**
*** Factory area of 130,000 sqm.**
*** Annual production capacity of 900 million pieces of condoms, 33.5 million pairs of gloves.**
*** Condoms by 100% electronic testing.**
*** UNFPA condom pre-qualified supplier.**

Double One was established in 1955 and was formerly state-owned Guangzhou No. 11 Rubber Factory. Double One has over 70 years professional experience manufacturing condoms and is the 1st latex condom manufacturer in China. Double One covers an area of 130,000 sqm with annual production capacity of 900 million pcs of condoms, and 33.5 million pairs of gloves.

Double One obtained a number of management systems including ISO9001, ISO14001, OHSAS18001, ISO13485 and SA8000, and international product certifications including CE, ANVISA and SABS, and Double One has been continuously listed as one of the UNFPA pre-qualified suppliers since 2008. Our condom products are sold well all over China, and exported to American, European, Africa and Southeast Asia countries.

Double One produced the 1st generation gloves in 1957. Through 70 years of continuous improvement and development, Double One brand household gloves, industrial gloves and rubber gloves have been penetrated world-widely including Middle-east, South-east Asian countries.

Double One will persist on developing innovation products and provide perfect after-sales service world-widely for continuous improvement to meet customer needs.



Development History

1956 — Produced China's first condom, the first generation of military weather balloons.

1957 — The first generation of medical gloves and industrial gloves were produced.

1988 — Condom impregnation, electrical testing technology integration equipment won the national technology development outstanding achievement award.

1989 — Double one brand bare condom product was awarded the Guangzhou Standard Achievement Award.

1997 — Double one rubber condom won the title of Guangzhou famous brand products.

2004 — Double one trademark won the title of famous trademark in Guangdong Province.

2007 — Double one brand pavilion rubber condom won the title of China famous brand products.

2010 — Double One was supplying 50 million condoms for the World Cup in South Africa.

2013 — Double One has become the designated supplier of condom procurement of the United Nations Population Fund, and has become a partner of the United Nations global AIDS prevention cause.

2014 — Double One partnered with the Brazilian Ministry of Health to deliver 200 million condoms directly.

2016 — Double One is providing 200 million condoms for the Olympics in Brazil.

2018 — Double One has partnered with the Brazilian Ministry of Health to deliver 470 million condoms directly.

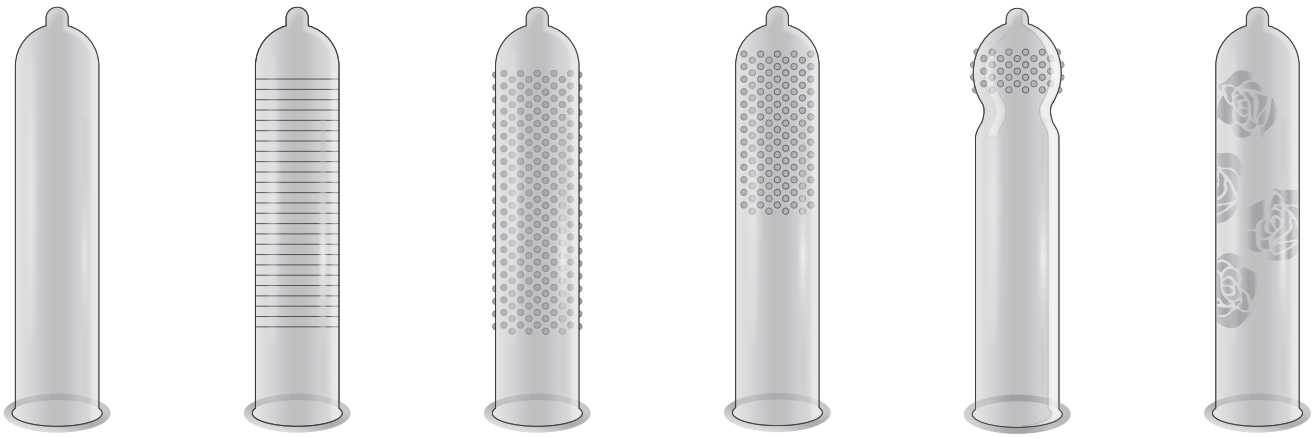
2022-2024 — Distribution of 700 million condoms for the Brazilian Ministry of Health;

COMPANY ADDRESS: South Area of 3# Rubber Road, Chini Town, Huadu District, Guangzhou City, 510830, China
TEL: +86 20 84368172
FAX: +86 20 84368172
WEB: www.doubleone.net

gzdoubleone@126.com
katry_doubleone@163.com
maydoubleone@163.com

Double One Condom Specifications

Male Latex Condoms



Smooth | Ribbed | Big-dotted | Dotted | Ribbed/dotted combined | Rose patterned

Main Composition	Natural Latex
Nominal Length	≥160mm, ≥170mm, ≥180mm
Nominal Width	49±2mm, 52±2mm, 53±2mm, 55±2mm
Thickness	0.04 - 0.08mm
Colors	Natural, Pink, Orange and customerizable colors.
Flavors	Natural, Aloe, Vanilla, Mint, Jasmine, Grape, Blueberry, Strawberry, Rose, Lemon, Peach, Banana, Coffee and customizable flavors.

UNFPA

ISO9001

ISO9001:2015

Presafe

A DNV GL & NEMKO COMPANY

ISO 13485:2016

CE

ISO 14001:2015

WSC

OHSAS18001:2007

INTERTEK SA8000

SA 8000:2014

SABS

ISC

ISO10012:2003

FDA

Double One Condom Series

Smooth — No Color	
Main Composition	Natural Latex
Width	53mm
Packing Specification	3pcs
Type	Smooth
Flavor	Natural

Smooth — Red Color	
Main Composition	Natural Latex
Width	53mm
Packing Specification	3pcs
Type	Smooth
Flavor	Strawberry

Smooth — Purple Color	
Main Composition	Natural Latex
Width	53mm
Packing Specification	3pcs
Type	Smooth
Flavor	Grapes

Smooth — Yellow Color	
Main Composition	Natural Latex
Width	53mm
Packing Specification	3pcs
Type	Smooth
Flavor	Banana

Ultra Thin 003 XL	
Main Composition	Natural Latex
Width	55mm
Packing Specification	3pcs
Type	Smooth
Flavor	Natural

Ultra Thin 003 XL	
Main Composition	Natural Latex
Width	55mm
Packing Specification	3pcs
Type	Smooth
Flavor	Natural

Smooth	
Main Composition	Natural Latex
Width	52mm
Packing Specification	3pcs
Type	Smooth
Flavor	Natural

Rose-patterned	
Main Composition	Natural Latex
Width	52mm
Packing Specification	3pcs
Type	Rose-patterned
Flavor	Strawberry

Ribbed-No color	
Main Composition	Natural Latex
Width	53mm
Packing Specification	3pcs
Type	Ribbed
Flavor	Mint

Ribbed-No color	
Main Composition	Natural Latex
Width	53mm
Packing Specification	3pcs
Type	Ribbed
Flavor	Strawberry

Ribbed-No color	
Main Composition	Natural Latex
Width	53mm
Packing Specification	3pcs
Type	Ribbed
Flavor	Grapes

Double One Condom Series

Smooth- Pink	
Main Composition	Natural Latex
Width	53mm
Packing Specification	5pcs
Type	Smooth
Flavor	Rose

Smooth- No Color	
Main Composition	Natural Latex
Width	53mm
Packing Specification	5pcs
Type	Smooth
Flavor	Mint

Smooth- Pink	
Main Composition	Natural Latex
Width	53mm
Packing Specification	5pcs
Type	Smooth
Flavor	Tutti Frutti

Ultra thin-No Color	
Main Composition	Natural Latex
Width	53mm
Packing Specification	5pcs
Type	Smooth
Flavor	Strawberry

Dotted-No color	
Main Composition	Natural Latex
Width	53mm
Packing Specification	12pcs
Type	Dotted
Flavor	Lemon

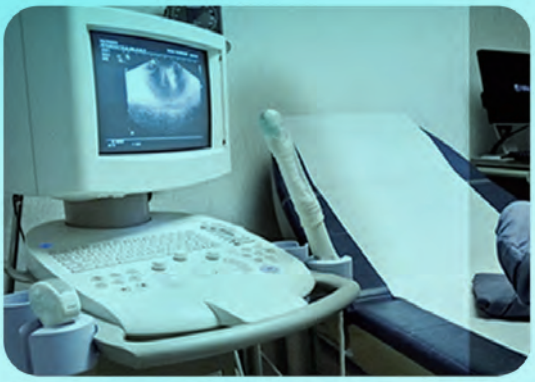
Dotted-No color	
Main Composition	Natural Latex
Width	53mm
Packing Specification	12pcs
Type	Dotted
Flavor	Strawberry

Dotted-No color	
Main Composition	Natural Latex
Width	53mm
Packing Specification	12pcs
Type	Dotted
Flavor	Orange

Ultrasound Probe Cover (Clinical condom)

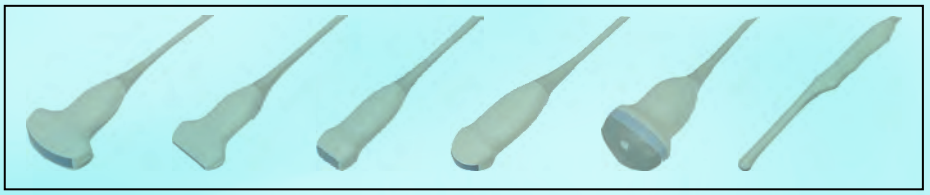
—— Medical-grade Assurance, Professional-quality Care——

SCOPE OF APPLICATION



Product Name	Ultrasound Probe Cover		
Lubricant	Without Lubricant,Methyl silicone oil Hyaluronic acid	Specification	W49、W52、W53、W55
Quantity	100 pcs/box	Length	≥180mm
Shelf Life	5 years	Standard	Q/HGSY 42 Ultrasound Probe Cover
Main Composition	Mainly made of natural rubber latex, disposable.		
Scope of application	It is compatible with ultrasound therapy instruments and installed on the sound transmission window of the treatment head to prevent cross infection between patients.		
Model	U type（without a reservoir tip）		
	Y type （with a reservoir tip)		

ADAPTIVE



Natural Latex Rubber Female Condom

—— Medical-grade Assurance, Professional-quality Care——

Product Name	Natural Latex Rubber Female Condom
Model	Smooth/ Texture
Specification	W49、W52、W53、W55
Width	79.5±2mm
Quantity	1pcs/pack
Main structure	The product consists of a condom, an inner ring, and lubricant. The condom is made of natural rubber latex, forming a thin-film sleeve structure. The open end features a rolled edge serving as the outer ring, designed to secure the condom opening to the external genitalia. A polyurethane inner ring is integrated at the closed end (tip) of the condom to facilitate expansion and maintain structural integrity. The lubricant is methyl silicone oil or hyaluronic acid.
Scope of application	This product is designed for women to prevent the union of sperm and egg during sexual intercourse, thereby reducing the likelihood of conception. It also aids in lowering the risk of sexually transmitted infections (STIs).

