Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2091443-1

Organization: Hebei Titans Hongsen Medical Technology Co., Ltd.
Eastern Industrial Zone, Nangong City, Xingtai City,
051800 Hebei, P.R. China

Scope: Manufacture and Distribution of Single-use Patient Examination Gloves

Digitally signed by Bolea Petru
Date: 2023.08.03 18:46:18 EEST
Reason: MoldSign Signature
Location: Moldova

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190131519 110
Effective date: 2021-05-28
Expiry date: 2024-05-10
Issue date: 2021-05-31

TÜV Rheinland LGA Products GmbH

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

CERTIFICATE OF REGISTRATION

MedNet EC-REP GmbH
Borkstraße 10
48163 Münster
Germany

in its function of the European Authorized Representative, in accordance with the Regulation (EU) 2017/745 on medical devices of the European Parliament and of the Council dated 5 April 2017 in its latest version and including its amendments, hereby confirms the registration of the following medical devices into the German DMIDS data base

Sinlge-use Nitrile Patient Examination Gloves, Single-use Examination Vinyl Gloves, Disposable Medical VinylNitrile mixed Examination Gloves, class I
DMIDS Registration Number DE/CA22/00130718

on behalf of

Hebei Titans Hongsen Medical Technology Co., Ltd.
Eastern Industrial Zone,
Nangong City, Xingtai City, Hebei Province, 051800, P.R. China

according to the Regulation (EU) 2017/745 of the European Parliament and of the Council of the European Union relating to medical devices.

Münster, 17.05.2023

MEDNET EC-REP
MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany
Phone: +49 251 322 66-64
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Birthe Harms
on behalf of MedNet EC-REP GmbH

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Phone +49 251 32266-64 | Fax +49 251 32266-22 | e-mail: contact@mednet-ecrep.com | www.mednet-ecrep.com
Local Reg. Number HRB 17791 | Managing Directors: Matthias Heinz, Ole Stein
Bank Account: Vereinigte Volksbank Münster eG | IBAN: DE97 4036 1906 7233 1271 00 | BIC: GENODEM1IBB

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00339625

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
Form for Medical Devices except In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA22**		
	Bezeichnung / Name **Bezirksregierung Münster, Dezernat 24**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Münster**		Postleitzahl / Postal code **48143**
	Straße, Haus-Nr. / Street, house no. **Domplatz 36**		
	Telefon / Phone **+49-251-4110**		Telefax / Fax **+49-251-4112525**
	E-Mail / E-mail **mitteilungen-dimdi@brms.nrw.de**		

Anzeige / Notification

	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **31.05.2021**		Registriernummer / Registration number **DE/CA22/00130718**

Rechtsgrundlage / legal basis

☐ Medizinprodukte (93/42/EWG bzw. 90/385/EWG) / German Medical Device Act (93/42/EWG or 90/385/EWG)

☒ Verordnung (EU) 2017/745 (MDR) / Regulation (EU) 2017/745 (MDR)

Typ der Anzeige / Notification type

☐ Erstanzeige / Initial notification

☒ Änderungsanzeige / Notification of change

☐ Widerrufsanzeige / Notification of withdrawal

Frühere Registriernummer bei Änderungs- und Widerrufsanzeige
Previous registration number if notification has been changed or withdrawn
DE/CA22/1311-1161

Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG

☐ Hersteller / Manufacturer

☒ Bevollmächtigter / Authorised Representative

☐ Einführer / Importer

☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG

☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV
Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV

☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG
Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG

Anzeigender / Reporting organisation (person)

	Code **DE/0000048589**		
	Bezeichnung / Name **MedNet EC-REP GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Münster**		Postleitzahl / Postal code **48163**
	Straße, Haus-Nr. / Street, house no. **Borkstrasse 10**		
	Telefon / Phone **025132266-61**		Telefax / Fax **025132266-22**
	E-Mail / E-mail **ear-admin@medneteurope.com**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Hebei Titans Hongsen Medical Technology Co., Ltd.**		
	Staat / State **CN**		
	Ort / City **Nangong City, Xingtai City, Hebei Province**		Postleitzahl / Postal code **051800**
	Straße, Haus-Nr. / Street, house no. **Eastern Industrial Zone**		
	Telefon / Phone **+86 -311-85370099**		Telefax / Fax
	E-Mail / E-mail		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **David Thaler**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Münster**		Postleitzahl / Postal code **48163**
	Straße, Haus-Nr. / Street, house no. **Borkstrasse 10**		
	Telefon / Phone **025132266-50**		Telefax / Fax
	E-Mail / E-mail **david.thaler@medneteurope.com**		

