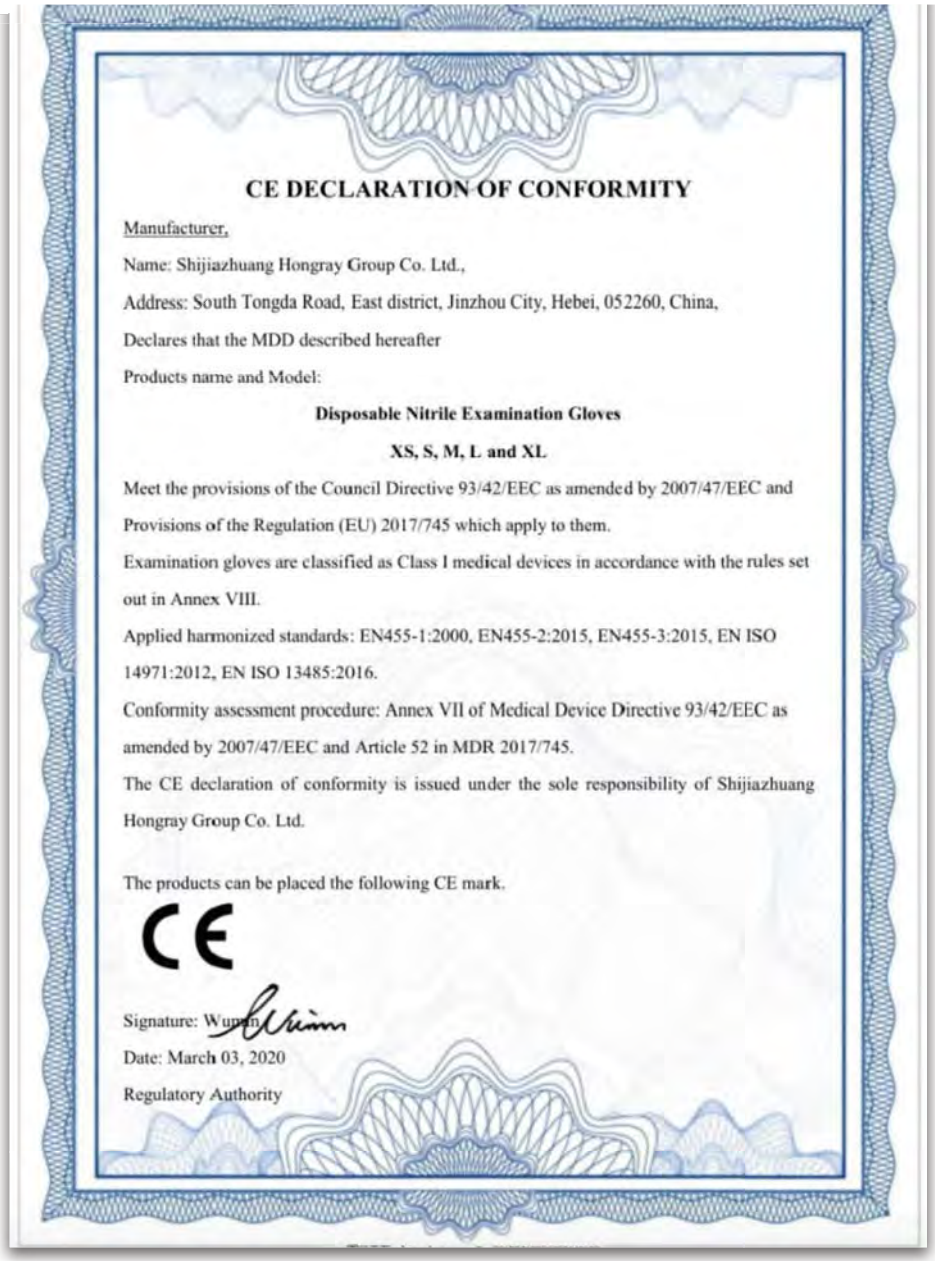
Hongray®

Disposable Nitrile

EXAMINATION GLOVES

Updated Sep 2020



CE DECLARATION OF CONFORMITY

Manufacturer,

Name: Shijiazhuang Hongray Group Co. Ltd.,

Address: South Tongda Road, East district, Jinzhou City, Hebei, 052260, China,

Declares that the MDD described hereafter

Products name and Model:

Disposable Nitrile Examination Gloves

XS, S, M, L and XL

Meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EEC and Provisions of the Regulation (EU) 2017/745 which apply to them.

Examination gloves are classified as Class I medical devices in accordance with the rules set out in Annex VIII.

Applied harmonized standards: EN455-1:2000, EN455-2:2015, EN455-3:2015, EN ISO 14971:2012, EN ISO 13485:2016.

Conformity assessment procedure: Annex VII of Medical Device Directive 93/42/EEC as amended by 2007/47/EEC and Article 52 in MDR 2017/745.

The CE declaration of conformity is issued under the sole responsibility of Shijiazhuang Hongray Group Co. Ltd.

The products can be placed the following CE mark.

CE

Signature: Wumin

Date: March 03, 2020

Regulatory Authority

• CE Certificate

CERTIFICATE
of Conformity

TÜV

Registration No.: AK 60003547 0001

Report No.: 21100703 003

Holder: Shijiazhuang Hongray Group
Syntex Healthcare Products
Co., Ltd. Hebei Province
No. 1 Fanjiazhuang Industrial Zone
Xinji City, 052360
China

Product: Schutzhandschuhe
Protective Gloves

Identification: medical gloves for single use
Nitrile gloves, blue sizes S, M and L

Tested acc. to: EN 455-1:2000
EN 455-2:2000
EN 455-3:1999

The certificate of conformity refers to the above mentioned product. This is to certify that the specimen is in conformity with the assessment requirement mentioned above. This certificate does not imply assessment of the production of the product and does not permit the use of a TÜV Rheinland mark of conformity.

