

# SETINO®



## Vinyl / Nitrile Blended GLOVES



EN  
455



FDA



# 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: 2020-09-30  
Certificate Registration No.: SX 60151704 0001  
An audit was performed. Report No.: 16801058 009  
This Certificate is valid until: 2023-04-25

Certification Body



Date 2020-09-30



Wenxiang Zhang

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

Tel.: +49 221 806-1371 Fax: +49 221 806-3985 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety

# 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.  
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Tel.: +49 221 806-1371 Fax: +49 221 806-3985 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc 3/3, Rev 0

**Attachment to  
Certificate**

**Registration No.:** SX 60151704 0001  
**Report No.:** 16801058 009

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

**Scope:**

Sites included:

Hong Di Plastic Products Co., Ltd.  
Donggao Industrial Zone, Zanhuang, 050000, Hebei, P.R. China

Manufacture of Patient Examination Gloves

Shanxi Hongjin Plastic Technology Co., LTD.  
Coal Bed Gas Industrial Zone, Qu'e Town, Daning County,  
Linfen City, 042300, Shanxi, P.R. China

Manufacture of Patient Examination Gloves

**Certification Body**



**Date:** 2020-09-30



**Wenxiang Zhang**

**Business Stream Products**  
Certification Department

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

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

Contact

Tel. +49 911 655-5225  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)

Date April 15, 2020

**Application for** : QMS  
Certificate No. : SX 60148697 Sheet 0001  
Device : Only for QM-System audit  
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the  
new certificate No. SX 60148697 0001  
replacing the previous certificate.

Kind regards

Certification body



Jing Zhang

Test sample: no, documentation available

TÜV Rheinland  
LGA Products GmbH

Tillystraße 2  
90431 Nürnberg

Tel. +49 911 655-5225  
Fax +49 911 655-5228  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)  
Web [www.tuv.com/safety](http://www.tuv.com/safety)

Board of Management:

Dipl.-Ing.  
Jörg Mälire, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schlosse

Chairman of the  
Supervisory Board

Dipl.-Ing.  
Ralf Scheller

Nuremberg HRB 28013  
VAT No. DE 811825450

# Annex to certificate

Standard **ISO 9001:2015**

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

No.	Location	Scope
/01	<p>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</p>	Distribution of Patient Examination Gloves
/02	<p>Syntex Healthcare Products Co., Ltd. Unified Social Credit Code: 91130181734364356G Registration Address: Southern No. 307 National Highway Rd., Western Fanjiazhuang Village, Xinji City, 052360 Hebei, P. R. China Operation Address: same as above</p>	Manufacture and Distribution of Patient Examination Gloves
/03	<p>Grand Work Plastic Products Co., Ltd. Unified Social Credit Code: 91130100752433415G Registration Address: Donggao Industrial Zone, Zanhuang, 050000 Hebei, P. R. China Operation Address: same as above</p>	Manufacture and Distribution of Patient Examination Gloves



# Annex to certificate

Standard **ISO 9001:2015**

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

/06	<p>Shijiazhuang Jiahe Plastic Glove Co., Ltd. Unified Social Credit Code: 91130107563240147C Registration Address: Northern Jiandi Village, Western Jiafeng Road, Mining Area, Shijiazhuang City, 050100 Hebei, P. R. China Operation Address: same as above</p>	Manufacture and Distribution of Patient Examination Gloves
/08	<p>Purtech Cleanroom Products Co., Ltd. Unified Social Credit Code: 91130181777701957N Registration Address: Fanjiazhuang Industrial Zone, Xinji City, 052360 Hebei, P. R. China Operation Address: same as above</p>	Manufacture and Distribution of Patient Examination Gloves
/09	<p>Ever Light Plastic Products Co., Ltd. Unified Social Credit Code: 91130100784064765D Registration Address: Donggao Industrial Zone, Zanhuang, 050000 Hebei, P. R. China Operation Address: same as above</p>	Manufacture and Distribution of Patient Examination Gloves



