Zhonghong Pulin Medical Products Co., Ltd.

EU-Overensstemmelseserklæring

Fabrikant

Zhonghong Pulin Medical Products Co., Ltd.

West Industrial Park, Luannan County, Tangshan City, Hebei Province 063500, China

SRN: CN-MF-000001108

Bemyndiget repræsentant

Lotus NL B.V

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hauge, Netherlands

SRN: NL-AR-000000121

Fabrikanten erklærer herved alene på eget ansvar, at det(de) specificerede produkt(er) er i overensstemmelse med alle krav i/under forordningen og standarder i Den Europæiske Union (EU), der gælder for produktet. Det(de) specificerede produkt(er) er derfor mærket med CE-mærkning:

Produkt navn	Produkt nummer	Produkt beskrivelse
Nitril Undersøgelseshandsker	NG002	Beskyttelseshandsker, kemiske risici. Medicinsk udstyr, til engangsbrug. Kontakt med fødevarer. Størrelse: XS, S, M, L, XL GMDN Code: 56286

Grundlæggende UDI-DI
697040580ZHPFN02XY

Risikoklasse / kategori
Medicinsk udstyr, klasse I
Personligt værnemiddel (PV), kategori III

Produktet er i overensstemmelse med følgende europæiske forordninger:

Forordning nummer	Forordning navn
2017/745	Europa-Parlamentets og Rådets forordning (EU) af 5. april 2017 om medicinsk udstyr
2016/425	Europa-Parlamentets og Rådets forordning (EU) af 9. marts 2016 om personlige værnemidler

Produktet er i overensstemmelse med følgende EU-harmoniserede standarder:

Standard nummer	Standard navn
EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms
EN 420:2003 +A1:2009	Protective gloves - General requirements and test methods
EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009	Medical gloves for single use
ISO 188:2011	Rubber, vulcanized or thermoplastic – Accelerated ageing and heat resistance tests
ISO 21171:2006	Medical gloves – Determination of removable surface powder
ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010	Biological evaluation of medical devices
EN ISO 15223-1:2016	Symbols to be used with medical device labelling and information to be supplied
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 62366-1:2015+AC:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 13485:2016	Medical devices - Quality management systems
Resolution ResAP (2004) 4	Food Contact Material – Rubber

Produktet er i overensstemmelse med følgende fælles specifikationer (CS):

CS	
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Det bemyndigede organ

TÜV Rheinland LGA Products GmbH

Tillystraße 2, 90431 Nürnberg, Germany

Identifikationsnummer: 0197

har foretaget EU-typeafprøvning (modul B) og udstedt EU-typeafprøvningsattest:

Certifikat nr.: 60221944-001

Dato: 08.03.2019

Udløbsdato: 07.03.2024

PV'et er omfattet af overensstemmelsesvurderingsprocedure (modul C2 / modul D) under overvågning af ovennævnte bemyndigede organ.

..oOo..

Denne overensstemmelseserklæring er udstedt alene på fabrikantens ansvar.

Underskrevet for og på vegne af Zhonghong Pulin Medical Products Co.,Ltd.

China, 11.06.2021:

Zhonghong Pulin Medical Products Co., Ltd.

Shawn Su, Deputy General Manager EMEA & Americas

Zhonghong Pulin Medical Products Co., Ltd.

EU-Konformitätserklärung

Hersteller

Zhonghong Pulin Medical Products Co., Ltd.

West Industrial Park, Luannan County, Tangshan City, Hebei Province 063500, China

SRN: CN-MF-000001108

Bevollmächtigten

Lotus NL B.V

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hauge, Netherlands

SRN: NL-AR-000000121

Der Hersteller erklärt hiermit unter unserer Verantwortung, dass das/die angegebene(n) Produkt(e) allen Anforderungen der/unter den für das Produkt geltenden Verordnungen und Normen in der Europäischen Union (EU) entspricht. Das/die angegebene(n) Produkt(e) sind daher mit der CE-Kennzeichnung gekennzeichnet:

Produktname	Produktnummer	Produktbeschreibung
Nitrile untersuchungshandschuhe	NG002	Schutzhandschuhe, chemische Risiken. Medizinprodukt, zum einmaligen Gebrauch. Lebensmittelkontakt. Größe: XS, S, M, L, XL GMDN Code: 56286

Basis-UDI-DI
697040580ZHPFN02XY

Risikoklasse / Kategorie
Medizinprodukt, Klasse I
Persönliche Schutzausrüstung (PSA), Kategorie III

Das Produkt entspricht der folgenden europäischen Verordnung:

Verordnungsnummer	Verordnungsname
2017/745	Verordnung (EU) des Europäischen Parlaments und des Rates vom 5. April 2017 über Medizinprodukte
2016/425	Verordnung (EU) des Europäischen Parlaments und des Rates vom 9. März 2016 über persönliche Schutzausrüstungen

Das Produkt entspricht den folgenden harmonisierten Unionsnormen:

Normen Nummer	Normen Name
EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms
EN 420:2003 +A1:2009	Protective gloves - General requirements and test methods
EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009	Medical gloves for single use
ISO 188:2011	Rubber, vulcanized or thermoplastic – Accelerated ageing and heat resistance tests
ISO 21171:2006	Medical gloves – Determination of removable surface powder
ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010	Biological evaluation of medical devices
EN ISO 15223-1:2016	Symbols to be used with medical device labelling and information to be supplied
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 62366-1:2015+AC:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 13485:2016	Medical devices - Quality management systems
Resolution ResAP (2004) 4	Food Contact Material – Rubber

Das Produkt entspricht den folgenden Spezifikationen (CS):

CS	
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Die notifizierten Stelle

TÜV Rheinland LGA Products GmbH

Tillystraße 2, 90431 Nürnberg, Germany

Kennnummer: 0197

hat die EU-Baumusterprüfung (Modul B) durchgeführt und die EU-Baumusterprüfbescheinigung ausgestellt:

Bescheinigung nummer: 60221944-001

Datum: 08.03.2019

Gültig bis: 07.03.2024

Die PSA unterliegt folgendem Konformitätsbewertungsverfahren (Module C2 / Module D) unter Überwachung der oben notifizierten Stelle.