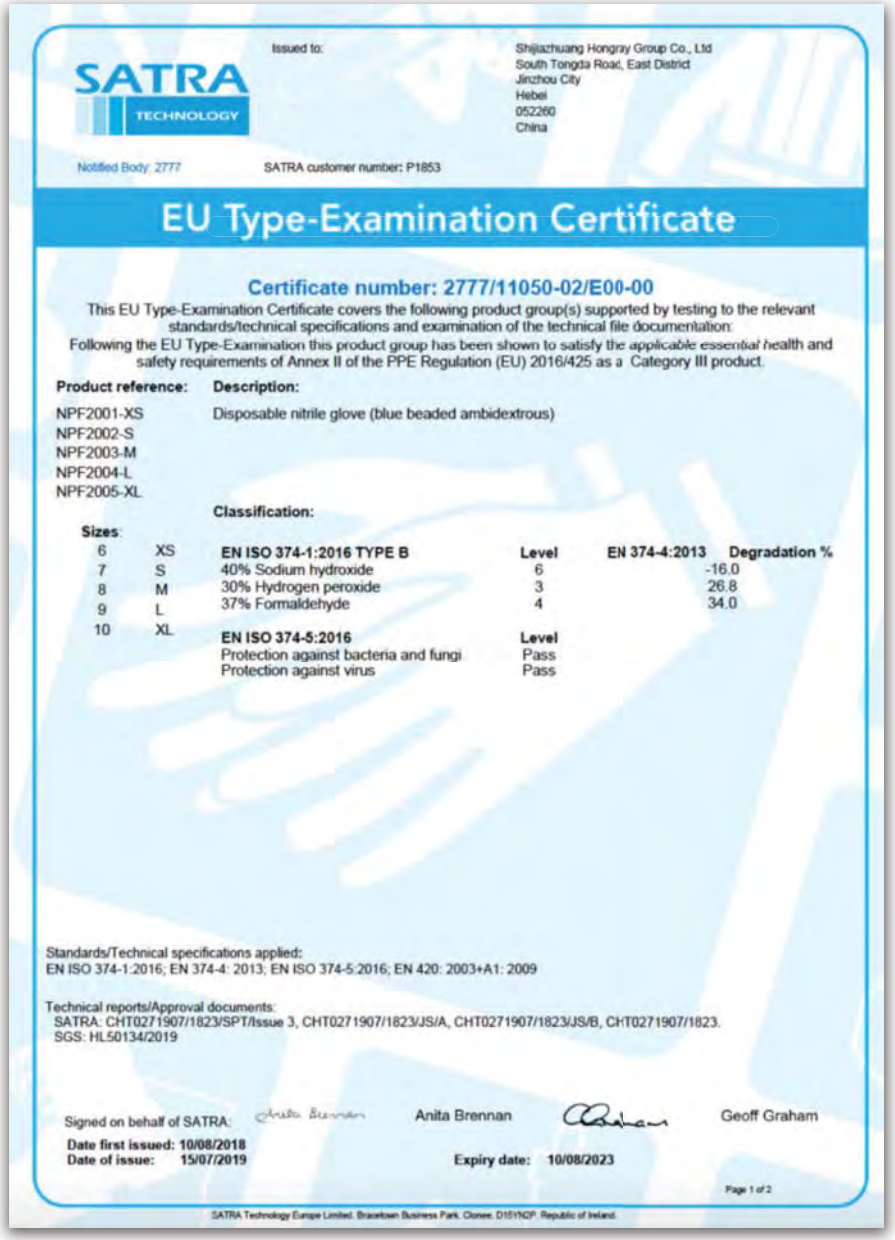
Certification Body

Cologne, 25.10.2002

Dipl.-Ing. H.-J. Krüger

TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln

• CE Certificate



Issued to:

Shijiazhuang Hongray Group Co., Ltd
South Tongda Road, East District
Jinzhou City
Hebei
052260
China

Notified Body: 2777

SATRA customer number: P1853

EU Type-Examination Certificate

Certificate number: 2777/11050-02/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:

Following the EU Type-Examination this product group has been shown to satisfy the *applicable essential* health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

NPF2001-XS
NPF2002-S
NPF2003-M
NPF2004-L
NPF2005-XL

Description:

Disposable nitrile glove (blue beaded ambidextrous)

Classification:

Sizes:

6	XS
7	S
8	M
9	L
10	XL

EN ISO 374-1:2016 TYPE B	Level	EN 374-4:2013 Degradation %
40% Sodium hydroxide	6	-16.0
30% Hydrogen peroxide	3	26.8
37% Formaldehyde	4	34.0

EN ISO 374-5:2016	Level
Protection against bacteria and fungi	Pass
Protection against virus	Pass

Standards/Technical specifications applied:
EN ISO 374-1:2016; EN 374-4: 2013; EN ISO 374-5:2016; EN 420: 2003+A1: 2009

Technical reports/Approval documents:
SATRA: CHT0271907/1823/SPT/Issue 3, CHT0271907/1823/JS/A, CHT0271907/1823/JS/B, CHT0271907/1823.
SGS: HL50134/2019

Signed on behalf of SATRA: Anita Brennan Anita Brennan Geoff Graham

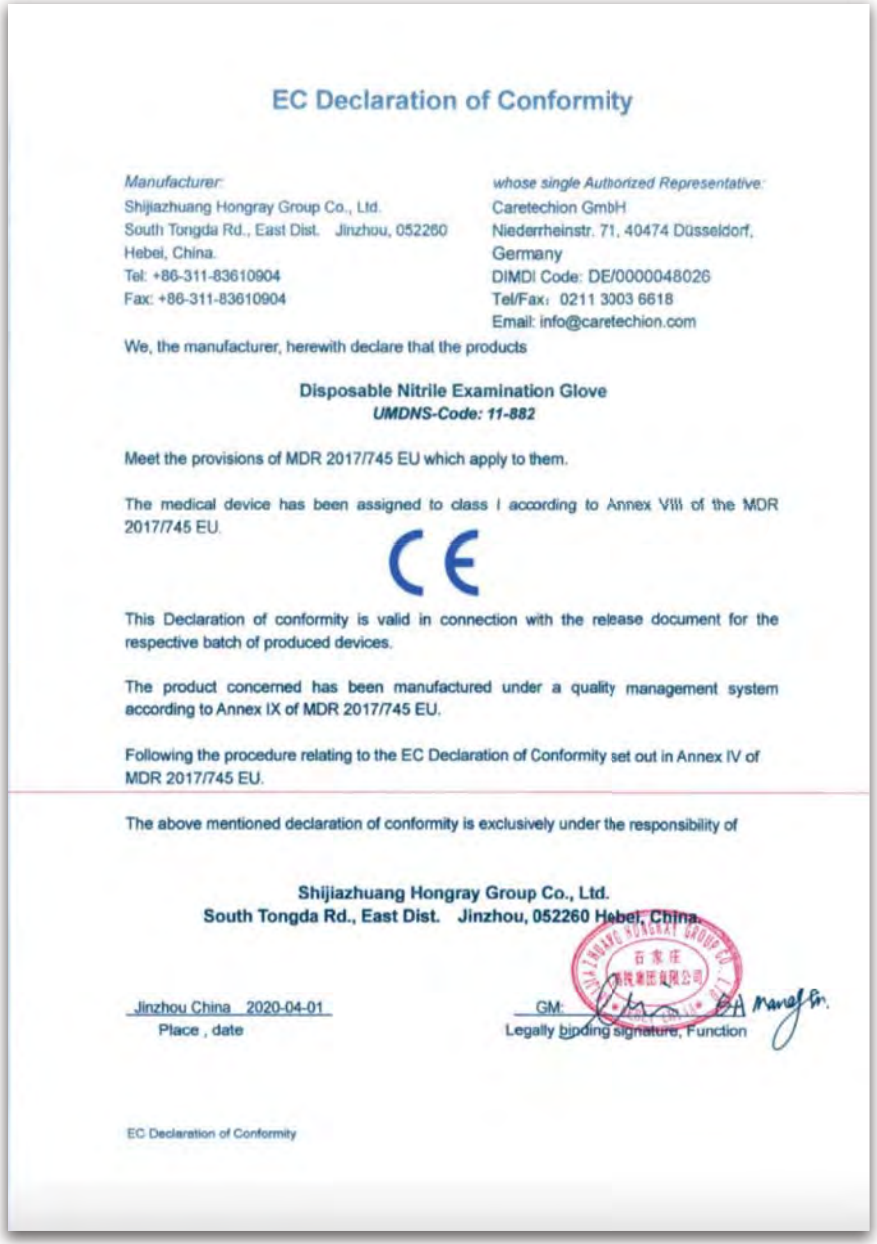
Date first issued: 10/08/2018
Date of issue: 15/07/2019

Expiry date: 10/08/2023

Page 1 of 2

SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15Y5DP, Republic of Ireland.

• EU Exam Certificate



EC Declaration of Conformity

Manufacturer:
Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou, 052260
Hebei, China.
Tel: +86-311-83610904
Fax: +86-311-83610904

whose single Authorized Representative:
Caretechion GmbH
Niederrheinstr. 71, 40474 Düsseldorf,
Germany
DIMDI Code: DE/0000048026
Tel/Fax: 0211 3003 6618
Email: info@caretechion.com

We, the manufacturer, herewith declare that the products

Disposable Nitrile Examination Glove
UMDNS-Code: 11-882

Meet the provisions of MDR 2017/745 EU which apply to them.

The medical device has been assigned to class I according to Annex VIII of the MDR 2017/745 EU.

CE

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The product concerned has been manufactured under a quality management system according to Annex IX of MDR 2017/745 EU.

Following the procedure relating to the EC Declaration of Conformity set out in Annex IV of MDR 2017/745 EU.

The above mentioned declaration of conformity is exclusively under the responsibility of

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou, 052260 Hebei, China.

Jinzhou China 2020-04-01
Place , date

GM
Legally binding signature, Function

EC Declaration of Conformity

• EC Declaration

CE TECHNICAL DOCUMENTATION REVIEW REPORT

Company Name:	Shijiazhuang Hongray Group Co. Ltd.
Address:	South Tongda Road, East district, Jinzhou City, Hebei, 052260, China
Review Intention:	Review the completeness of the Technical Documentation according to the requirements of Medical Devices Directive 93/42/EEC Annex VII & the Regulation (EU) 2017/745 Annex II and III
Product(s):	Examination Nitrile Gloves
Type(s) / Model(s):	Powder Free / XS, S, M, L, XL
Classification:	Class I (According to Annex IX Section III 1.1 and 1.4 of the Medical Devices Directive 93/42/EEC & Annex VIII Chapter III 4.1 rule 1 of Medical Device Regulations 2017/745)
Review period:	June 06, 2019
Review Result:	During the examination of the Technical Documentation (No: HRG-JSWJ-003, Revision: C, Dated 2019-05-10), no non-compliance according to the requirements of Medical Devices Directive 93/42/EEC Annex VII & the Regulation (EU) 2017/745 Annex II and III was detected.