Vertreter / Deputy (optional)			
	Bezeichnung / Name **Ole Stein**		
	Telefon / Phone **025132266-16**		Telefax / Fax
	E-Mail / E-mail **ole.stein@medneteurope.com**		
	☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change		

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
	Klasse / Class ☒ I ☐ I - steril / sterile ☐ I - mit Messfunktion / with measuring function ☐ I - steril und mit Messfunktion / sterile and with measuring function ☐ I - Wiederaufbereitung / Reprocessing ☐ I - steril und Wiederaufbereitung / sterile and reprocessing ☐ I - mit Messfunktion und Wiederaufbereitung / with measuring function and reprocessing ☐ I - steril und mit Messfunktion und Wiederaufbereitung / sterile and with measuring function and reprocessing ☐ IIa ☐ IIb ☐ III ☐ III - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012 ☐ Aktives implantierbares Medizinprodukt / Active implantable medical device ☐ Aktives implantierbares Medizinprodukt - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 Active implantable medical device - manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012
	App (Software auf mobilen Endgeräten) ☐ ja / yes ☒ nein / no
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	Handelsname des Produktes / Trade name of the device
	Produktbezeichnung / Name of device **Sinlge-use Nitrile Patient Examination Gloves, Single-use Examination Vinyl Gloves, Disposable Medical VinylNitrile mixed Examination Gloves**
	Nomenklaturcode / Nomenclature code **11-882**
	Nomenklaturbezeichnung / Nomenclature term **Handschuh, Untersuchung/Behandlung**
	Kategoriecode / Category code **10**
	Kategorie / Category **Produkte zum Einmalgebrauch**
	Kurzbeschreibung deutsch / German short description
	Kurzbeschreibung englisch / English short description

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)	
	☐ Semikritische Medizinprodukte / Semicritical medical devices ☐ Gruppe A / Group A ☐ Gruppe B / Group B
	☐ Kritische Medizinprodukte / Critical medical devices ☐ Gruppe A / Group A ☐ Gruppe B / Group B ☐ Gruppe C / Group C Nummer der Bescheinigung / Certificate number
	Sterilisationsverfahren / Sterilisation procedures ☐ Dampfsterilisation / Steam sterilisation ☐ Gassterilisation / Gas sterilisation ☐ Strahlensterilisation / Radiation sterilisation ☐ andere / others Angewandtes Verfahren / Applied procedure

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **Münster**

Datum
Date **2021-05-31**

Name
Isabel Uhlenbrock

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible		Telefon / Phone

EC Declaration of Conformity

Manufacturer:

Hebei Titans Hongsen Medical Technology Co., Ltd.
Eastern Industrial Zone, Nangong City, Xingtai City, 051800 Hebei, China

EC Representative:

MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany

Product and Trade Name: **Single-use Nitrile Patient Examination Gloves**
Single-use Examination Vinyl Gloves

Product Model/Specification: **See Attachment #1(Table1;Table 2)**
Basic UDI-DI:

6973442901218 6973442901225 6973442901232 6973442901249 6973442901256 6973442901263
6973442902215 6973442902222 6973442902239 6973442902246 6973442902253 6973442902260
6973442903113 6973442903120 6973442903137 6973442903144 6973442903151 6973442903168
6973442901218 6973442901225 6973442901232 6973442901249 6973442901256 6973442901263
6973442902215 6973442902222 6973442902239 6973442902246 6973442902253 6973442902260
6973442903113 6973442903120 6973442903137 6973442903144 6973442903151 6973442903168
6973442901317 6973442901324 6973442901331 6973442901348 6973442901355 6973442901362
6973442902314 6973442902321 6973442902338 6973442902345 6973442902352 6973442902369

Classification (MDR EU 2017/745 Annex VIII, Chapter III, 4.1): Class I, Rule 1
Conformity Assessment Route: Annex II and Annex III

We, the manufacturer, herewith declare under our sole responsibility that the above devices is inconformity with the Medical Device Regulation / MDR(EU) 2017/745 and other relevant union legislation.

Applied Standards:
EN ISO14971:2019, EN ISO 20417:2021, EN ISO15223.1: 2021 EN ISO13485: 2016/A11:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 21171:2006, EN 62366:2008, ISO 12243:2003+A1:2012, ISO 11193-1:2008, ISO 11193-2:2006,ISO 10993-1:2018, ISO10993-5:2009, ISO10993-10: 2010, MEDDEV 2.7/1 rev 4, MEDDEV 2.12/1 rev 8, EN ISO 21420:2020
PD CEN/TR 16953:2017, ASTM F1671/ F1671M-13.