Latex Household and Industrial Gloves

Give You Protection

With more than 70 years'professional experience, Double One gloves are designed with unique ergonomics, made by refined rubber latex and high-density dipping technolo-gy,with characteristics of comfort to wear, steadiness of grabbing, better flexible and durable.

Dazzle color household gloves

Color	light purple rose red mint green cherry pink
Size	S M L
Weight(g)/pair	45/50/55
Length(mm)	270
Thickness(mm)	0.40

Size S W:92mm (for reference)
Size M W:97mm (for reference)
Size L W:105mm (for reference)

"A" type household gloves

Color	Yellow Red Pink Green
Size	S/M/L
Weight(g)/pair	58/62/65
Length(mm)	290
Thickness(mm)	0.40

Size S W:92mm (for reference)
Size M W:97mm (for reference)
Size L W:105mm (for reference)

Latex Industrial Gloves

Color	Black
Size	S/M/L/XL
Weight(g)/pair	81/88/95/105
Length(mm)	300/310/320/330
Thickness(mm)	0.50

Size S W:90mm (for reference)
Size M W:101mm (for reference)
Size L W:107mm (for reference)
Size XL W:113mm (for reference)

Thin household gloves

Color	Rose Red
Size	S/M/L
Weight(g)/pair	40/44/48
Length(mm)	290
Thickness(mm)	0.35

Size S W:92mm (for reference)
Size M W:97mm (for reference)
Size L W:105mm (for reference)

Latex Industrial Gloves

Double color industrial gloves

Color	Double Color
Size	S/M/L
Weight(g)/pair	81/88/95
Length(mm)	300/310/320
Thickness(mm)	0.50

Size S W:90mm (for reference)
Size M W:101mm (for reference)
Size L W:107mm (for reference)

Natural color industrial gloves

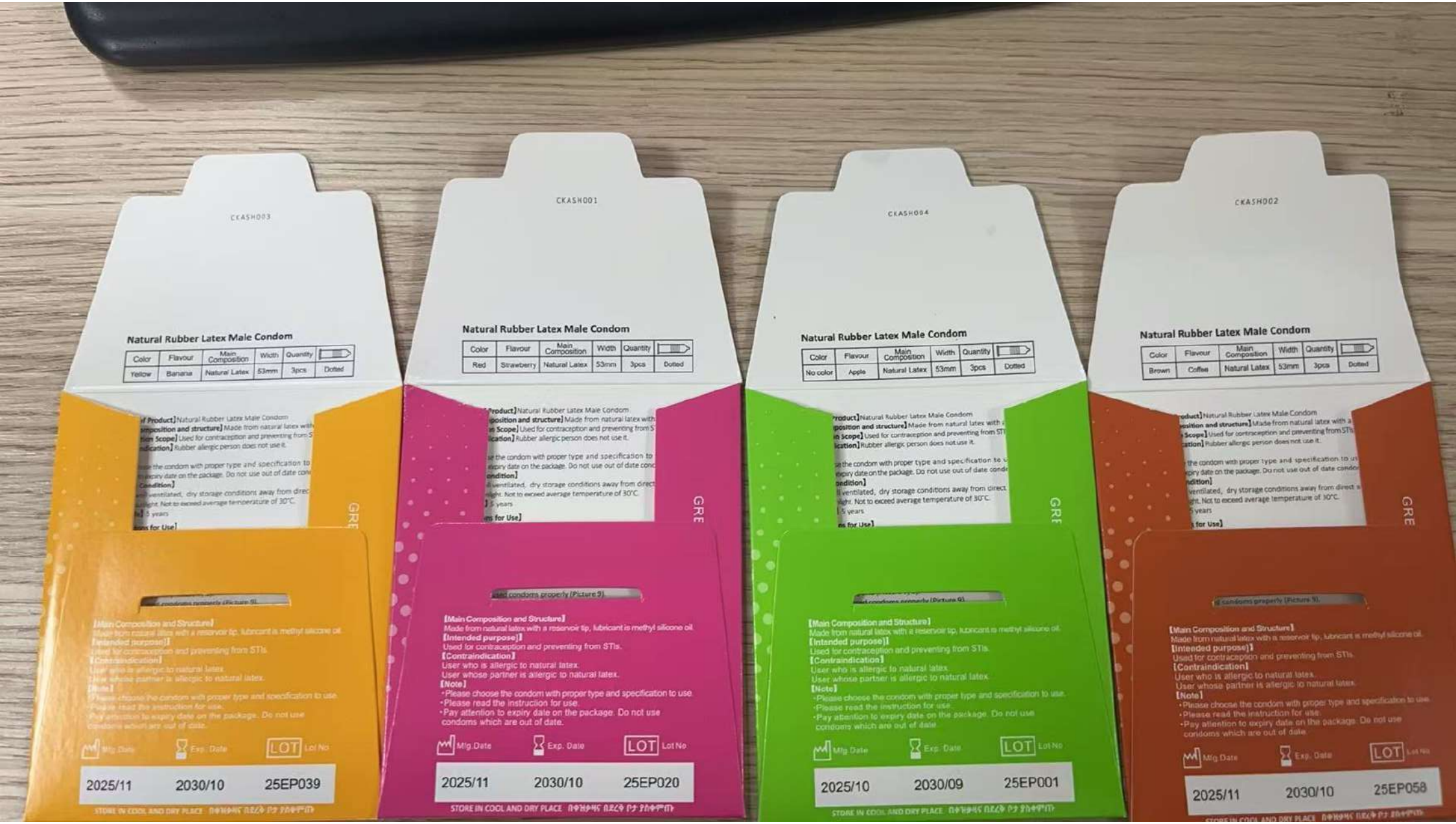
Color	Natural
Size	S/M/L
Weight(g)/pair	87/97/105
Length(mm)	300/310/320
Thickness(mm)	0.50

Size S W:90mm (for reference)
Size M W:101mm (for reference)
Size L W:107mm (for reference)

Butyl rubber gloves with nylon lining

Color	Green
Size	S/M/L
Weight(g)/pair	110/120/130
Length(mm)	290
Thickness(mm)	0.60

Size S W:96mm (for reference)
Size M W:104mm (for reference)
Size L W:112mm (for reference)


CKASH003
Natural Rubber Latex Male Condom
Color | Flavour | Main Composition | Width | Quantity | Dotted
Yellow | Banana | Natural Latex | 53mm | 3pcs | Dotted
【Main Composition and Structure】
【Intended purpose】
Used for contraception and preventing from STIs.
【Contraindication】
User who is allergic to natural latex.
User whose partner is allergic to natural latex.
【Note】
Please choose the condom with proper type and specification to use.
Please read the instruction for use.
Pay attention to expiry date on the package. Do not use condoms which are out of date.
Mfg Date
Exp. Date
LOT Lot No
2025/11
2030/10
25EP039
CKASH001
Natural Rubber Latex Male Condom
Color | Flavour | Main Composition | Width | Quantity | Dotted
Red | Strawberry | Natural Latex | 53mm | 3pcs | Dotted
【Main Composition and Structure】
Made from natural latex with a reservoir tip, lubricant is methyl silicone oil.
【Intended purpose】
Used for contraception and preventing from STIs.
【Contraindication】
User who is allergic to natural latex.
User whose partner is allergic to natural latex.
【Note】
•Please choose the condom with proper type and specification to use.
•Please read the instruction for use.
•Pay attention to expiry date on the package. Do not use condoms which are out of date.
Mfg Date
Exp. Date
LOT Lot No
2025/11
2030/10
25EP020
STORE IN COOL AND DRY PLACE
CKASH004
Natural Rubber Latex Male Condom
Color | Flavour | Main Composition | Width | Quantity | Dotted
No color | Apple | Natural Latex | 53mm | 3pcs | Dotted
【Main Composition and Structure】
Made from natural latex with a reservoir tip, lubricant is methyl silicone oil.
【Intended purpose】
Used for contraception and preventing from STIs.
【Contraindication】
User who is allergic to natural latex.
User whose partner is allergic to natural latex.
【Note】
•Please choose the condom with proper type and specification to use.
•Please read the instruction for use.
•Pay attention to expiry date on the package. Do not use condoms which are out of date.
Mfg Date
Exp. Date
LOT Lot No
2025/10
2030/09
25EP001
CKASH002
Natural Rubber Latex Male Condom
Color | Flavour | Main Composition | Width | Quantity | Dotted
Brown | Coffee | Natural Latex | 53mm | 3pcs | Dotted
【Main Composition and Structure】
Made from natural latex with a reservoir tip, lubricant is methyl silicone oil.
【Intended purpose】
Used for contraception and preventing from STIs.
【Contraindication】
User who is allergic to natural latex.
User whose partner is allergic to natural latex.
【Note】
•Please choose the condom with proper type and specification to use.
•Please read the instruction for use.
•Pay attention to expiry date on the package. Do not use condoms which are out of date.
Mfg Date
Exp. Date
LOT Lot No
2025/11
2030/10
25EP058


CKASH004
Natural Rubber Latex Male Condom
Color
No color
Flavour
Apple
Main Composition
Natural Latex
Width
53mm
Quantity
3pcs
Dotted

包装系列产品：摩尔多瓦光面，原色，无味
代　　码：
产品编码：
成品规格：93×75mm
材　　质：250g白卡
主要工艺要求：磨砂、双面印刷

工艺示意图

黑色区域磨砂
红色区域不磨砂

背面

EC CERTIFICATE
Full Quality Assurance System

Certificate no.:
9776-2017-CE-RGC-NA-PS

Initial certification date:
19 July 2017

Valid Until:
18 May 2024

This is to certify that the management system of

Guangzhou Double One Latex Products Co., Ltd.