Signature: W[illegible]
Date: June 06, 2019
Regulatory Authority

• CE Technical Certificate

SGS

VERIFICATION OF EN 455 CONDITIONAL COMPLIANCE

No.:	SHHG1510041938MDC
Product Name:	NITRILE GLOVE(NO-STERILE, AMBIDEXTROUS,POWDER FREE)
Style No:	XS, S, M, L, XL
Applicant:	SHIJIAZHUANG HONGRAY GROUP CO., LTD. SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI, 052260, CHINA
Manufacturer:	SHIJIAZHUANG HONGRAY GROUP CO., LTD. SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI, 052260, CHINA

Sufficient samples of the product have been tested and found to be in conformity with

Test Standard:	BS EN455-1:2000 MEDICAL GLOVES FOR SINGLE USE-PART1:REQUIREMENTS AND TESTING FOR FREEDOM FROM HOLES BS EN455-2:2015 MEDICAL GLOVES FOR SINGLE USE-PART2:REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIE BS EN455-3:2015 MEDICAL GLOVES FOR SINGLE USE-PART 3: REQUIREMENTS AND TESTING FOR BIOLOGICAL EVALUATION (CLAUSE4.4&4.6 POWDER&LABELLING)
as shown in the Test Report Number(s):	SHHG1510041938MD

This verification is only valid for the equipment and configuration described, and in conjunction with the test data detailed. It contains the result of the single examination of the subject being in hand and does not represent any universally valid decision concerning the quality of any subject of the current production.

Vincent Feng
CTS/HEC Handgoods Regional Technical Manager
SGS-CSTC Standards Technical Services Co., Ltd.

December 11, 2015

SGSPAPER 16317741

• SGS EN455 Compliance

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：冀石药监械出 20200026
Certificate NO.: Certificate of medical device exports made in shijiazhuang issued by Hebei Drug Supervision Administration No. 20200026

产品名称：详见附表
Product(s): Details as per attached list.

规格型号：详见附表
Model: Details as per attached list.

产品注册或备案凭证号：详见附表
Registration certificate(s): Details as per attached list.

生产企业：石家庄鸿欣橡胶制品有限公司
Manufacturer: Shijiazhuang Syntex Rubber Products Co., Ltd.

生产企业住所：河北省辛集市范家庄村西 307 国道路南
Address of manufacturer: South 307 National Road, Fanjiazhuang, Xinji, Hebei Province

生产许可或备案凭证号：冀辛食药监械生产备 20180002 号
Manufacturing License(s): Medical device on file under xinji Food and Drug Supervision Administration, Hebei Province No. 20180002

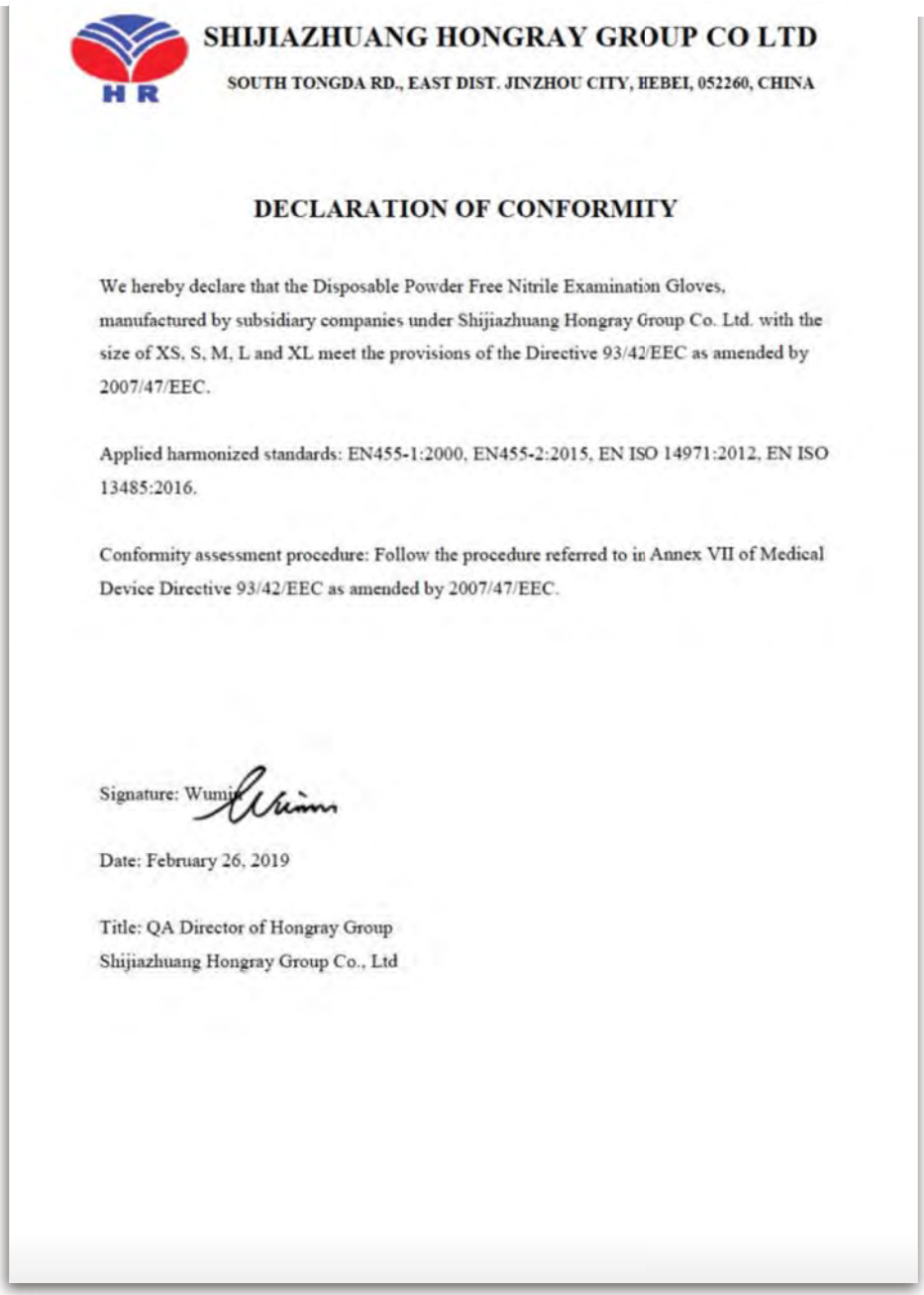
兹证明上述产品已准许在中国生产和销售。 This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至： 2022 年 03 月 28 日
This certification valid until: Mar. 28, 2022

备注：无
Remark: nothing

2020 年 03 月 29 日
（出具单位盖章）

• China Medical Export Certificate



SHIJIAZHUANG HONGRAY GROUP CO LTD

SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI, 052260, CHINA

DECLARATION OF CONFORMITY

We hereby declare that the Disposable Powder Free Nitrile Examination Gloves, manufactured by subsidiary companies under Shijiazhuang Hongray Group Co. Ltd. with the size of XS, S, M, L and XL meet the provisions of the Directive 93/42/EEC as amended by 2007/47/EEC.

Applied harmonized standards: EN455-1:2000, EN455-2:2015, EN ISO 14971:2012, EN ISO 13485:2016.

Conformity assessment procedure: Follow the procedure referred to in Annex VII of Medical Device Directive 93/42/EEC as amended by 2007/47/EEC.