Place and Date: Xingtai City, Dec.31, 2020

Name: Wenxin LU

Function: General Manager

Signature: Wenxin Lu

Attachment #1

Table 1. Product model / specification of Single-use Nitrile Patient Examination Gloves

Single-use Nitrile Patient Examination Gloves								
Color	Average weight of size M	Trade mark	Sizes					
Blue	3,5g	Titanfine®	XS	S	M	L	XL	XXL

Table 2. Product model / specification of Single-use Examination Vinyl Gloves

Single-use Examination Vinyl Gloves								
Color	Average weight of size M	Trade mark	Sizes					
Clear	4,5g	Titanfine®	XS	S	M	L	XL	XXL

Certificate – 증명서 – شهادة – Certificat – 證明書 – Сертификат

No. 2G200411I.ZZD0413

Declaration of Conformity

Test report no.: DE22BTHI 001

Certificate' s Holder: HebeiTitansHongsenMedicalTechnologyCo.,Ltd. EasternIndustrialZone,NangongCity,Xingtai, Hebei,China

This EU Declaration of Type Conformity covers the following product groups that have passed the relevant standard tests:
The product meets the applicable basic health and safety requirements of Regulation (EU) No 2016/425 Category III and the following standards

Product Name:	Schutzhandschuhe / Protective gloves
Identification / Type no.:	N48CBL1
Product Description:	Disposable Powder Free Nitrile Gloves. Colour: Blue
Sizes:	XS, S, M, L, XL

Test items	Performance level achieved		
EN ISO 374-1:2016+A1:2018/Type C Protective gloves against dangerous Chemicals and Micro-organisms	K NaOH 40% J N-Heptan	Permeation: Klasse/ level 6 Permeation: Klasse/ level 3	Degradation: -4,4 % Degradation: 44,1 %
EN ISO 374-2:2019 Determination of resistance to penetration			
Water leak		Pass	
Air leak		Pass	
EN 374-4:2013 degradation by chemicals			
Perforation test		Pass	
EN ISO 374-5:2016 Protection against Bacterial and Fungi		Pass	
EN ISO 21420:2020 Performance level achieved			
General requirements			
Dexterity		5	

Remark: This statement relates to the above sample. Without the permission of the test center, this test report shall not Allow copying in excerpts. The test report corresponding to this statement is not authorized to carry any test marks.his

CE

Additional information and clarification about the Marking:
The manufacturer must consult the notified body about the process of using the CE mark, if necessary. This document is issued in accordance with the provisions of the voluntary mark for product certification by testing agencies

Issuance date:26 February 2023

Expiry date: 25 February 2028

Reviewer Betty

Client name	:	HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO.,LTD.
Client address	:	EASTERN INDUSTRIAL ZONE, NANGONG CITY, XINGTAI CITY, HEBEI, CHINA
Sample Description	:	SINGLE-USE MEDICAL POLY (VINYL CHLORIDE) EXAMINATION GLOVES
Lot No.	:	NOT PROVIDED
Lot Size	:	NOT PROVIDED
Sample Quantity	:	S: 200PCS, M: 200PCS, L: 200PCS, XL: 200PCS
Style/ Item No.	:	S, M, L, XL
Manufacture	:	HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO.,LTD.
Country of Origin	:	CHINA
Country of Destination	:	EUROPE

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

****

Sample Receiving Date	:	MAY.13,2020
Test Performing Date	:	MAY.13,2020 TO MAY.29,2020
SGS Ref. No.	:	TJHL2004002182MD

****

Test Requested	Result
1. BS EN 455-1:2000 MEDICAL GLOVES FOR SINGLE USE – PART 1: REQUIREMENTS AND TESTING FOR FREEDOM FROM HOLES (CLAUSE 5.1) (FOR SIZE S ONLY)	Pass
2. BS EN 455-2:2015 MEDICAL GLOVES FOR SINGLE USE – PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIES (CLAUSE 4.2, 4.3) (FOR SIZE M ONLY)	Pass
BS EN 455-2:2015 MEDICAL GLOVES FOR SINGLE USE – PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIES (CLAUSE 5.2, 5.3) (FOR SIZE XL ONLY)	Pass
3. BS EN 455-3:2015 MEDICAL GLOVES FOR SINGLE USE—PART 3: REQUIREMENTS AND TESTING FOR BIOLOGICAL EVALUATION (CLAUSE 4.4) (FOR SIZE L ONLY)	Pass

Remark: - Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.

SGS-CSTC Standards
Technical Services (Qingdao)
Co., Ltd.

scan to see the report
QDHL2005004147MD

Jessica Gao
Approved Signatory

Test Conducted:

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

Number of test sample	:	200 Pieces
Sample size	:	S
Number of non-conforming gloves	:	4PCS

Clause	Test Items	Result
5	Watertightness test for detection of holes	---
5.1	Referee testing	Pass (See note 1)

Note	:	1	Sample quantity: 200pcs, AQL:1.5, Ac:7, Re:8, Found:4. The sample selecting amount for this clause is deviated to 200 pcs as assessed by SGS.