South Area of 3# Rubber Road, Chini Town, Huadu District, Guangzhou City, Guangdong Province, 510830, China

For design, production and final product inspection/testing of:

Natural Latex Rubber Condom

has been assessed and found to comply with respect to:

the conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

Place and date:
Høvik, 21 May 2021

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate History		
Revision	**Description**	**Issued Date**
0.0	Replace the certificate 7582-2015-CE-RGC-NA 0.0 (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460) issued	19 July 2017
1.0	Editorial Changes and blockchain information	21 May 2021

Products covered by this Certificate:		
Product Description	**Product Name**	**Class**
Condoms	• Smooth condom (Plain condom) • Ribbed condom • Dotted condom • Combined condom (Note: this kind combines one or more of the former three) The above-mentioned condoms include natural color condom, color condom and flavor condom	IIa

Sites covered by this certificate	
Site Name	**Site Address**
Guangzhou Double One Latex Products Co., Ltd.	South Area of 3# Rubber Road, Chini Town, Huadu District, Guangzhou City, Guangdong Province, 510830, China

EU Representative
Wellkang Ltd T/A Wellkang Tech Consulting- Suite B, 29 Harley Street - London W1G 9QR England, United Kingdom

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
216277-2017-AQ-RGC-NA-PS

Initial certification date:
19 May 1999

Valid:
27 February 2025 – 26 February 2028

This is to certify that the management system of

Guangzhou Double One Latex Products Co., Ltd.

South Area of 3# Rubber Road, Chini Town, Huadu District, Guangzhou City, Guangdong Province, 510830, China (Unicode: 914401143046506946)

has been found to conform to the Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope:

Design, Manufacture, Sales and Distribution of condoms and Latex Probe Covers.

Place and date:
Høvik, 03 January 2025

NORWEGIAN ACCREDITATION
MSYS 018

For the issuing office:
DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

Date: 2025-09-26

GUANGZHOU DOUBLE ONE LATEX PRODUCTS CO., LTD.
South Area of 3# Rubber Road, Chini Town,
Huadu District,
Guangzhou City,
Guangdong Province,
510830,
China

SUBJECT: AUDIT REPORT

Dear Mr Huang Wen Zheng

Please find attached the Audit Report documenting

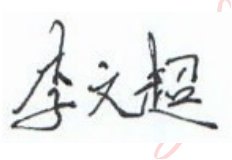
The results of our [Special audit]-of your medical devices to the

- MDR (European medical device regulation- Regulation (EU) 2017/745 of the European Parliament and the council of 5 April 2017 on medical devices)

We thank you and your organization for the support and co-operation provided during the audit and if you have any question or comment, please contact the undersigned.

Best regards,

Li Wen Chao
Lead auditor.
DNV Product Assurance AS



数字签名者：Li, Wen Chao
日期：2025.09.26 15:55:16 +08'00'

MANAGEMENT SYSTEM AUDIT AND MDR REPORT

PURPOSE:

The purpose of the audit was to evaluate the extent of conformity and capability of the QMS to ensure compliance with the referenced standard and applicable regulatory requirements, confirm the effective interaction between all elements of the system, and verify demonstrated commitment to maintain the effectiveness of the system.

The audit was conducted by DNV Product Assurance AS in respect of client's application for assessment.

This report, issued based on the audit conducted, applies only to matters, which were evident to DNV Product Assurance AS at the time of the audit within the audit scope. DNV Product Assurance AS does not warrant or otherwise comment upon the suitability of the contents of the report or the certificate for any particular purpose or use. DNV Product Assurance AS accepts no liability whatsoever for consequences to, or actions taken by, third parties as a result of or in reliance upon information contained in this report or any certificate based on it.

DNV Product Assurance AS audits are carried out within the requirements of DNV Product Assurance AS procedures that also reflect the requirements and guidance provided in the international standards relating to audit practice such as ISO/IEC 17021-1, ISO 17065, and other normative criteria. DNV Product Assurance AS auditors are assigned to audits according to knowledge of devices, processes, technologies, specialties appropriate to the organization being audited.

Please note that audit reports are subject to independent review and approval. Should changes to the outcomes of this report be necessary as a result of the review, a revised report will be issued and shall supersede this report. DNV Product Assurance AS reserves the right to request further information as part of this process.

Medical device regulations (Regulation (EU) 2017/745 of 5 April 2017 on medical devices) is referred in this report as MDR.

DNV Product Assurance AS is notified by the Norwegian Ministry of Health and Care Services according to:

- MDR - European Medical Device Regulation- Regulation (EU) 2017/745 of the European Parliament and the council of 5 April 2017 on medical devices.

DNV is an accredited Certification Body, MSYS 018, for certifications according to ISO 13485:2016.

Appendices to this audit report:

- DMSP-5-PA-MDR-04-A2 List of findings (if relevant)
- Test protocols and reports from testing required or tests performed by DNV.

SECTION 1 - COMPANY INFORMATION

Company name	Company address
GUANGZHOU DOUBLE ONE LATEX PRODUCTS CO., LTD.	South Area of 3# Rubber Road, Chini Town, Huadu District, Guangzhou City, Guangdong Province, 510830, China
Name and title of contact person	**Contact person phone number/e-mail address**
Li Miao, QMS engineer	86 13922491015, 86 020-86748846 250000422@qq.com
Site audited (manufacturer)	**Site audited (supplier) if applicable**
South Area of 3# Rubber Road, Chini Town, Huadu District, Guangzhou City, Guangdong Province, 510830, China	NA

Corporate Identity of the manufacturer:	Single Registration Number (SRN):
NA	CN-MF-000023131
Name and title of senior management	**Company phone number/web address**
Wen Huan/G.M	86-020-86748988/ 86748808 / www.doubleone.net
Authorized representative (if applicable)	**Authorized representative address:**
Wellkang Ltd	Enterprise Hub, NW Business Complex, 1 Beraghmore R d. Derry, BT48 8SE, Northern Ireland

SECTION 2 – MANAGEMENT SYSTEM, SCOPE, AND EXCLUSIONS

Audit Criteria: MDR – Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices Special Audit

Audit Objectives: To verify continued compliance between the requirements of the MDR and the implemented quality management system including meeting quality objectives. The assessment of the manufacturer's conformity to the MDR Annex IX excluding chapter II

Issue/Revision status of the quality manual (documented system): SY-QMS-2025, B/10

Rev. / Issue or date of issue: 2025-06-18.

The management system manual revision was reviewed and found to be in conformance with the requirements.

At Recertifications: Need for full or partial stage 1 audit:

Justifiable exclusions:

The following requirement(s) from Section 7 of the standard has/have been identified in the Quality Manual as exclusions: None

It was verified during the audit that the exclusions claimed are justifiable, and that their exclusion does not affect the organization's ability, or responsibility, to provide product that fulfils customer and applicable regulatory requirements.

Non-justifiable exclusions (ISO 13485:2016):

The claimed exclusion of the following requirement(s) of the standard from the company's management system is not considered justifiable: none.

This major non-conformity is documented in LOF: NA

Non-Applications :

The following requirements are Not Applicable to this location:
7.5.3, 7.5.4, 7.5.5, 7.5.7, 7.5.9.2.

Technical documentation assessments since last audit.

- NA, this is MDR special audit.

Scope of certification.

Standard/regulation	Certificate ID	Expiry date	Certificate scope
MDR, EU Quality Management System Certificates (Annex IX, chapter I and III)	C558623	Pending	Design, Production and final inspection/testing Natural rubber latex male condoms.

Multi-site certifications:

Not Applicable

Statutory and Regulatory Requirements Referenced:

Applicable Regulatory Requirements	Type of medical devices	Organizations Role (Legal manufacturer, Contract manufacturer, Authorized Representative, Importer, Distributor etc.)
MDR- Regulation (EU) 2017/745 – Annex IX excluding chapter II.	Natural rubber latex male condoms.	Legal manufacturer

The organization has established, implemented, and maintained procedure, activity, or arrangement to identify all relevant regulatory requirements, and documented the role(s) undertaken by the organization under the applicable regulatory requirements.

SECTION 3 - AUDIT DETAILS AND RESULTS

Type of Audit	Standard/requirements
Special Audit	MDR (Regulation (EU) 2017/745 of the European Parliament and the council of 5 April 2017 on medical devices) Annex Annex IX, chapter I and III
Date of audit	**Total on-site audit time/Total remote audit time (if applicable)**
2025-09-26	1 Manday
Project number	**Audit ID**
Lead Auditor	**Technical or Clinical Assessors (if applicable)**
Auditors	**Technical or Clinical Experts (if applicable)**
Observers/organization (if applicable)	**Interpreters/organization (if applicable)**
MDN, MDA, MDS, MDT codes relevant to the audit (Only relevant if the device is CE-marked):	
MDN 1210; MDT 2004; MDT 2008; MDT 2011	
Technical area(s) relevant to the audit (only applicable for ISO 13485):	
NA	

Audit Language:

- Chinese spoken and English written

Executive Overview

All applicable processes follow audit plan were audited.