Signature: Wumi

Date: February 26, 2019

Title: QA Director of Hongray Group
Shijiazhuang Hongray Group Co., Ltd

• Declaration of Conformity

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303**

Certificate Holder: **Shijiazhuang Hongray Group Co., Ltd.**
Unified Social Credit Code: 91130100728799919R
Registration Address: South Tongda Rd., East Dist.,
Jinzhou City, 052260 Hebei, P. R. China
Operation Address: same as above

including the locations according to annex

Scope: Manufacture and Distribution of Patient Examination Gloves

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-04-10 until 2020-10-19.
It remains valid subject to satisfactory surveillance audits.
First certification 2017

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2020-04-14

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

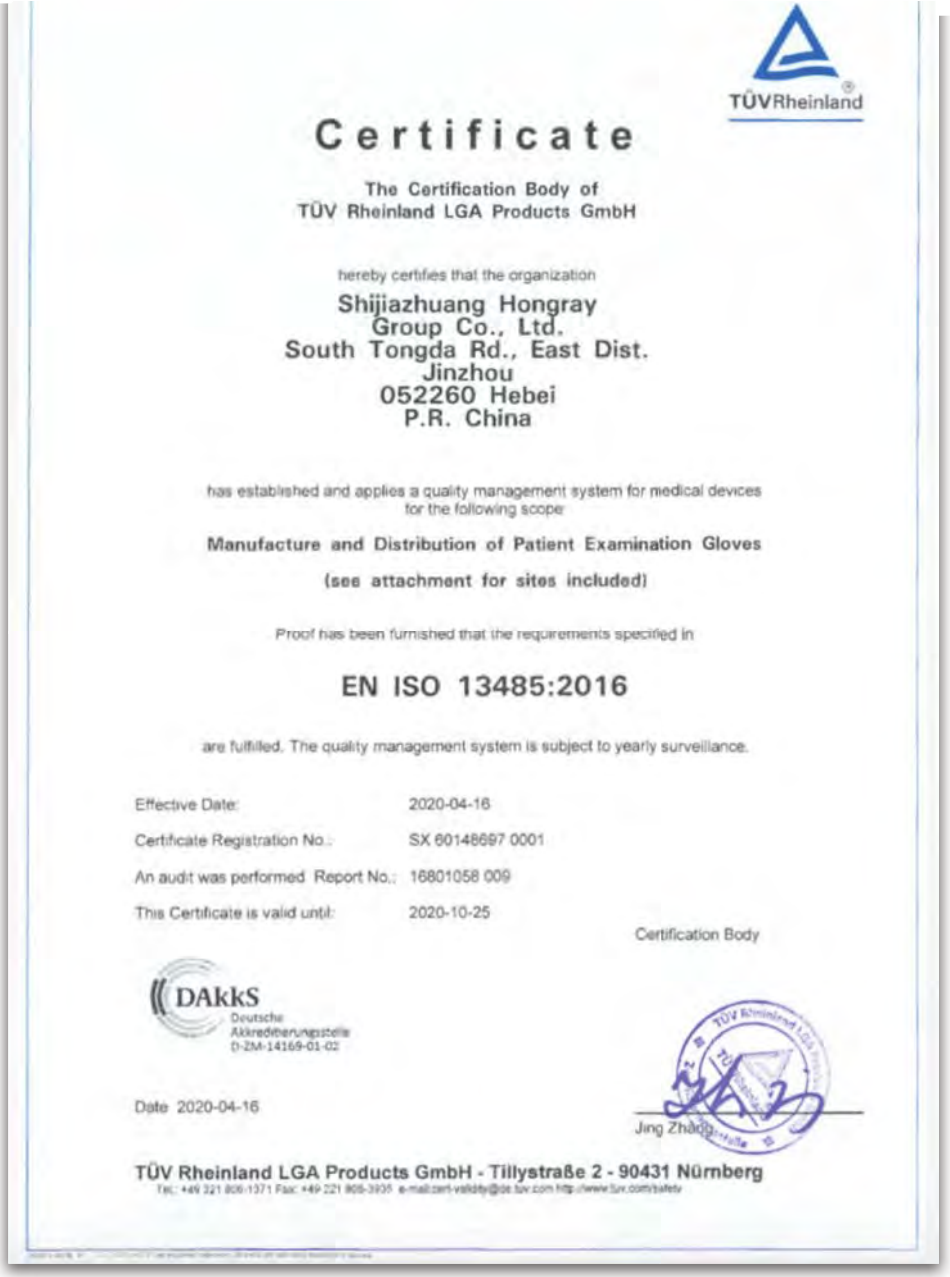
www.tuv.com

IAF

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

- ISO 9001 Certificate



TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Shijiazhuang Hongray
Group Co., Ltd.
South Tongda Rd., East Dist.
Jinzhou
052260 Hebei
P.R. China

has established and applies a quality management system for medical devices for the following scope

Manufacture and Distribution of Patient Examination Gloves

(see attachment for sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-04-16
Certificate Registration No.: SX 60148697 0001
An audit was performed. Report No.: 16801058 009
This Certificate is valid until: 2020-10-25

Certification Body

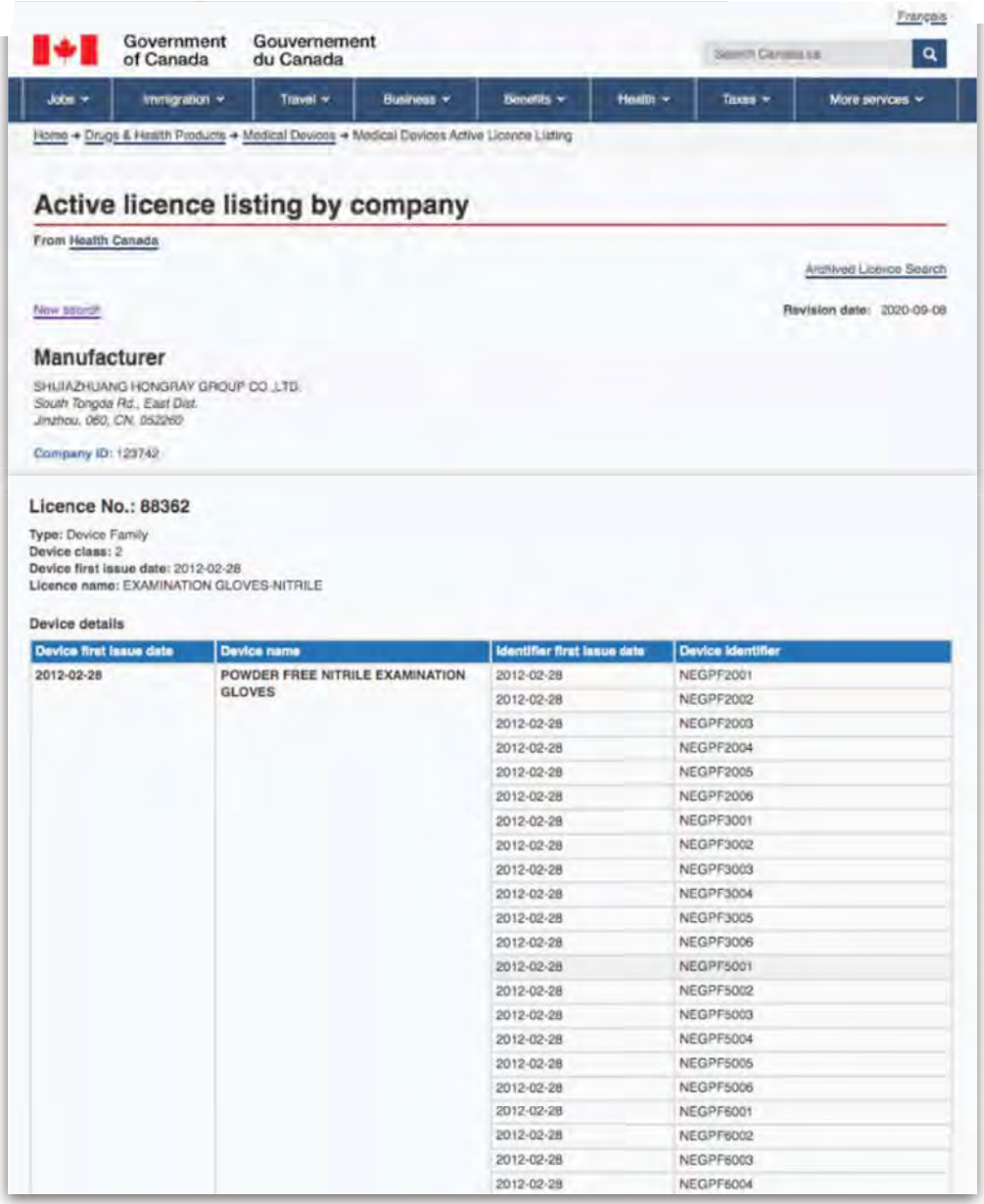
DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Date 2020-04-16