# Annex to certificate

Standard **ISO 9001:2015**

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

- /10 Better Care Plastic Technology Co., Ltd. Manufacture and Distribution of Patient Examination Gloves  
Unified Social Credit Code: 911301286920575093  
Registration Address: Shenze Industrial Base (Fuqian Xi Road), Shenze County, 050000 Hebei, P. R. China  
Operation Address: same as above
- /11 Shijiazhuang Hongzan Plastic Technology Co., Ltd. Manufacture and Distribution of Patient Examination Gloves  
Unified Social Credit Code: 91130129567387090Y  
Registration Address: Donggao Industrial Zone, Zanhuang, Shijiazhuang City, 050000 Hebei, P. R. China  
Operation Address: same as above

# Annex to certificate

Standard **ISO 9001:2015**

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

/12 Shanxi Hongjin Plastic Technology Co., Ltd. Manufacture and Distribution of Patient Examination Gloves  
Unified Social Credit Code: 91141030MA0HDY6R5D  
Registration Address: Coal Bed Gas Industrial Zone, Qu'e Town, Daning County, Linfen City, 042300 Shanxi, P. R. China  
Operation Address: same as above

2020-08-18



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

Page 4 of 4

# 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, 52260 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 2020-10-20 until 2023-04-19.  
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>

2020-08-18



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Certificate

Standard **ISO 9001:2015**

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

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

Site: **c/o 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

Scope: 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 in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.  
It remains valid subject to satisfactory surveillance audits.

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

2020-08-18



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/02**

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

Site: **c/o Syntex Healthcare Products Co., Ltd.**  
Unified Social Credit Code: 91130181734364356G  
Registration Address: Southern No. 307 National Highway Rd.,  
Western Fanjiazhuang Village, Xinji City,  
052360 Hebei, P. R. China  
Operation Address: same as above

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 in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.  
It remains valid subject to satisfactory surveillance audits.

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

2020-08-18



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# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/03**

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

Site: **c/o Grand Work Plastic Products Co., Ltd.**  
Unified Social Credit Code: 91130100752433415G  
Registration Address: Donggao Industrial Zone,  
Zanhuang, 050000 Hebei, P. R. China  
Operation Address: same as above

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 in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.  
It remains valid subject to satisfactory surveillance audits.

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

2020-08-18



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# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/06**

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

Site: **c/o Shijiazhuang Jiahe Plastic Glove Co., Ltd.**  
Unified Social Credit Code: 91130107563240147C  
Registration Address: Northern Jiandi Village,  
Western Jiafeng Road, Mining Area, Shijiazhuang City,  
050100 Hebei, P. R. China  
Operation Address: same as above

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 in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.  
It remains valid subject to satisfactory surveillance audits.

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

2020-08-18



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# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/08**

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

Site: **c/o Purtech Cleanroom Products Co., Ltd.**  
Unified Social Credit Code: 91130181777701957N  
Registration Address: Fanjiazhuang Industrial Zone,  
Xinji City, 052360 Hebei, P. R. China  
Operation Address: same as above

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 in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.  
It remains valid subject to satisfactory surveillance audits.

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

2020-08-18



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# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/09**

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

Site: **c/o Ever Light Plastic Products Co., Ltd.**  
Unified Social Credit Code: 91130100784064765D  
Registration Address: Donggao Industrial Zone, Zanhuang,  
050000 Hebei, P. R. China  
Operation Address: same as above

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 in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.  
It remains valid subject to satisfactory surveillance audits.

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

2020-08-18



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# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/10**

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

Site: **c/o Better Care Plastic Technology Co., Ltd.**  
Unified Social Credit Code: 911301286920575093  
Registration Address: Shenze Industrial Base (Fuqian Xi Road),  
Shenze County, 050000 Hebei, P. R. China  
Operation Address: same as above

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 in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.  
It remains valid subject to satisfactory surveillance audits.

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

2020-08-18



TÜV Rheinland Cert GmbH  
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# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/11**

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

Site: **c/o Shijiazhuang Hongzan Plastic Technology Co., Ltd.**  
Unified Social Credit Code: 91130129567387090Y  
Registration Address: Donggao Industrial Zone, Zanhuang,  
Shijiazhuang City, 050000 Hebei, P. R. China  
Operation Address: same as above

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 in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.  
It remains valid subject to satisfactory surveillance audits.