Guangzhou Double One Latex Products Co., Ltd. is established in 2014-09-14. The predecessor is Guangzhou No. 11 rubber factory which established in 1955. It is the first professional production of condoms of the state-owned enterprise in China.

The main products are natural rubber latex male condoms and medical surgical gloves. There are approximate 76 employees with 3 shifts with the MDR scope device: Natural rubber latex male condoms. Guangzhou Double One Latex Products Co., Ltd. established a quality management system, per ISO 13485:2016 and the relevant requirements of China's medical device regulations, ANVISA regulations, FDA regulations and MDR.

The manufacturer has got NDV's ISO13485 certificate since 1999-05-19, the ISO13485 certificate No.: 216277-2017-AQ-RGC-NA-PS, scope: Design, Manufacture, Sales and Distribution of Condoms and Disposable Medical Face Masks, valid till: 26 February 2025. The compliance with ISO13485, MDR can be confirmed.

Description of activities covered during the audit.

Site audited (manufacturer/supplier)	List product and processes audited relevant to site
South Area of 3# Rubber Road, Chini Town, Huadu District, Guangzhou City, Guangdong Province, 510830, China	**Design, Production and final inspection/testing Natural rubber latex male condoms.**

Audit plan revision no and date sent to manufacturer prior to audit:	**Rev. 0, 2025-9-09**
In case of changes to the audit plan compared to what is stated in the original plan sent to the manufacturer prior to the audit indicate the changes	
Audit plan revision no and date after change (if any):	**Rev. 1, 2025-09-24**
Indicate changes (if any):	**Audit is postponed one day due to Typhoon Ragasa.**

Previous audits

MDR IA is conducted on 2024-10-08 to 2024-10-12, no NC issued.

Documentation used as input for this audit:

- *Previous audit reports from IA, PA or RC and audit report from any Unannounced audit, Scope extension audit or Special audit performed after last IA, PA, or RC*

Audit ~~Status Record~~

Audit Notes and conclusions.

üor (OK)= Audited, no non-conformance

MNC# = Open major non-conformities identified

mNC# = Open minor non-conformities identified

(-) = Not fully audited

NA = Not applicable

NAU = Not audited

(OK) Review of major changes and new devices.

Organizational Changes

- There has been no significant change to the organization structure, key personnel, ownership, facilities, scope, medical devices, processes and QMS since last audit:

New devices since last audit.
List the devices added: NA

(OK) Usage of Marks, Logos and Certificate:

No evidence of misuse of marks, logos or certificate identified during the audit activities, as part of review of the company homepage and marks not used in labelling or packaging of product.

Previous Audit Issues:

(OK) (Follow-up on past non-conformities):

There was no past non-conformity identified from the previous audit requiring follow up.

Management & Quality Processes:

(OK) **Quality Management System Processes: 4.1.2**

Procedure:

- Quality manual, SY-QMS-2024, B/10, 2025/6/18

Records Reviewed:

- Updated QMS procedures

Audited that the organization has determined the processes needed for the quality management system and the application of these processes throughout the organization considering the roles undertaken by the organization. The sequence and interaction between these processes are determined.

The organization has determined the processes needed for quality management system and the roles undertaken by the organization.

(OK) **Change Control: 4.1.4**

Procedure:

- Quality manual, SY-QMS-2024, B/10, 2025/6/18
- Change management control procedure, SY-QESR-62, A1, 2023-06-30

Records Reviewed:

- Management review report, 2025-1-24

Audited that changes made to the quality management system processes are evaluated for their impact on the quality management system, evaluated for their impact on the medical devices provided under this quality management system, and that the changes are controlled in accordance with the requirements in this standard and applicable regulatory requirement.

Number of significant changes since last audit:
Audited the following changes implemented in in the quality management system processes since last audit:

Change ID	Short Description	Date of approval/ implementation
NA		

The change control process is well implemented.

NAU **Validation of Computer Software: 4.1.6, 7.5.6, 7.6**

NAU **Medical Device File: 4.2.3**

NAU **Control of Documents (including document number, revision etc.): 4.2.4**

NAU **Control of Quality Records: 4.2.5**

(OK) **MDR specific. Single registration Number, UDI**
Procedure:

- UDI control procedure for products, SY-QESP-50, A1, 2023-06-30

Records Reviewed:

- UDI for CE marked condoms, QESW（05）－110, A/0, 2024-07-10

Audited the process for ensuring and controlling that the data in the data bases are correct and compliance has been established.

(OK) **Management Responsibilities, Commitment: 5.1, 5.5**

Audited currently implemented organization chart [Section 0.4.2 of Quality manual, SY-QMS-2024, B/10], [2025-6-18] with satisfactory results.

Job descriptions were reviewed for the following positions:

Initials of the employee	Function	Job description Doc ID and Version no/ other applicable documents
HWZ	MANAGEMENT REPRESENTATIVE PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE (PRRC, PERSON AUTHORIZED TO SIGN THE DOC)	QMR APPOINTMENT LETTER SIGNED BY GM DATED 2025/6/18 PRRC APPOINTMENT LETTER SIGNED BY GM DATED 2025/6/18 DOC CONTROL PROCEDURE (SY-QESP-52, A/1)
MJY	CONDOM WORK-SHOP DEPUTY MANAGER	QESW (12)-012, C/1
XY	R&D	QESW (12)-012, C/1
WJG	SALES MANAGER	QESW (12)-012, C/1
ZHL	HR SUPERVISOR	QESW (12)-012, C/1
LM	QMS ENGINEER	QESW (12)-012, C/1

Responsibilities, authorities, and the interrelation of all personnel are defined, documented, and communicated within the organization.

(OK) **Quality Policy: 5.3**

Based on the results of this audit, the management system is effectively implemented and

fulfils the stated quality policy.

The quality policy is stated in the current Quality Manual and is appropriate to the purpose of the organization, includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system.

The quality policy and quality objectives are established by top management and reviewed for continuing suitability at least annually in management review records and is communicated and understood within the organization.

(OK) **Performance Monitoring and Measurements: 8.2.5|/5.4.1**

There continues to be a satisfactory level of input and support from top management to ensure the quality management system provides the intended controls, customer feedback and improvement opportunities. The health and performance of the system continues to be monitored via KPI's and related targets. The stated quality objectives are being met.

(OK) **Management Review: 5.6**
Procedure:

- Management Review Control Procedure, SY-QESP-03, ver. C/4, 2025/04/18

Meetings verified and dated on: 2025-01-24

Records of the most recent management review meetings were verified and found to meet the requirements of the standard. All inputs were reflected in the records and appear suitably managed as reflected by resulting actions and decisions.

(OK) **Analysis of Data: 8.4/8.1**
Procedure:

- Data analysis control procedure, SY-QESP-21, ver. C/2, 2023/6/30

Records Reviewed:

- Year 2025 management review meeting report, QESR(06)-110,2025-2-8
- Company level quality objective:
  Final inspection qualification rate 100%, For Year 2024, 100%, meet the target
  Customer satisfied rate＞85%, for Year 2024,94.45%,meet the target
  NMPA sample qualification inspection rate 100%, For Year 2024,100%, meet the target

  The quality objective for Year 2025 is the same as year 2024.

Documented procedures are available and implemented with records of all required analysis of data per ISO 13485, section 8.4.

(OK) **Internal Audit: 8.2.4**
Procedure:

- Internal audit control procedure, SY-QESP-17, ver.C2, 2023/06/30

Records Reviewed:

- 2025 internal audit opening and closing meeting, QESR(06)-090, Rev. A/1,2025-3-25 to 2025-3-27
- Internal audit plan, QESR(06)-107,2025-3-24
- Internal audit report, QESR(06)-108,2025-4-3,3mNCs issued.
- Internal audit NC summary report, QESR(06)-107,2025-4-3
- NC report, QESR(06)-082,2025-3-25

Reviewed the following internal audit reports:

Date of Internal Audit	Process audited	Results (# of NC and observations)	Status for issued NC(open, in progress or closed)
2025-3-25 TO 2025-3-27	MANAGEMENT	1 NC	CLOSED
2025-3-25 TO 2025-3-27	R&D	1 NC	CLOSED
2025-3-25 TO 2025-3-27	STORAGE	1 NC	CLOSED
2025-3-25 TO 2025-3-27	PRODUCTION	0 NC	CLOSED

Internal audits are being conducted at planned intervals to ensure conformance to planned arrangements, the requirements of the ISO 13485 standard plus applicable regulations and the established management system. Resulting actions were taken without undue delay to eliminate nonconformities. Follow-up activities included reports of the verification of the actions and results.

(OK) **Improvement: 8.2.3, 8.3.3, 7.2.3**
Procedure:

- Medical device vigilance and recall control procedure, SY-QESP-05, ver. C/3, 2023-06-30
- Medical device adverse event control procedure, SY-QESP-27, ver. C/4, 2023-06-30
- Advisory notice procedure, SY-QESP-44, C2, 2023-06-30
- Medical device accident reporting procedure, SY-QESP-45, C3, 2023-06-30
- Vigilance system control procedure, SY-QESP-56, ver. A/1, 2023-06-30

The manufacturer has established vigilance system control procedure as per the requirement of MDR. Because the manufacturer hasn't got the MDR license, there was no sales in EU since the MDD certificate expire in 2021. There was no adverse event received in EU.

The medical device adverse event monitoring control procedure has been established as per China medical device regulation. Since the last audit, there were 19 suspicious adverse event cases received in China NMPA medical device adverse event reporting system, all of them are applicable for Condoms. Most of adverse event for condoms are allergy and condom fractured. Of these cases 10 cases were Local NMPA has approved, waiting the final review of NMPA or reviewed and approved by NMPA.