Jing Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

- ISO 13485 Certificate



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Home → Drugs & Health Products → Medical Devices → Medical Devices Active Licence Listing

Active licence listing by company

From Health Canada

Archived Licence Search

New search

Revision date: 2020-09-08

Manufacturer

SHIJIAZHUANG HONGRAY GROUP CO.,LTD.
South Tongda Rd., East Dist.
Jinzhou, 060, CN, 052260

Company ID: 123742

Licence No.: 88362

Type: Device Family
Device class: 2
Device first issue date: 2012-02-28
Licence name: EXAMINATION GLOVES-NITRILE

Device details

Device first issue date	Device name	Identifier first issue date	Device identifier
2012-02-28	POWDER FREE NITRILE EXAMINATION GLOVES	2012-02-28	NEGPF2001
		2012-02-28	NEGPF2002
		2012-02-28	NEGPF2003
		2012-02-28	NEGPF2004
		2012-02-28	NEGPF2005
		2012-02-28	NEGPF2006
		2012-02-28	NEGPF3001
		2012-02-28	NEGPF3002
		2012-02-28	NEGPF3003
		2012-02-28	NEGPF3004
		2012-02-28	NEGPF3005
		2012-02-28	NEGPF3006
		2012-02-28	NEGPF5001
		2012-02-28	NEGPF5002
		2012-02-28	NEGPF5003
		2012-02-28	NEGPF5004
		2012-02-28	NEGPF5005
		2012-02-28	NEGPF5006
		2012-02-28	NEGPF6001
		2012-02-28	NEGPF6002
		2012-02-28	NEGPF6003
		2012-02-28	NEGPF6004

- Canadian Medical Licensing Licence MDALL #88362

SATRA TECHNOLOGY

SATRA Technology Services (Dongguan) Ltd
Unit 110, Xinzhongyin Garden, Xiping
Nancheng District, Dongguan City
Guangdong Province, China
Tel: +86 (0) 769 22888020
email: info@satrafe.com

Customer details: Shijiazhuang Hongray Group Co., Ltd
South Tongda Road, East District
Jinzhou City
Hebei
China
052260

For the attention of: Renmin

SATRA reference: CHT0271907 /1823

Your reference: NPF2001-2005

Date of report: 17th July 2018

Samples received: 8th June 2018

Date(s) work carried out: 4th -12th July 208

TECHNICAL REPORT

Subject: Test against EN420:2003+ A1:2009 for the disposable nitrile glove (XS, S, M, L, XL, blue). Ref as NPF2001-2005.

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked ≠ fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides for a confidence level of approximately 95%.

Report signed by: A J Reed
Position: Technical Manager
Department: China Testing

(Page 1 of 7)

- EN420 Technical Certificate

U.S. FOOD & DRUG ADMINISTRATION

December 10, 2018

Syntex Healthcare Products Co., Ltd
% Kathy Liu
Project Manager
Hongray USA Medical Products Inc
3973 Schaefer Avenue, Chino, CA 91810, USA

Re: K182156
Trade/Device Name: Powder-Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: September 15, 2018
Received: October 10, 2018

Dear Kathy Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray Iii III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

- FDA 510k Certification
  Licence #K182156

SPECS

- 100% Latex Free, No allergy
- Protein Free, Nitrile Gloves
- 5 Mil Thickness
- Highly Elastic and Super Soft
- Rolled Rim to facilitate easy donning
- Designed to give a natural rubber-like feel
- Textured in finger tips for enhanced grip
- Fluid Resistant: Yes
- Puncture resistant and powder-free nitrile

CERTIFCATIONS

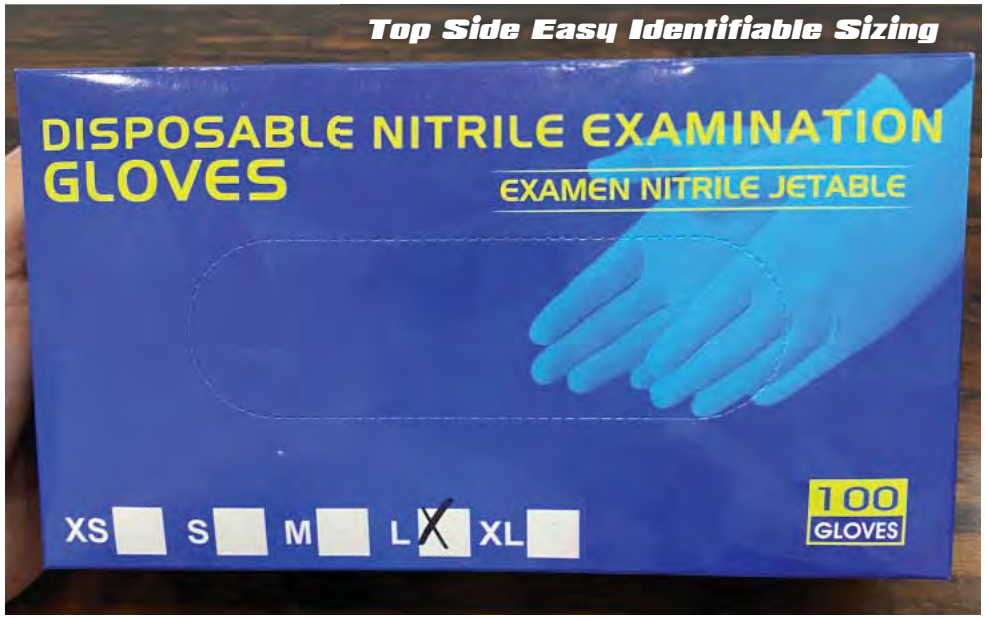
- CE Certification, FDA 510K Listing
- EN-374 Resistance to Chemical Certification
- EN-455 Certification
- CHEMO Certification
- EU Type - Examination
- Health Canada MDL Licensed

Hongray

Health Canada Santé Canada

Medical Device Licence Approved
Licence NO: 88362

510(k) Cleared
United States FDA Medical
Licence NO: K182156


Top Side Easy Identifiable Sizing
DISPOSABLE NITRILE EXAMINATION GLOVES
EXAMEN NITRILE JETABLE
XS S M L X XL
100 GLOVES


French + English Side Labels
DISPOSABLE NITRILE EXAMINATION GLOVES
EXAMEN NITRILE JETABLE
NON - STERILE | POWDER - FREE | AMBIDEXTROUS
SINGLE USE | LATEX - FREE
non stérile | sans poudre | ambidextre
à usage unique | sans latex


Corner Sides
DISPOSABLE NITRILE EXAMINATION
GLOVES
Easy Donning Technology
100 GLOVES


Back Side
Hongray
• Store in a cool, dry place.
• Shield open box from direct sunlight, fluorescent lighting or x-rays.
EN 455
510K
• Conservez dans un endroit frais et sec.
• Protégez la boîte ouverte de la lumière directe du soleil, de l'éclairage fluorescent ou des rayons X.
LOT 04D0HNF
2020 08 04
2023 08 03
PRODUCT ID
X-Small# NEGPF9002 | Small# NEGPF 9003
Medium# NEGPF 9004 | Large# NEGPF9005
X-Large# NEGPF9006
6 948794 410138
Health Canada Santé Canada
MADE IN CHINA
Manufactured by
Shijiazhuang Hongray Group Co. Ltd
South Tongda Road, East Dist- Jinzhou
052262 Heble China
www.hongray.com