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

2020-08-18



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/12**

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

Site: **c/o Shanxi Hongjin Plastic Technology Co., Ltd.**  
Unified Social Credit Code: 91141030MA0HDY6R5D  
Registration Address: Coal Bed Gas Industrial Zone,  
Qu'e Town, Daning County, Linfen City,  
042300 Shanxi, P. R. China  
Operation Address: same as above

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 in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.  
It remains valid subject to satisfactory surveillance audits.

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

2020-08-18



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# 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

*Distributor:*

Setino Hungary Kft.  
Száva 4/B 1107  
Budapest, Hungary  
Tel.: +36-1-349-1053

We, the manufacturer, herewith declare that the products

**Disposable Vinyl / 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.



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:  *Manager*  
Legally binding signature, Function



# 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.de

We, the manufacturer, herewith declare that the products

**Disposable Vinyl/Nitrile Blend Examination Gloves**

**With the size of XS, S, M, L, XL and XXL**

**UMDNS-Code: 11-882**

**UDI:**

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.



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

The glove is a disposable non-sterile device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

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.

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

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 2020-05-10

Place, date

EC Declaration of Conformity

GM: 

Legally binding signature. Function





## 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): Disposable Vinyl/Nitrile Blend Examination Gloves

Type(s) / Model(s): Powder Free / XS, S, M, L, XL, XXL

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: January 20, 2020

Review Result: During the examination of the Technical Documentation (No: HRG-JSWJ-003, Revision: A, Dated 2020-01-15), 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: Wu Min

Date: January 20, 2020

Regulatory Authority

# EU 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

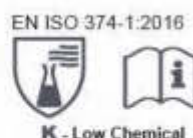
*Distributor:*

Setino Hungary Kft.  
Száva 4/B 1107  
Budapest, Hungary  
Tel.: +36-1-349-1053

under its sole responsibility declares, that the personal protective equipment specified below:

**Disposable Vinyl / Nitrile Blend Glove  
VNPF2001-2005  
SETINO CODE: VN-3**

was classified in category III. - PPE (EU) 2016/425 II. according to its annex  
EN ISO 374-1: 2016; EN ISO374-4:2019; EN ISO 374-5: 2016; EN ISO21 420:2020



The protective equipment complies with the requirements of Regulation 2016/425 (EU) and the harmonized European standards EN ISO 374-1: 2016, EN ISO 374-5: 2016, EN ISO374-4:2019, EN ISO21 420:2020 and identical to PPE covered by EU type examination (Module B); certificate number: 2777/15012-01/E00-00.

issuing certification body:

**SATRA Technology Europe Limited. Bracetown Business Park. Clonee. D15YN2P. Republic of Ireland  
Notified Body: 2777**

According to module C2 for PPE, a conformity assessment procedure is carried out under the supervision of the notified body, supervising:

**SATRA Technology Europe Limited. Bracetown Business Park. Clonee. D15YN2P. Republic of Ireland  
Notified Body: 2777**

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

2020.10.16.

Place, date



Signature



# EU Type-Examination Certificate

## Certificate number: 2777/15012-01/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:**

VNPF2001-2005

**Description:**

Disposable Vinyl/Nitrile Blend Examination Gloves.

Colour: Blue, Green, Black.

**Sizes:**

XS(6)-XL(10)

**Classification:**

EN ISO 374-1:2016+A1:2018/ Type B	Level	EN ISO 374-4:2019 Degradation %
40% Sodium hydroxide (K)	6	-1.2
30% Hydrogen peroxide (P)	6	2.7
37% Formaldehyde (T)	6	-8.1

**EN ISO 374-5:2016**

Protection against Bacteria and Fungi	Pass
Protection against Viruses	Pass

**Standards/Technical specifications applied:**

EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

**Technical reports/Approval documents:**

SATRA: CHT0298236/2021, CHM0298451/2022/LH/A, CHM0298451/2022/LH/B, CHM0298451/2022/EN/C

Signed on behalf of SATRA:

*Daisy He*

Daisy He

*Quincey Brown*

Quincey Brown

**Date first issued: 08/09/2020**

**Date of issue: 08/09/2020**

**Expiry date: 08/09/2025**