The manufacturer has established the medical device adverse event reporting and handling procedure.

If they received the medical adverse event, the manufacturer should perform the medical adverse event and report the competent authority.

There is 0 medical adverse event received from oversea since last audit.

- **ID**: 12133040720240004 94
  - **Name of the Medical device**: condom
  - **Batch number**: 23030902
  - **Date of registration**: **2024-12-16**
  - **Authority reported to: NMPA**
  - **Description of the reason**: The device was damaged during use, and lead to failed contraception.
  - **Actions**: No action needed. Justification, As condoms are mass-produced products, in the national product standards and the technical requirements acceptance criteria of enterprises, sampling and testing are conducted based on probability, allowing for a certain number of defective products. We have self-checked that the production records and process testing records of this batch all comply with the management requirements of the production process regulations and intermediate process control. The factory inspection report of this batch of products shows that the acceptance limit of this batch meets the requirements of the technical standards. For the feedback of non-conforming products, the company will handle them by returning the goods.

- **Status**: in progress

- **ID**: **1376105062025000004**
  - **Name of the Medical device**: condom
  - **Batch number**: **22110403**
  - **Date of registration**: **2025-02-17**
  - **Authority reported to: NMPA**
  - **Description of the reason: Patients complaints that the device is too thick and not well lubricated.**
  - **Actions:** No action needed. After investigation, it was found that the user did not experience any allergic reactions or discomfort. They merely had different feelings about the comfort level of the product type selected, which does not constitute an adverse event.
  - **Status:** Local NMPA has approved, waiting the final review of NMPA

- **ID**: **1355308122025000013**
  - **Name of the Medical device**: condom
  - **Batch number**: WMK24A
  - **Date of registration**: **2025-03-29**
  - **Authority reported to: NMPA**
  - **Description of the reason**: allergy after use
  - **Actions**: No action needed. In 2024, the rate of defective condom sales due to allergies was 0.000016%, which was a very low proportion. The natural latex material of condoms contains a considerable amount of protein by itself, which may cause contact allergies. The main protein that causes allergies in the human body is water-soluble protein. During the manufacturing process of latex condoms, our company has reduced the protein content through pre-vulcanization, centrifugation and other procedures. However, due to individual differences, some people may still be allergic to protein. After risk assessment, it has been decided to disclose the following remaining risks [contraindications] in the form of product instructions.
  - **Status**: Local NMPA has approved, waiting the final review of NMPA

No identified recalls, or mandatory problem reports issued by the manufacturer.

Responsibility and authority for mandatory problem reporting and recall process is with G.M. plus alternate person PRRC.

(OK) Corrective and Preventive Action: 8.5.2/8.5.3
Procedure:

- SY-QESP-23 CAPA control procedure, D/0, 2025-08-01

Records Reviewed:

- Corrective and Preventive Action handling lists_ QESR(06)-255, A/1, 2025-09-13

Since last audit, 2 CAPA have been registered; of these 1 have status closed.

Audited the following CAPA:

CAPA ID	Date of registration	Description	Status (open, in progress or closed)
CAPA-2025-001-01	2025-01-30	UNIT PROVIDED IN STRIPS, COULD NOT BE PROPERLY SEPARATED BY HAND	CLOSED
CAPA-202509-01	2025-09-13	PRODUCT COULD NOT BE PROPERLY OPENED	IN PROGRESS

The system for capturing details of corrective and preventive action was confirmed as being appropriately utilized for internal non-conformity, supplier defects, customer complaints and preventive measures. Required actions are determined, recorded in the database, effectiveness, or

results followed-up and closed in a timely manner. Follow up any non-conformities issued as part assessment activities have been audited to determine if the activities are systemic in nature.

(OK) Customer Complaints: 8.2.2
Procedure:

- SY-QESP-26 Complaint handle control procedure, C3, 2023-06-30

Records Reviewed:

- Customer complaint handle record, QESR(08)-013, A/0, 2025-09-13

Since the past year, 21 customer complaints have been registered. Of these 2 cases received from the customer directly, refer to the below table. And 19 cases were received from China NMPA medical device adverse event reporting system, refer to section “Improvement: 8.2.3, 8.3.3, 7.2.3” in this audit report.

Audited the following customer complaints and specific situations/ followed up by the manufacturer:

ID	Date of registration	Product name	Customer*	Description	ID for related CAPA	Reported to regulatory authorities	Status (open, in progress or closed)
082025013001	2025-01-30	CONDOM	UN	UNIT PROVIDED IN STRIPS, COULD NOT BE PROPERLY SEPARATED BY HAND	CAPA-2025-001-01	NO	CLOSED
082025091301	2025-09-13	CONDOM	CUSTOMER NO. BZL	PRODUCT COULD NOT BE PROPERLY OPENED	CAPA-202509-01	NO	IN PROGRESS

*If the customer is a person only initials shall be documented.

The company is implementing an effective process for the management of customer complaints, including the implementation of appropriate corrective action measures. Complaints are reviewed and evaluated to determine whether an investigation and/or corrective action are necessary; if not, the reason is justified and recorded.

NAU Resource Management: 6.1/ 6.2

Sales Process:

NAU Customer Related Processes / Customer Focus: 7.2/ 5.2

NAU Feedback systems: 8.2.1

Design and Development Process:

(OK) Design and Development Process: 7.3
Procedure:

- R&D control procedure, SY-QESP-07, ver.C/3, 2025-01-08
- Clinical evaluation procedure, SY-QESP-64, ver.A/1, 2023-06-30
- PMS control procedure, QESP-059, ver.B/2, 2023-07-14
- Condoms IFU, label and marking management procedure, QESW(05)-039, ver.B/2, 2023-

07-14

Records Reviewed:

- MDR TD:
  - History of design & development, SY-CE-01-075, SY-CE-01-075
  - Key product-design specifications listing, SY-CE-01-013, ver.A2, 2024-09-16
  - Design control matrix, SY-CE-01-052, ver.A/0, 2022-03-20
- R&D records of Natural rubber latex male condoms

The design & development process contains following phases: Product Planning, Design Input, Design Output, Design Review, Design Verification, Design Verification, Design Validation, Pilot production/ Production Transfer, Design change control.

Audited that the organization has implemented a method to ensure traceability of design and development outputs to design and development input. Audited also that resources used in the design and development project, including design and development changes have the necessary competence.

Audited that the design and development verification plan and validation plan include methods, acceptance criteria and statistical techniques with rationale for sample size.

Audited that the following medical device type or medical device family have a design and development file:

- Natural rubber latex male condoms, 2023-06-30

The following new medical device have been developed since last audit and is launched in the following markets:

- NA

Audited the following design project: Natural rubber latex male condoms

- Project proposal, QESR(05)-049, ver.A/0, 2020-07-10
- R&D plan, QESR(05)-052, ver.A/0, 2020-07-01
- R&D input list, QESR(05)-053, ver.A/0, 2020-07-10
- R&D validation report, 2021-10-28
- Risk management report
- R&D input review record, 2023-11-23
- R&D output list, QESR(05)-054, ver.A/0, 2023-11-23, including product technical requirement, manufacturing flow chart, purchasing material list, manufacturing and inspection SOP, IFU & label drawing, etc.
- Product performance test report, biological evaluation report, clinical evaluation report, etc.
- R&D output review record, 2023-11-23

Design changes:

Design Change Process: Change request> Approval> Assign project team> Conduct change impact assessment> Change order> Execute project activity> Prepare change summary report> Review and approve change summary report, including product safety and performances, related regulatory > Execute design change activity> Verification of design change> Design change review> Validation of design change, if necessary> Implementation into production> Information of release> Closure of change project.

Since last audit, 0 significant design changes have been implemented.

Reviewed the following design changes: NA

- **ID design change:**
- **Name of the medical device:**
- **Title of design change:**
- **Documents reviewed:**
- **Status:**

Audited the following design change project: NA

Devices covered by certificates according to MDD and the transitional provisions under Article 120 of the MDR:

Documented procedures are available for design and development, and design and development transfer to manufacturing, and are adequately implemented.

Technical documentation, PMS, PMCF, PSUR & SSCP

(OK) Technical documentation establishment and maintenance.

Procedure:

- Technical documentation and its change control procedure, SY-QESP-53, ver.A/1, 2023-06-30
- Clinical evaluation procedure, SY-QESP-64, ver.A/1, 2023-06-30
- Product registration and listing control procedure, SY-QESP-63, ver.A/1, 2023-06-30
- Medical device classification control procedure, SY-QESP-61, ver.A/1, 2023-06-30
- Condoms IFU, label and marking management procedure, QESW(05)-039, ver.B/2, 2023-07-14

Audited the MDR technical documentation for:

- [Natural rubber latex male condoms], Model:

W49mm Smooth no color no flavour condom,
W53mm Smooth no color no flavour condom,
W55mm Smooth no color no flavour condom,
W53mm Smooth no color strawberry flavour condom,
W53mm Smooth red color strawberry flavour condom

The establishment and maintenance of the technical file was audited, and the following documents were identified:

- GSPR checklist, 2024-01-29
- Draft Doc, SY-CE-01-005, ver.A/3
- Clinical evaluation report, SY-CE-01-009, ver.A/7, 2025-07-17
- Product description, SY-CE-01-049, ver.A/4, 2024-09-16
- Biological evaluation report, SY-CE-01-019, ver.A/3, 2024-05-22
- Product performance test reports
- Accelerated stability verification report, SY-CE-01-007, ver.A/0, 2021-10-15

Audited the technical documentation for devices under the NB confirmation letter:

- [NA]

The technical file audited was established and was maintained in relation to design changes, revision of standards, feedback from PMS, Feedback from technical file assessments performed by DNV etc.