DISPOSABLE NITRILE EXAMINATION GLOVES
EXAMEN NITRILE JETABLE
NON - STERILE | POWDER - FREE | AMBIDEXTROUS
SINGLE USE | LATEX - FREE
non stérile | sans poudre | ambidextre
à usage unique | sans latex
XS S M L XL
100 GLOVES
Easy Donning Technology
Hongray
Store in a cool, dry place.
Shield open box from direct sunlight, fluorescent lighting or x-rays.
Conservez dans un endroit frais et sec.
Protégez la boîte ouverte de la lumière directe du soleil, de l'éclairage fluorescent ou des rayons X.
PRODUCT ID
X-Small# NEGPF9002 | Small# NEGPF9003
Medium# NEGPF9004 | Large# NEGPF9005
X-Large# NEGPF9006
LOT 0000024154-5
2020 08 06
2025 08 05
Manufactured by
Shijiazhuang Hongray Group Co. Ltd
South Tongda Road, East Dist- Jinzhou
0552260 - Hebei Province, China
www.hongray.com
MADE IN CHINA


Box Packaging
DISPOSABLE NITRILE EXAMINATION GLOVES
EXAMEN NITRILE JETABLE
XS S M L XL
100 GLOVES
NON - STERILE | POWDER - FREE | AMBIDEXTROUS
SINGLE USE | LATEX - FREE


Sample Glove


Sample Glove

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou City,Hebei , 052260,China

Performance Testing

The Standards used for production of Powder Free Nitrile Examination Gloves (Blue) are mainly based on ASTM D6319-19. In accordance with physical requirements established by ASTM standard, the following are the physical requirements and dimensional testing results:

Technological Characteristics	Standard/Test/FDA Guidance	Inspection Level and AQL	Result Summary	Conclusion
Length (mm)	220mm for size XS-S 230mm for size M-XL minimum	S-2, AQL4.0	XS: 230-238mm S: 234-242mm M: 230-242mm L: 238-244mm XL：232-241 mm	Pass
Width (mm)	XS:70±10	S-2, AQL4.0	77-78mm	Pass
	S: 80±10		86-88 mm	
	M: 95±10		96 -98mm	
	L: 110±10		108-110 mm	
	XL: 120±10		116-117 mm	
Palm Thickness (mm)	0.125mm minimum	S-2, AQL4.0	0.125-0.13mm	Pass
Finger Thickness (mm)	0.12mm minimum	S-2, AQL4.0	0.12-0.13mm	Pass
Tensile Strength (Mpa)				
Before aging	14Mpa minimum	S-2, AQL4.0	15.7-19.9Mpa	Pass
After aging	14Mpa minimum		15.2-18.6Mpa	Pass
Ultimate Elongation (%)				
Before aging	500% minimum	S-2, AQL4.0	500-550%	Pass
After aging	400% minimum		430-530%	Pass
Freedom from holes	AQL 2.5	G-I, AQL2.5	0/125, meet AQL2.5 requirements	Pass
Residual Powder	Not more than 2mg per glove	N=5	0.58mg	Pass

The detailed testing report of the gloves is attached herein.

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou City,Hebei , 052260,China

Powder Testing

Testing requested:
For compliance with residual powder content defined in ASTM D6319-19 Standard Specification For Nitrile Examination Gloves.

Test Methods:
As specified in ASTM D6124-06（2017）Standard Test Method for Residual Powder on Medical Gloves

Testing results:

Size	XS	S	M	L	XL
Sample quantity	5	5	5	5	5
Average content (mg/glove)	0.55	0.56	0.59	0.60	0.61
Powder Content Criteria: Not more than 2mg/glove for powder free glove					

Conclusion:
The samples for Powder Free Nitrile Examination Gloves, (Blue) comply with residual powder content requirements specified in ASTM D6319-19 Standard Specification for Nitrile Examination Gloves.

Approved by: Zhu Chunyan

Reviewed by: Xu Lihua

Prepared by: Xing Lifang　Zhang Hui

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou City,Hebei , 052260,China

PHYSICAL&PINHOLE TESTING

Testing requested:
For compliance with ASTM D6319-19 Standard Specification for Nitrile Examination Gloves, testing items are as follows:
1. Physical Dimensions and Physical Property;
2. Pinhole

Testing Methods:
As specified in ASTM D6319-19, ASTM D5151-19 and FDA 1000ml Water Leak Test (21 CFR 800.20).
1. Testing results for Physical Dimensions and Physical Property (13 pieces for each size are tested):

Size	Item		Std	1	2	3	4	5	6	7	8	9	10	11	12	13
XS	Length (mm) (min)		220	230	234	237	238	234	236	231	236	235	239	237	235	230
	Width (mm)		70±10	77	77	78	77	77	78	78	77	77	78	77	78	77
	Thickness (mm) (min)	Finger	0.12	0.12	0.12	0.12	0.11	0.12	0.12	0.13	0.13	0.13	0.14	0.13	0.13	0.13
		Palm	0.14	0.13	0.12	0.12	0.13	0.14	0.13	0.13	0.13	0.14	0.14	0.14	0.13	0.13
	Before aging	Tensile Strength (Mpa) (min)	14	16.8	17.9	16.8	15.9	16.7	17.8	16.8	16.9	17.5	18.4	18.6	18.9	20
		Elongation (%) (min)	500	530	520	510	530	510	530	530	530	510	520	500	530	520
	After aging	Tensile Strength (Mpa) (min)	14	16.1	15.9	16.4	15.9	16.7	17.4	17.8	16.9	16.8	16.4	18.6	18.6	18.8
		Elongation (%) (min)	400	530	530	510	530	510	490	510	500	500	500	520	510	490
S	Length (mm) (min)		220	233	238	237	238	236	236	234	236	236	239	242	239	242
	Width (mm)		80±10	87	88	87	86	87	86	88	86	88	88	87	87	87
	Thickness (mm) (min)	Finger	0.13	0.12	0.13	0.12	0.13	0.13	0.14	0.12	0.13	0.12	0.13	0.13	0.13	0.13
		Palm	0.13	0.14	0.14	0.13	0.13	0.13	0.14	0.14	0.13	0.13	0.13	0.12	0.13	0.13
	Before aging	Tensile Strength (Mpa) (min)	14	17.0	16.1	16.4	15.9	16.6	18.1	17.4	17.6	17.0	18.4	17.6	18.4	18.0
		Elongation (%) (min)	500	510	520	550	540	510	530	530	540	510	500	540	520	510
	After aging	Tensile Strength (Mpa) (min)	14	15.7	15.9	16.4	17.0	16.7	17.4	17.5	16.9	16.8	16.4	18.6	18.6	19.0
		Elongation (%) (min)	400	480	480	520	430	510	500	410	500	520	500	420	500	530

Shijiazhuang Hongray Group Co., Ltd.

South Tongda Rd., East Dist. Jinzhou City,Hebei , 052260,China

M	Length (mm) (min)		230	240	238	242	238	236	238	236	240	230	239	242	242	242
	Width (mm)		95±10	97	97	96	98	96	97	98	96	98	97	97	97	97
	Thickness (mm) (min)	Finger	0.13	0.13	0.14	0.12	0.13	0.14	0.14	0.13	0.13	0.13	0.12	0.14	0.013	0.13
		Palm	0.13	0.13	0.12	0.13	0.13	0.14	0.13	0.14	0.12	0.14	0.13	0.13	0.12	0.13
	Before aging	Tensile Strength (Mpa) (min)	14	16.2	15.9	16.4	15.9	16.7	18.1	17.8	16.9	17.9	18.4	18.6	18.6	19.9
		Elongation (%) (min)	500	530	520	550	500	510	500	550	510	520	520	530	500	540
	After aging	Tensile Strength (Mpa) (min)	14	16.4	15.8	16.4	16.2	16.7	17.4	17.5	16.9	16.8	17.0	17.6	18.6	18.4
		Elongation (%) (min)	400	500	480	510	500	510	490	510	500	490	450	520	530	500
L	Length (mm) (min)		230	240	238	242	238	238	240	238	240	238	239	244	242	240
	Width (mm)		110±10	109	110	110	110	109	109	109	109	109	109	108	110	109
	Thickness (mm) (min)	Finger	0.12	0.13	0.12	0.12	0.13	0.13	0.12	0.13	0.12	0.13	0.12	0.12	0.13	0.13
		Palm	0.13	0.13	0.13	0.12	0.13	0.13	0.14	0.13	0.13	0.14	0.12	0.12	0.13	0.14
	Before aging	Tensile Strength (Mpa) (min)	14	16.0	15.9	16.4	15.9	16.7	18.1	17.8	16.9	17.5	18.4	18.6	18.6	19.7
		Elongation (%) (min)	500	540	520	550	520	510	500	550	520	520	500	550	500	540
	After aging	Tensile Strength (Mpa) (min)	14	15.6	15.9	17.1	15.9	16.7	17.2	17.8	16.9	16.8	16.1	18.6	17.0	16.7
		Elongation (%) (min)	400	490	480	510	510	510	490	510	400	500	500	520	510	490
XL	Length (mm) (min)		230	241	238	232	238	236	240	238	240	238	239	240	236	240
	Width (mm)		120±10	117	117	116	116	116	116	116	116	116	116	116	116	116
	Thickness (mm) (min)	Finger	0.13	0.12	0.12	0.13	0.12	0.13	0.13	0.12	0.13	0.13	0.13	0.12	0.12	0.13
		Palm	0.13	0.12	0.13	0.13	0.13	0.13	0.14	0.12	0.13	0.13	0.14	0.12	0.13	0.13
	Before aging	Tensile Strength (Mpa) (min)	14	16.0	15.9	16.2	15.2	16.7	17.1	17.0	16.9	17.5	17.6	18.6	18.1	18.0
		Elongation (%) (min)	500	550	520	520	500	510	500	520	500	520	500	550	530	520
	After aging	Tensile Strength (Mpa) (min)	14	15.7	14.9	16.4	16.9	16.7	17.4	17.8	16.9	16.8	16.4	18.6	17.6	19.0
		Elongation (%) (min)	400	450	480	510	450	510	490	520	500	500	490	520	510	460