2. **BS EN 455-2:2015 Medical gloves for single use – Part 2: Requirements and testing for physical properties**

Number of test sample	:	26 Pieces
Type	:	Examination/procedure gloves c)
Size	:	Examination/procedure gloves: M, XL

Clause	Test Items	Result
4	Dimensions (for size M only)	---
4.2	Length	Pass (See result 1)
4.3	Width	Pass (See result 1)
5	Strength (for size XL only)	---
5.2	Force at break	Pass (See result 2)
5.3	Force at break after challenge testing	Pass (See result 2)

Result 1: Dimensions

Size	M	
No.	Length (mm)	Width (mm)
1	253	99
2	251	99
3	252	99
4	243	98
5	260	99
6	252	98
7	247	99
8	254	101
9	249	100
10	258	99
11	253	98
12	258	100
13	255	100
Standard requirement	≥240	95±10
Median value	253	99

Result 2: Strength

Size: XL			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	4.0	1	3.7
2	4.1	2	3.9
3	4.0	3	3.8
4	4.3	4	3.6
5	4.0	5	3.5
6	3.7	6	3.3
7	4.2	7	3.8
8	4.0	8	3.9
9	4.4	9	3.7
10	4.1	10	3.7
11	3.9	11	3.8
12	4.4	12	4.2
13	4.4	13	4.1
Standard requirement	≥3.6	Standard requirement	≥3.6
Median value	4.1	Median value	3.8

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

Number of test sample	:	5 Pieces
Sample size	:	L
Finishes of gloves	:	Powdered-free gloves other than surgeon's gloves

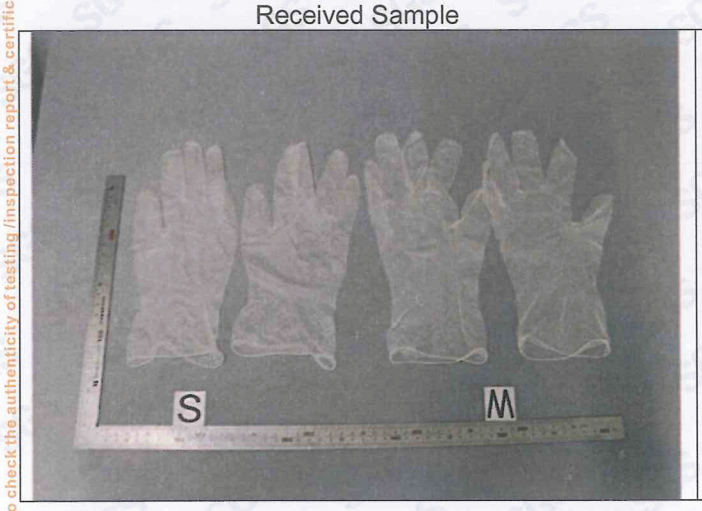
Clause	Test Items	Result
4.4	Powder-free gloves	Pass (See note 1)

Note	:	1	Test according to EN ISO 21171:2006, the average mass of powder per glove is 0.26mg. (Requirement: ≤2mg per powder-free glove)

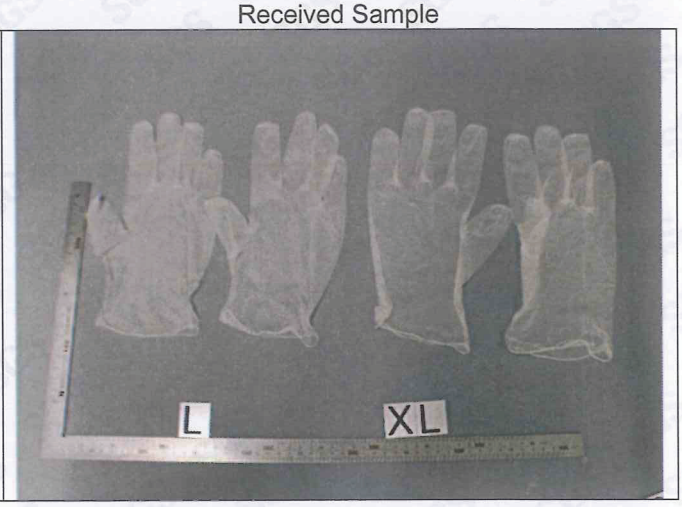
Remark: The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

Sample Photo:

Received Sample



Received Sample



SGS authenticate the photo on original report only

End of Report