(OK) **Post market surveillance, Post market clinical follow up and Periodical safety update reports, SSCP.**

Procedure:

- PSUR control procedure, SY-QESP-51, ver.A/1, 2023-06-30
- PMS control procedure, SY-QESP-59, ver.A/1, 2023-06-30
- Clinical evaluation control procedure, SY-QESP-63, ver.A/1, 2023-06-30

Records:

- PMS plan, SY-CE-01-020, A/1, 2025-03-04
- PSUR report, SY-CE-01-022, A/6, 2025-07-07
- PMCF plan, SY-CE-01-010, 2023-11-20
- PMCF interim report, SY-CE-01-073, A/1, 2025-03-05

Review the PMS procedure, PSUR procedure, PMS plan, PMCF plan, it's confirmed that the client has established the related procedure as per the MDR requirement and related PMS/PMCF plan had also be established as per the related procedure. The NC during clinical assessment related PMS, PMCF is not systematic problem.

Post market procedures (PMS, PMCF, PSUR and SSCP), processes or reports ´s were issued according to established plans (including post market clinical follow up).

Risk management

(OK) **Risk Management/ Planning and Product Realization: 7.1**

Procedure:

- Medical device risk management control procedure, QESW(05)-059, ver. B/3, 2025-02-07

Audited the following documented requirements and records:

- Risk Management Plan, Natural rubber latex male condoms, SY-CE-01-001, 2024-05-22
- Risk Management Report, Natural rubber latex male condoms, SY-CE-01-002, A/1.5, 2025-04-20

The risk management procedure has been updated as per EN ISO14971:2019.

The risk management team requirement had specified in section 4.1.4, which need to included these persons have knowledge of and experience with the particular medical device and its use (physician or clinical expert).

The risk management plan requirement has been specified in section 5.2 of the procedure.

The production and post-production information review requirement has specified in section 5.12 of the procedure.

Summary/conclusion:

EN ISO 14971:2019 is implemented for Natural rubber latex male condoms risk management. The Risk Management process comprises of 5 major stages: Risk Analysis, Risk Evaluation, Risk Control, Overall residual risk evaluation and Post-Production stages. The Risk Management team comprises qualified cross-functional team members from R&D, QA, RA, Production, Purchase & Sales. The Risk Management team shall prepare the risk management plan in accordance to the activities of product design & development process, product realization process and clinical application process. Summary of Risk Management Report contains the results of the analysis and is approved by GM. Feedback gathered through Post Production information triggers the review of Risk Management Report.

It's confirmed the assessment finding related risk management issued in TD assessment not systemic.

Documented procedure is available for the management of risk and product realization planning and is adequately implemented.

Requirements for test

NA **MDR requirement only.**

NA, this is special audit

Purchasing Process

NAU **Purchasing Process: 7.4.1/ 7.4.2**

NAU **Control of outsourced processes: 4.1.5, 7.4.1, 7.4.2**

NAU **Verification of purchased product: 7.4.3.**

Product Realization

NAU **Manufacturing and Process Controls: 7.5/ 8.2.6**

NAU **Control of non-conforming product: 8.3**

NAU **Preservation of Product: 7.5.11**

NAU **Identification (including labels of medical devices) and Traceability/ inspection status:7.5.8/ 7.5.9.**

NAU **Calibration: 7.6**

NAU **Infrastructure: 6.3**

NAU **Work Environment/Contamination Control: 6.4.1/6.4.2**

.

NAU **Cleanliness of Product and Contamination Control: 7.5.2**

NA **Installation: 7.5.3**

NA **Servicing: 7.5.4**

NA **Sterilization Processes: 7.5.5**

NA **Validation of processes for sterilization and sterile barrier systems: 7.5.7**

NAU **Validation of Processes: 7.5.6**

NA **Implantable medical devices: 7.5.9.2/8.2.6**

Section 4 - RECOMMENDATION

Recommendation: For Special Audit

Acceptable

The results of this periodical audit indicate that the management system of your company continues to be effectively implemented and meets the requirements of:
- MDR, Annex IX excluding chapter II

By meeting the quality and audit objectives for the scope of certification identified in this audit report, the management system remains registered/certified.

Recommendation on Notification of Changes/Scope Extension

NA.

Section 5 – AUDIT FINDINGS

Non-Conformities (NC's):

All the applicable requirements of the ISO 13485 and MDR were audited and considered to be adequately implemented.

There were no unresolved objections by the manufacturer to the issued non-conformities.

Areas Not Audited and revision of audit plan:

All areas within the scope of the audit as defined in the audit plan were audited and sufficiently covered.

There are no follow-up actions by DNV, including changes to the audit plan or changes to the number of audit-days, conditions, or observations.

Reliability and Obstacles of Audit:

No information was refused, and there were no obstacles encountered that may decrease the reliability of the audit findings and conclusion.

Audit termination:

Not applicable

Audit failure:

Not applicable

Other Issues:

NA

During our next audit the issues identified as requiring attention will be reviewed to ensure they have been adequately addressed, as well as the following:

- Internal audits, management review, customer complaints, issue of advisory notices, adverse event reporting, product recalls and corrective/ preventive actions will be covered during the next periodical audit.

SECTION 6 DEFINITIONS AND ACTION REQUIRED WITH RESPECT TO AUDIT FINDINGS

Major non-conformity:
Lack of compliance to the MDR (European medical device regulation- Regulation (EU) 2017/745 of the European Parliament and the council of 5 April 2017 and/or the UK Medical Device Regulation SI 2002 (SI 2002 No 618, as amended) (UK MDR 2002)

- That indicate a breakdown, gives doubt that devices products or services will meet requirements, or where evidence of compliance is not established.
- The absence of one or more required system elements or a situation which raises significant doubt that products or services will meet specified requirements.
- A group of minor non-conformities indicating inadequate implementation or effectiveness of the system relevant to an element of the standard.
- A minor non-conformity from previous audit that has not been closed by the company as agreed shall be upgraded to a major non-conformity.
- A non-conformity from previous audit where the actions made to close the nonconformity are not effective.

Minor non-conformity:
A lapse of either discipline or control during the implementation of system/procedural requirements, which does not indicate a system breakdown or raise doubt that products or services will meet requirements. Overall system requirement is defined, implemented and effective.

Response to non-conformities (action plan):
Customer shall respond to major and minor non-conformities within 30 days of the last day of audit. The response shall include:

- Root cause analysis
- Corrections and corrective actions
- Method of verification of effectiveness
- Deadline for implementation of actions
- Verification of effectiveness

Evidence for closeout (including verification of effectiveness)

- Major non-conformities shall be closed within 90 days.
- Minor non-conformities shall be closed out without any undue delay and verification of the effectiveness of the corrective actions will occur at the next audit.

广州双一乳胶制品有限公司
Guangzhou Double One Latex Products CO., Ltd
避孕套检验综合报告
General Report of Condom Testing

QESR(06)－004

订单号 PO No.	UNFPA-70191019				
名称及批号 Batch No.	25UN008	品种 Variety	光面　Smooth	标称宽度 Width	53mm
生产日期 Date of Manufacturing	2025-08-14	检验依据 Testing Standard	WHO 规范—2020 WHO Specification—2020	抽样基数 Sampling Base	495360 pcs
检验日期 Date of Testing	2025-08-15 至 2025-08-23		报告日期 Date of Report	2025-08-23	

检验项目 Testing Items		技术指标 Technique index	AQL	检验结果 Testing Result				单项评价 Evaluation	
				测试值 Testing Value	样本大小 No.of Samples	不合格数 No.of Unqualified Samples		AQL	判定 Result
老化前爆破 Before Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	15.6-57.0	315	2	2	＜1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		0.87-2.64	315	2			
老化后爆破 After Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	13.8-55.6	315	2	2	＜1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		0.84-2.67	315	1			
针孔检验 Freedom From Holes		无针孔 No Holes	0.25		315	0		＜0.25	合格 Qualified
严重可见缺陷 Critical Visible Defects		无缺陷 No Defects	0.4		315	0		＜0.4	合格 Qualified
可见密封开口的单个包装 Visibly open package seals		无任何可见的密封开口 No visibly sealing opening	0.4		315	0		＜0.4	合格 Qualified
包装完整性 Package Integrity		无渗漏 No Leakage	2.5		32	0		＜2.5	合格 Qualified
润滑剂量 Quantity of lubricant(mg)		550±150	4.0	466-508	13	0		＜4.0	合格 Qualified
尺寸 Size	长度 Length (mm)	≥180	1.0	183-189	13	0		＜1.0	合格 Qualified
	宽度 Width (mm)	53±2	1.0	52.0-53.0	13	0		＜1.0	合格 Qualified
	厚度 Thickness(mm)	0.065±0.01	1.0	0.056-0.065	13	0		＜1.0	合格 Qualified
包装和标志 Packaging and Labeling		符合 Qualified	2.5		32	0		＜2.5	合格 Qualified

综合判定结论 Conclusion	符合客户和 WHO 规范—2020 标准要求。 Conformed to WHO Specification—2020 and Customers Request.