Shijiazhuang Hongray Group Co., Ltd.

South Tongda Rd., East Dist. Jinzhou City,Hebei , 052260,China

2. Testing Results for pinhole testing: as per ASTM D5151-19 and FDA 1000ml Water Leak Test (21 CFR 800.20).

Testing Criteria						Testing Result	Conclusion
Lot size	Round	Sample size	Cumulative sample size	Accepted/ Rejected Criteria			
				Ac	Re		
35,000 and above	First	125	125	1	7	125 glove are sampled, 0 piece leak	Pass
	Second	125	250	4	10		
	Third	125	375	8	13		
	Fourth	125	500	12	17		
	Fifth	125	625	17	20		
	Sixth	125	750	21	23		
	Seventh	125	875	25	26		

Conclusion:

The samples for Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs (Blue) complies with ASTM D6319-19 Standard Specification for Nitrile Examination Gloves.

Approved by : Zhun Chunyan Reviewed by: Xu Lihua Prepared by: Xing Lifang Zhang Hui

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou City,Hebei , 052260,China

Pinhole Testing results and conclusion:

Sequential Sample Run	Defects locations devoted by "O" and type (V=Visual Defect, I=Immediate Leak, 2= Two Minute Leak)					Cumulative # Defects/ Cumulative # Gloves tested
Round # 1	Gloves #	Gloves #	Gloves #	Gloves #	Gloves #	0/125
Round # /	Gloves #	Gloves #	Gloves #	Gloves #	Gloves #	/
Round # /	Gloves #	Gloves #	Gloves #	Gloves #	Gloves #	/
Round # /	Gloves #	Gloves #	Gloves #	Gloves #	Gloves #	/
Round # /	Gloves #	Gloves #	Gloves #	Gloves #	Gloves #	/
Round # /	Gloves #	Gloves #	Gloves #	Gloves #	Gloves #	/

Conclusion: The pinhole testing for Powder Free Nitrile Examination Gloves (Blue) meet the requirements of FDA 1000ml Water Leak Test (21 CFR 800.20).

Approved by : Zhu Chunyan

Reviewed by: Xu Lihua

Prepared by: Xing Lifang Zhang Hui

SGS

Test Report No.: SHHL1602007536MD-01 Date: APR. 06,2016 Page: 1 of 8

SHIJIAZHUANG HONGRAY GROUP CO., LTD
SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI, 052260, CHINA

THE TEST REPORT IS TO SUPERSEDE THE TEST REPORT No.: SHHL1602007536MD
DATE: MAR. 28, 2016
The following sample(s) was/were submitted and identified by the client as:

Sample Description	: DISPOSABLE NITRILE GLOVE
Style/ Item No.	: XS,S,M,L,XL,XXL
Country of Origin	: CHINA
Sample Receiving Date	: FEB. 29, 2016
Testing Period	: FEB. 29, 2016 TO MAR. 28, 2016
Test Performed	: SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested	: 1. EN 455-1:2000 MEDICAL GLOVES FOR SINGLE USE – PART 1: REQUIREMENTS AND TESTING FOR FREEDOM FROM HOLES 2. EN 455-2: 2015 MEDICAL GLOVES FOR SINGLE USE – PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIE 3. EN 455-3: 2015 MEDICAL GLOVES FOR SINGLE USE— PART 3: REQUIREMENTS AND TESTING FOR BIOLOGICAL EVALUATION CLAUSE 4.4 & 4.6
Test Result(s)	: FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S)
Conclusion	: THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT.

****

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

Vincent Feng
Technical Manager

Member of the SGS Group (SGS SA)

Additional Test Reports SGS

Test Conducted:

1. EN 455-1:2000 Medical gloves for single use – part 1: Requirements and testing for freedom from holes

Number of test sample	:	200 Pieces
The type of gloves	:	examination/procedure gloves
Manufacturing batch code	:	/
Batch size	:	/
Sample size	:	XS, S, M, L, XL, XXL
Number of non-conforming gloves	:	None
Defects observed before testing	:	No defects
Test Result	:	Pass

Clause	Test Items	Result	Note
5	Watertightness test for detection of holes	—	—
5.1	Referee testing		# 1&2

2. EN 455-2: 2015 Medical gloves for single use – part 2: Requirements and testing for physical propertie

Number of test sample	:	104 Pieces
Type	:	examination/procedure gloves
The manufacturing batch code	:	/
Size	:	XS, S, M, L, XL, XXL
Defects observed before testing	:	No defects
Test Result	:	Pass

Clause	Test Items	Result	Note
4	Dimensions	Pass	#3
5	Strength	Pass	#1&4
7	Labeling	Pass	/

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3. EN 455-3: 2015 Medical gloves for single use—Part 3: Requirements and testing for biological evaluation

Number of test sample	:	5 Pieces
Finishes of gloves	:	Powdered-free gloves other than surgeon's gloves
Defects observed before testing	:	No defects
Test Result	:	Pass

Clause	Test Items	Result	Note
4.4	Powder	Pass	#1, 5&6
4.6	Labeling	Pass	/

Note:
1. As per client's declare, these gloves (four size: XS, S, M, L, XL, XXL) only size different, the material is the same, and only the glove of size M was tested.
2. See result 1.
3. See result 2.
4. See result 3.
5. Test according to EN ISO 21171-2006.
6. The powder of sample was 0.3mg＜2mg.

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Member of the SGS Group (SGS SA)

Test Results:

1. Watertightness test for detection of holes

Sample Quantity: 200pcs

AQL: 1.5 Accept: 7 Reject: 8 Found: 0

2. Dimensions

Sample Quantity: 78pcs

Size	XS												
Length(mm)	253	253	253	254	252	256	256	254	253	254	252	253	253
Width(mm)	79	78	79	77	78	77	78	77	78	79	78	79	78

Median value:
Length (mm): 253
Width (mm): 78

Size	S												
Length(mm)	245	244	242	243	244	246	245	244	245	246	244	243	243
Width(mm)	88	85	87	86	88	87	86	88	87	88	87	86	86

Median value:
Length (mm): 244
Width (mm): 87

Size	M												
Length(mm)	244	245	245	246	245	247	246	245	244	245	246	247	246
Width(mm)	96	95	97	96	95	97	96	96	95	96	97	96	97

Median value:
Length (mm): 245
Width (mm): 96

Size	L												
Length(mm)	243	242	241	242	243	242	242	242	242	243	241	242	243
Width(mm)	109	108	107	109	108	107	108	107	108	109	108	107	107

Median value:
Length (mm): 242
Width (mm): 108

Size	XL												
Length(mm)	249	248	250	249	247	248	249	248	248	249	248	249	248
Width(mm)	114	113	114	115	113	114	115	115	114	115	116	114	115