审核(Verified by): 黄文正　　复核(Evaluated by): 周美珍　　填表 (Filled by): 任洁静

广州双一乳胶制品有限公司
Guangzhou Double One Latex Products CO., Ltd
避孕套检验综合报告
General Report of Condom Testing

QESR(06)－004

订单号 PO No.	UNFPA-70191019				
名称及批号 Batch No.	25UN009	品种 Variety	光面　Smooth	标称宽度 Width	53mm
生产日期 Date of Manufacturing	2025-08-15	检验依据 Testing Standard	WHO 规范—2020 WHO Specification—2020	抽样基数 Sampling Base	495360 pcs
检验日期 Date of Testing	2025-08-16 至 2025-08-25		报告日期 Date of Report	2025-08-25	

检验项目 Testing Items		技术指标 Technique index	AQL	检验结果 Testing Result				单项评价 Evaluation	
				测试值 Testing Value	样本大小 No.of Samples	不合格数 No.of Unqualified Samples		AQL	判定 Result
老化前爆破 Before Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	14.2-57.0	315	2	2	<1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		0.80-2.36	315	2			
老化后爆破 After Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	12.3-57.0	315	3	3	<1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		0.95-2.52	315	2			
针孔检验 Freedom From Holes		无针孔 No Holes	0.25		315	0		<0.25	合格 Qualified
严重可见缺陷 Critical Visible Defects		无缺陷 No Defects	0.4		315	0		<0.4	合格 Qualified
可见密封开口的单个包装 Visibly open package seals		无任何可见的密封开口 No visibly sealing opening	0.4		315	0		<0.4	合格 Qualified
包装完整性 Package Integrity		无渗漏 No Leakage	2.5		32	0		<2.5	合格 Qualified
润滑剂量 Quantity of lubricant(mg)		550±150	4.0	475-500	13	0		<4.0	合格 Qualified
尺寸 Size	长度 Length (mm)	≥180	1.0	181-189	13	0		<1.0	合格 Qualified
	宽度 Width (mm)	53±2	1.0	51.5-52.5	13	0		<1.0	合格 Qualified
	厚度 Thickness(mm)	0.065±0.01	1.0	0.056-0.070	13	0		<1.0	合格 Qualified
包装和标志 Packaging and Labeling		符合 Qualified	2.5		32	0		<2.5	合格 Qualified

综合判定结论 Conclusion	符合客户和 WHO 规范—2020 标准要求。 Conformed to WHO Specification—2020 and Customers Request.

审核(Verified by): 黄文正　　复核(Evaluated by): 周美珍　　填表 (Filled by): 任洁静

广州双一乳胶制品有限公司
Guangzhou Double One Latex Products CO., Ltd
避孕套检验综合报告
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订单号 PO No.	UNFPA-70191019				
名称及批号 Batch No.	25UN010	品种 Variety	光面　Smooth	标称宽度 Width	53mm
生产日期 Date of Manufacturing	2025-08-16	检验依据 Testing Standard	WHO 规范—2020 WHO Specification—2020	抽样基数 Sampling Base	495360 pcs
检验日期 Date of Testing	2025-08-18 至 2025-08-26		报告日期 Date of Report	2025-08-26	

检验项目 Testing Items		技术指标 Technique index	AQL	检验结果 Testing Result				单项评价 Evaluation	
				测试值 Testing Value	样本大小 No.of Samples	不合格数 No.of Unqualified Samples		AQL	判定 Result
老化前爆破 Before Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	21.0-57.5	315	0	0	＜1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		1.15-2.67	315	0			
老化后爆破 After Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	15.4-55.9	315	1	1	＜1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		0.80-2.62	315	1			
针孔检验 Freedom From Holes		无针孔 No Holes	0.25		315	0		＜0.25	合格 Qualified
严重可见缺陷 Critical Visible Defects		无缺陷 No Defects	0.4		315	0		＜0.4	合格 Qualified
可见密封开口的单个包装 Visibly open package seals		无任何可见的密封开口 No visibly sealing opening	0.4		315	0		＜0.4	合格 Qualified
包装完整性 Package Integrity		无渗漏 No Leakage	2.5		32	0		＜2.5	合格 Qualified
润滑剂量 Quantity of lubricant(mg)		550±150	4.0	475-497	13	0		＜4.0	合格 Qualified
尺寸 Size	长度 Length (mm)	≥180	1.0	183-194	13	0		＜1.0	合格 Qualified
	宽度 Width (mm)	53±2	1.0	51.5-52.5	13	0		＜1.0	合格 Qualified
	厚度 Thickness(mm)	0.065±0.01	1.0	0.059-0.067	13	0		＜1.0	合格 Qualified
包装和标志 Packaging and Labeling		符合 Qualified	2.5		32	0		＜2.5	合格 Qualified

综合判定结论 Conclusion	符合客户和 WHO 规范—2020 标准要求。 Conformed to WHO Specification—2020 and Customers Request.

审核(Verified by): 黄文正　　复核(Evaluated by): 周美珍　　填表 (Filled by): 任洁静

广州双一乳胶制品有限公司
Guangzhou Double One Latex Products CO., Ltd
避孕套检验综合报告
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订单号 PO No.	UNFPA-70191019				
名称及批号 Batch No.	25UN012	品种 Variety	光面　Smooth	标称宽度 Width	53mm
生产日期 Date of Manufacturing	2025-08-19	检验依据 Testing Standard	WHO 规范—2020 WHO Specification—2020	抽样基数 Sampling Base	495360 pcs
检验日期 Date of Testing	2025-08-20 至 2025-08-28		报告日期 Date of Report	2025-08-28	

检验项目 Testing Items		技术指标 Technique index	AQL	检验结果 Testing Result				单项评价 Evaluation	
				测试值 Testing Value	样本大小 No.of Samples	不合格数 No.of Unqualified Samples		AQL	判定 Result
老化前爆破 Before Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	14.8-56.8	315	2	2	＜1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		1.08-2.39	315	0			
老化后爆破 After Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	16.7-57.3	315	1	1	＜1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		1.01-2.49	315	0			
针孔检验 Freedom From Holes		无针孔 No Holes	0.25		315	0		＜0.25	合格 Qualified
严重可见缺陷 Critical Visible Defects		无缺陷 No Defects	0.4		315	0		＜0.4	合格 Qualified
可见密封开口的单个包装 Visibly open package seals		无任何可见的密封开口 No visibly sealing opening	0.4		315	0		＜0.4	合格 Qualified
包装完整性 Package Integrity		无渗漏 No Leakage	2.5		32	0		＜2.5	合格 Qualified
润滑剂量 Quantity of lubricant(mg)		550±150	4.0	479-491	13	0		＜4.0	合格 Qualified
尺寸 Size	长度 Length (mm)	≥180	1.0	189-192	13	0		＜1.0	合格 Qualified
	宽度 Width (mm)	53±2	1.0	52.0-52.5	13	0		＜1.0	合格 Qualified
	厚度 Thickness(mm)	0.065±0.01	1.0	0.061-0.068	13	0		＜1.0	合格 Qualified
包装和标志 Packaging and Labeling		符合 Qualified	2.5		32	0		＜2.5	合格 Qualified

综合判定结论 Conclusion	符合客户和 WHO 规范—2020 标准要求。 Conformed to WHO Specification—2020 and Customers Request.

审核(Verified by): 黄文正　　复核(Evaluated by): 周美珍　　填表（Filled by): 任洁静

广州双一乳胶制品有限公司
Guangzhou Double One Latex Products CO., Ltd
避孕套检验综合报告
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订单号 PO No.	UNFPA-70191019				
名称及批号 Batch No.	25UN013	品种 Variety	光面　Smooth	标称宽度 Width	53mm
生产日期 Date of Manufacturing	2025-08-20	检验依据 Testing Standard	WHO 规范—2020 WHO Specification—2020	抽样基数 Sampling Base	495360 pcs
检验日期 Date of Testing	2025-08-21 至 2025-08-29		报告日期 Date of Report	2025-08-29	

检验项目 Testing Items		技术指标 Technique index	AQL	检验结果 Testing Result				单项评价 Evaluation	
				测试值 Testing Value	样本大小 No.of Samples	不合格数 No.of Unqualified Samples		AQL	判定 Result
老化前爆破 Before Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	21.7-56.0	315	0	0	＜1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		1.13-2.54	315	0			
老化后爆破 After Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	14.9-56.9	315	2	2	＜1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		1.00-2.40	315	0			
针孔检验 Freedom From Holes		无针孔 No Holes	0.25		315	1		＜0.25	合格 Qualified
严重可见缺陷 Critical Visible Defects		无缺陷 No Defects	0.4		315	0		＜0.4	合格 Qualified
可见密封开口的单个包装 Visibly open package seals		无任何可见的密封开口 No visibly sealing opening	0.4		315	0		＜0.4	合格 Qualified
包装完整性 Package Integrity		无渗漏 No Leakage	2.5		32	0		＜2.5	合格 Qualified
润滑剂量 Quantity of lubricant(mg)		550±150	4.0	470-486	13	0		＜4.0	合格 Qualified
尺寸 Size	长度 Length (mm)	≥180	1.0	187-192	13	0		＜1.0	合格 Qualified
	宽度 Width (mm)	53±2	1.0	52.0-53.0	13	0		＜1.0	合格 Qualified
	厚度 Thickness(mm)	0.065±0.01	1.0	0.061-0.067	13	0		＜1.0	合格 Qualified
包装和标志 Packaging and Labeling		符合 Qualified	2.5		32	0		＜2.5	合格 Qualified

综合判定结论 Conclusion	符合客户和 WHO 规范—2020 标准要求。 Conformed to WHO Specification—2020 and Customers Request.

审核(Verified by): 黄文正　　复核(Evaluated by): 周美珍　　填表 (Filled by): 任洁静

广州双一乳胶制品有限公司
Guangzhou Double One Latex Products CO., Ltd
避孕套检验综合报告
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订单号 PO No.	UNFPA-70191019				
名称及批号 Batch No.	25UN014	品种 Variety	光面　Smooth	标称宽度 Width	53mm
生产日期 Date of Manufacturing	2025-08-21	检验依据 Testing Standard	WHO 规范—2020 WHO Specification—2020	抽样基数 Sampling Base	495360 pcs
检验日期 Date of Testing	2025-08-22 至 2025-08-30		报告日期 Date of Report	2025-08-30	

检验项目 Testing Items		技术指标 Technique index	AQL	检验结果 Testing Result				单项评价 Evaluation	
				测试值 Testing Value	样本大小 No.of Samples	不合格数 No.of Unqualified Samples		AQL	判定 Result
老化前爆破 Before Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	15.4-56.0	315	1	1	<1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		1.04-2.37	315	0			
老化后爆破 After Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	16.7-56.0	315	1	1	<1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		1.01-2.59	315	0			
针孔检验 Freedom From Holes		无针孔 No Holes	0.25		315	1		<0.25	合格 Qualified
严重可见缺陷 Critical Visible Defects		无缺陷 No Defects	0.4		315	0		<0.4	合格 Qualified
可见密封开口的单个包装 Visibly open package seals		无任何可见的密封开口 No visibly sealing opening	0.4		315	0		<0.4	合格 Qualified
包装完整性 Package Integrity		无渗漏 No Leakage	2.5		32	0		<2.5	合格 Qualified
润滑剂量 Quantity of lubricant(mg)		550±150	4.0	480-492	13	0		<4.0	合格 Qualified
尺寸 Size	长度 Length (mm)	≥180	1.0	190-197	13	0		<1.0	合格 Qualified
	宽度 Width (mm)	53±2	1.0	51.5-52.0	13	0		<1.0	合格 Qualified
	厚度 Thickness(mm)	0.065±0.01	1.0	0.061-0.066	13	0		<1.0	合格 Qualified
包装和标志 Packaging and Labeling		符合 Qualified	2.5		32	0		<2.5	合格 Qualified

综合判定结论 Conclusion	符合客户和 WHO 规范—2020 标准要求。 Conformed to WHO Specification—2020 and Customers Request.

审核(Verified by): 黄文正　　复核(Evaluated by): 周美珍　　填表 (Filled by): 任洁静

广州双一乳胶制品有限公司
Guangzhou Double One Latex Products CO., Ltd
避孕套检验综合报告
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订单号 PO No.	UNFPA-70191019				
名称及批号 Batch No.	25UN015	品种 Variety	光面　Smooth	标称宽度 Width	53mm
生产日期 Date of Manufacturing	2025-08-22	检验依据 Testing Standard	WHO 规范—2020 WHO Specification—2020	抽样基数 Sampling Base	495360 pcs
检验日期 Date of Testing	2025-08-23 至 2025-09-01		报告日期 Date of Report	2025-09-01	

检验项目 Testing Items		技术指标 Technique index	AQL	检验结果 Testing Result				单项评价 Evaluation	
				测试值 Testing Value	样本大小 No.of Samples	不合格数 No.of Unqualified Samples		AQL	判定 Result
老化前爆破 Before Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	15.0-56.8	315	1	1	＜1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		1.09-2.42	315	0			
老化后爆破 After Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	16.9-57.7	315	2	2	＜1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		1.03-2.44	315	0			
针孔检验 Freedom From Holes		无针孔 No Holes	0.25		315	0		＜0.25	合格 Qualified
严重可见缺陷 Critical Visible Defects		无缺陷 No Defects	0.4		315	0		＜0.4	合格 Qualified
可见密封开口的单个包装 Visibly open package seals		无任何可见的密封开口 No visibly sealing opening	0.4		315	0		＜0.4	合格 Qualified
包装完整性 Package Integrity		无渗漏 No Leakage	2.5		32	0		＜2.5	合格 Qualified
润滑剂量 Quantity of lubricant(mg)		550±150	4.0	480-495	13	0		＜4.0	合格 Qualified
尺寸 Size	长度 Length (mm)	≥180	1.0	187-194	13	0		＜1.0	合格 Qualified
	宽度 Width (mm)	53±2	1.0	51.0-52.0	13	0		＜1.0	合格 Qualified
	厚度 Thickness(mm)	0.065±0.01	1.0	0.062-0.069	13	0		＜1.0	合格 Qualified
包装和标志 Packaging and Labeling		符合 Qualified	2.5		32	0		＜2.5	合格 Qualified

综合判定结论 Conclusion	符合客户和 WHO 规范—2020 标准要求。 Conformed to WHO Specification—2020 and Customers Request.

审核(Verified by): 黄文正　　复核(Evaluated by): 周美珍　　填表 (Filled by): 任洁静

广州双一乳胶制品有限公司
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订单号 PO No.	UNFPA-70191019				
名称及批号 Batch No.	25UN016	品种 Variety	光面　Smooth	标称宽度 Width	53mm
生产日期 Date of Manufacturing	2025-08-23	检验依据 Testing Standard	WHO 规范—2020 WHO Specification—2020	抽样基数 Sampling Base	495360 pcs
检验日期 Date of Testing	2025-08-25 至 2025-09-02		报告日期 Date of Report	2025-09-02	

检验项目 Testing Items		技术指标 Technique index	AQL	检验结果 Testing Result				单项评价 Evaluation	
				测试值 Testing Value	样本大小 No.of Samples	不合格数 No.of Unqualified Samples		AQL	判定 Result
老化前爆破 Before Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	17.1-57.0	315	1	1	＜1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		0.97-2.45	315	1			
老化后爆破 After Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	13.3-56.4	315	2	2	＜1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		0.75-2.47	315	1			
针孔检验 Freedom From Holes		无针孔 No Holes	0.25		315	1		＜0.25	合格 Qualified
严重可见缺陷 Critical Visible Defects		无缺陷 No Defects	0.4		315	0		＜0.4	合格 Qualified
可见密封开口的单个包装 Visibly open package seals		无任何可见的密封开口 No visibly sealing opening	0.4		315	0		＜0.4	合格 Qualified
包装完整性 Package Integrity		无渗漏 No Leakage	2.5		32	0		＜2.5	合格 Qualified
润滑剂量 Quantity of lubricant(mg)		550±150	4.0	480-493	13	0		＜4.0	合格 Qualified
尺寸 Size	长度 Length (mm)	≥180	1.0	187-194	13	0		＜1.0	合格 Qualified
	宽度 Width (mm)	53±2	1.0	51.5-52.5	13	0		＜1.0	合格 Qualified
	厚度 Thickness(mm)	0.065±0.01	1.0	0.058-0.064	13	0		＜1.0	合格 Qualified
包装和标志 Packaging and Labeling		符合 Qualified	2.5		32	0		＜2.5	合格 Qualified

综合判定结论 Conclusion	符合客户和 WHO 规范—2020 标准要求。 Conformed to WHO Specification—2020 and Customers Request.

审核(Verified by): 黄文正　　复核(Evaluated by): 周美珍　　填表（Filled by): 任洁静

广州双一乳胶制品有限公司
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订单号 PO No.	UNFPA-70191019				
名称及批号 Batch No.	25UN017	品种 Variety	光面　Smooth	标称宽度 Width	53mm
生产日期 Date of Manufacturing	2025-08-25	检验依据 Testing Standard	WHO 规范—2020 WHO Specification—2020	抽样基数 Sampling Base	401760 pcs
检验日期 Date of Testing	2025-08-26 至 2025-09-03		报告日期 Date of Report	2025-09-03	

检验项目 Testing Items		技术指标 Technique index	AQL	检验结果 Testing Result				单项评价 Evaluation	
				测试值 Testing Value	样本大小 No.of Samples	不合格数 No.of Unqualified Samples		AQL	判定 Result
老化前爆破 Before Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	15.8-57.0	315	1	1	＜1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		1.13-2.50	315	0			
老化后爆破 After Aging	体积(dm^3) Bursting Volume	≥18.0	1.5	15.8-57.0	315	1	1	＜1.5	合格 Qualified
	压力(kPa) Bursting Pressure	≥1.0		0.93-2.30	315	1			
针孔检验 Freedom From Holes		无针孔 No Holes	0.25		315	0		＜0.25	合格 Qualified
严重可见缺陷 Critical Visible Defects		无缺陷 No Defects	0.4		315	0		＜0.4	合格 Qualified
可见密封开口的单个包装 Visibly open package seals		无任何可见的密封开口 No visibly sealing opening	0.4		315	0		＜0.4	合格 Qualified
包装完整性 Package Integrity		无渗漏 No Leakage	2.5		32	0		＜2.5	合格 Qualified
润滑剂量 Quantity of lubricant(mg)		550±150	4.0	483-491	13	0		＜4.0	合格 Qualified
尺寸 Size	长度 Length (mm)	≥180	1.0	187-194	13	0		＜1.0	合格 Qualified
	宽度 Width (mm)	53±2	1.0	51.5-52.5	13	0		＜1.0	合格 Qualified
	厚度 Thickness(mm)	0.065±0.01	1.0	0.063-0.069	13	0		＜1.0	合格 Qualified
包装和标志 Packaging and Labeling		符合 Qualified	2.5		32	0		＜2.5	合格 Qualified
综合判定结论 Conclusion	符合客户和 WHO 规范—2020 标准要求。 Conformed to WHO Specification—2020 and Customers Request.								

审核(Verified by): 黄文正　　复核(Evaluated by): 周美珍　　填表 (Filled by): 任洁静

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：粤食药监械出 20240754 号
Certificate NO.：粤食药监械出 20240754 号

产品名称：天然橡胶胶乳男用避孕套
Product(s)：**Natural rubber latex male condoms**

规格型号：标称宽度：49.0mm～55.0mm。 光面型（平纹型）、颗粒型（浮点型）、螺纹型、组合型。
Model：**49.0mm~55.0mm. Model: Smooth condom (Plain condom)、Dotted condom、 Ribbed condom、 combined condom.**

产品注册或备案凭证号：粤械注准 20162181025
Registration certificate(s)：粤械注准 20162181025

生产企业：广州双一乳胶制品有限公司
Manufacturer：**Guangzhou Double One Latex Products Co., Ltd.**

生产企业住所：广州市花都区赤坭镇橡胶路 3 号大院南区
Address of manufacturer：**South Area of 3# Rubber Road, Chini Town, Huadu District, Guangzhou City, Guangdong Province, China.**

生产许可或备案凭证号：粤食药监械生产许 20010152 号
Manufacturing License(s)：粤食药监械生产许 20010152 号

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至：2026 年 05 月 26 日
This certification valid until：26/05/2026

备注：无。
Remark:

2024 年 05 月 27 日
（出具单位盖章）