Median value:
Length (mm): 248
Width (mm): 114

Size	XXL												
Length(mm)	245	246	244	244	245	246	245	246	246	245	245	244	243
Width(mm)	119	118	120	119	118	119	118	120	119	118	119	120	119

Median value:
Length (mm): 245
Width (mm): 119

Requirements: see table 1&2

Table 1 Dimensions for surgical gloves

Size	Median length in mm	Median width in mm
5	⩾250	67±4
5.5	⩾250	72±4
6	⩾260	77±5
6.5	⩾260	83±5
7	⩾270	89±5
7.5	⩾270	95±5
8	⩾270	102±6
8.5	⩾280	108±6
9	⩾280	114±6
9.5	⩾280	121±6

Table 2 Dimensions for examination/procedure gloves

Size	Median length in mm	Median width in mm
Extra small	⩾240	⩽80
Small		80±10
Medium		95±10
Large		110±10
Extra Large		⩾110

3. Strength

Sample Quantity: 26pcs

Size	M												
Force at break(N)	9.19	8.79	9.27	9.02	8.25	9.35	9.27	9.36	8.98	8.38	9.02	8.90	9.58
Force at break after challenge testing(N)	9.41	9.50	9.50	9.38	9.58	9.46	9.23	9.38	9.77	9.50	9.58	9.18	9.65

Median value:

Force at break during shelf life (N): 9.02
Force at break after challenge testing (N): 9.50

Table 3 — Median values of force at break

	Force at break in Newton		
	Surgical gloves a)	Examination/procedure gloves b)	c)
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥ 9,0	≥ 6,0	≥ 3,6

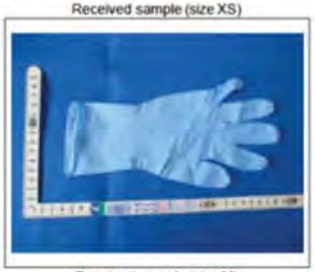
a) Requirements for all surgical gloves.
b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).
c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).

Remark:

1. The sample selecting amount for Watertightness test for detection of holes is deviated to 200 pcs as accessed by SGS.

Sample Photo:

Received sample (size XS)



Received sample (size S)

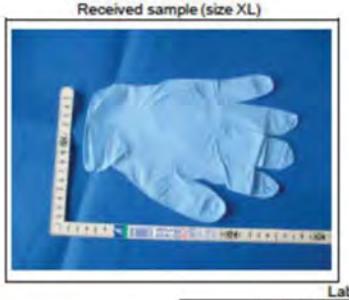
Received sample (size M)

Received sample (size L)

SGS

Test Report No.: SHHL1602007536MD-01 Date: APR. 06,2016 Page: 8 of 8

Received sample (size XL)



Received sample (size XXL)

Label

SGS authenticate the photo on original report only

End of Report

SATRA TECHNOLOGY

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Customer details: Shijiazhuang Hongray Group Co., Ltd
South Tongda Road, East District
Jinzhou City
Hebei
China
052260

For the attention of: Renmin

SATRA reference: CHT0271907 /1823 /SPT Issue 2

Your reference:

Date of report: 02 July 2018

Samples received: 8 June 2018

Date(s) work carried out: 26 – 27 June 2018

TECHNICAL REPORT

Subject: Testing of gloves identified as "Disposable nitrile glove reference NPF2001-2005" in accordance with EN 374-2:2014

Replaces report reference CHT0271907 /1823 /SPT dated 29 June 2018

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked ≠ fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides for a confidence level of approximately 95%.

Report signed by: Sue Clayton
Position: Technologist
Department: Safety Product Testing

Work Requested

Samples of gloves, see Table 1, were received by SATRA for testing in accordance with EN 374-2:2014 Protective gloves against dangerous chemicals and microorganisms - Determination of resistance to penetration.

Table 1 – Samples received

Sample description as stated by the client	Sizes submitted for testing	Colour of samples submitted
"Disposable nitrile glove reference NPF2001-2005"	XS, S, M, L, XL	Blue

"Disposable nitrile glove reference NPF2001-2005"

Conclusion

Standard	Clause / Property		Result
EN 374-2:2014	7.2	Air leak	See Note ●
	7.3	Water leak	PASS

Note ● – As per clause 4.3 of EN 374-2:2014, the gloves submitted for testing were found to be unsuitable for the Air leak test. Therefore, as per EN 374-2, only the Water leak test has been performed.

Testing

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2) °C and (50±5) % relative humidity. Testing was carried out within the same environment.

Requirements

Table 2 - Requirements for EN 374-2: 2014

7.2	Air leak test	No leak to be detected
7.3	Water leak test	No leak to be detected

Test Results

Table 3 - EN 374-2:2014 Test results for gloves identified as "Disposable nitrile glove reference NPF2001-2005"

Clause / Test	Test Results		UoM	Result
7.2 Air leak test	Total air pressure used:	2.62 kPa	± 2.8 mm$H_2$0	See Note ●
	Sample size	Leaks		
	XS			
	S			
	M	Gloves over-inflated during testing		
	L			
	XL			
7.3 Water leak test	Sample size	Leaks	N/A	PASS
	XS	No leaks detected		
	S	No leaks detected		
	M	No leaks detected		
	L	No leaks detected		
	XL	No leaks detected		

Testing

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2) °C and (50±5) % relative humidity. Testing was carried out within the same environment.

Requirements

Table 2 - Requirements for EN 374-2: 2014

7.2	Air leak test	No leak to be detected
7.3	Water leak test	No leak to be detected

Test Results

Table 3 - EN 374-2:2014 Test results for gloves identified as "Disposable nitrile glove reference NPF2001-2005"

Clause / Test	Test Results		UoM	Result
7.2 Air leak test	Total air pressure used:	2.62 kPa	± 2.8 mmH_20	See Note •
	Sample size	Leaks		
	XS			
	S			
	M	Gloves over-inflated during testing		
	L			
	XL			
7.3 Water leak test	Sample size	Leaks	N/A	PASS
	XS	No leaks detected		
	S	No leaks detected		
	M	No leaks detected		
	L	No leaks detected		
	XL	No leaks detected		

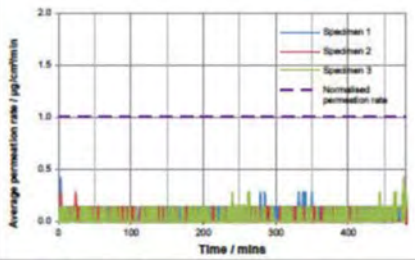
APPENDICES:

Sample described as Disposable Nitrile Glove NPF2001-2005

Test/Property	Sample reference:	Disposable nitrile glove NPF2001-2005		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-009	Test information:	Chemical: 40% Sodium hydroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Conductimetry (continuous measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)⌂	Breakthrough time (mins)	
	1	0.07	>480	
	2	0.07	>480	
	3	0.06	>480	
		Test result:	>480	
		UoM:	<1	
Visual appearance of specimens after testing:		Swollen and discoloured		

PERMEATION RATE GRAPHS

Challenge chemical: 40% Sodium Hydroxide



RESULTS:

Sample description:	Disposable Nitrile Glove NPF2001-2005		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	15.4	3.8	-67.2
Mean degradation (DR) / %:	-16.0		
Standard deviation (σ_{DR}) / %:	44.8		
UoM ♦ / ± %:	33.8		
Appearance of samples after testing:	Swollen		

Sample description:	Disposable Nitrile Glove NPF2001-2005		
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	47.8	15.0	17.4
Mean degradation (DR) / %:	26.8		
Standard deviation (σ_{DR}) / %:	18.3		
UoM ♦ / ± %:	22.3		
Appearance of samples after testing:	Swollen and slightly discoloured		

Sample description:	Disposable Nitrile Glove NPF2001-2005		
Challenge chemical:	37% Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	44.9	21.7	35.2
Mean degradation (DR) / %:	34.0		
Standard deviation (σ_{DR}) / %:	11.6		
UoM ♦ / ± %:	20.6		
Appearance of samples after testing:	Swollen and discoloured		

♦ Absolute measurement uncertainty of the mean degradation value; it is therefore inferred that the true degradation value, with 95% confidence, lies within the range (DR ± UoM) %.

NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.