..oOo..

Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller.

Unterzeichnet für und im Namen von Zhonghong Pulin Medical Products Co.,Ltd.

China, 11.06.2021:

Zhonghong Pulin Medical Products Co., Ltd.

Shawn Su, Deputy General Manager EMEA & Americas

Zhonghong Pulin Medical Products Co., Ltd.

EU Declaration of Conformity

Manufacturer

Zhonghong Pulin Medical Products Co., Ltd.

West Industrial Park, Luannan County, Tangshan City, Hebei Province 063500, China

SRN: CN-MF-000001108

Authorised representative

Lotus NL B.V

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hauge, Netherlands

SRN: NL-AR-000000121

The manufacturer hereby declare under our responsibility that the specified product(s) conforms with all requirements in/under the regulation and standards in the European Union (EU) which applies to the product. The specified product(s) are therefore labelled with the CE marking:

Product name	Product number	Product Description
Nitrile Examination Gloves	NG002	Protective gloves, chemical risks. Medical device, for single use. Food contact. Size: XS, S, M, L, XL GMDN Code: 56286

Basic UDI-DI
697040580ZHPFN02XY

Risk classification / categorisation
Medical device, class I
Personal protective equipment (PPE), category III

The product is in conformity with the following European Regulation:

Regulation number	Regulation name
2017/745	Regulation (EU) of the European Parliament and of the Council of 5. April 2017 on medical devices
2016/425	Regulation (EU) of the European Parliament and of the Council of 9 March 2016 on Personal Protective Equipment

The product is in conformity with the following Union harmonized standards:

Standard number	Standard name
EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms
EN 420:2003 +A1:2009	Protective gloves - General requirements and test methods
EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009	Medical gloves for single use
ISO 188:2011	Rubber, vulcanized or thermoplastic – Accelerated ageing and heat resistance tests
ISO 21171:2006	Medical gloves – Determination of removable surface powder
ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010	Biological evaluation of medical devices
EN ISO 15223-1:2016	Symbols to be used with medical device labelling and information to be supplied
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 62366-1:2015+AC:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 13485:2016	Medical devices - Quality management systems
Resolution ResAP (2004) 4	Food Contact Material – Rubber

Zhonghong Pulin

The product is in conformity with the following common specifications (CS):

CS	
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The Notifoed Body

TÜV Rheinland LGA Products GmbH

Tillystraße 2, 90431 Nürnberg, Germany

Identification no. 0197

performed the EU-type-examination (Module B) and issued the EU type-examination certificate:

Certificate no.: 60221944-001

Date: 08.03.2019

Expiry Date: 07.03.2024

The PPE is subject to the conformity assessment procedure (Module C2 / Module D) under surveillance of the above mentioned notified body.

..oOo..

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Signed for and on behalf of Zhonghong Pulin Medical Products Co.,Ltd.

China, 11.06.2021:

Shawn Su, Deputy General Manager EMEA & Americas

Zhonghong Pulin Medical Products Co., Ltd.

EU-Declaracíon UE de Conformidad

Fabricante

Zhonghong Pulin Medical Products Co., Ltd.

West Industrial Park, Luannan County, Tangshan City, Hebei Province 063500, China

SRN: CN-MF-000001108

Representante autorizado

Lotus NL B.V

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hauge, Netherlands

SRN: NL-AR-000000121

Por la presente, el fabricante declara bajo nuestra responsabilidad que los productos especificados cumplen con todos los requisitos en / bajo la regulación y estándares en la Unión Europea (UE) que se aplican al producto. Por lo tanto, los productos especificados están etiquetados con el marcado CE:

Nombre del producto	Número de producto	Descripción del producto
Guantes de examen de nitrilo	NG002	Guantes protectores, riesgos químicos. Productos sanitarios, Solo uso. Contacto con alimentos. Tamaños: XS, S, M, L, XL GMDN Code: 56286

UDI-DI básico
697040580ZHPFN02XY

Clase / categoría de riesgos
Productos sanitarios, clase I
Protección individual (EPI), categoría III

El producto cumple con la siguiente normativa europea:

Número de regulación	Nombre de la regulación
2017/745	Reglamento (UE) del Parlamento Europeo y del Consejo de 5 de abril de 2017 sobre los productos sanitarios
2016/425	Reglamento (UE) del Parlamento Europeo y del Consejo de 9 de marzo de 2016 relativo a los equipos de protección individual

El producto cumple las siguientes normas armonizadas de la Unión:

Número de normas	Nombre de normas
EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms
EN 420:2003 +A1:2009	Protective gloves - General requirements and test methods
EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009	Medical gloves for single use
ISO 188:2011	Rubber, vulcanized or thermoplastic – Accelerated ageing and heat resistance tests
ISO 21171:2006	Medical gloves – Determination of removable surface powder
ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010	Biological evaluation of medical devices
EN ISO 15223-1:2016	Symbols to be used with medical device labelling and information to be supplied
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 62366-1:2015+AC:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 13485:2016	Medical devices - Quality management systems
Resolution ResAP (2004) 4	Food Contact Material – Rubber

El producto cumple con las siguientes especificaciones comunes (CS):

CS	
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En su caso, el organismo notificado
TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431 Nürnberg, Germany
Número de identificación: 0197

ha efectuado el examen UE de tipo (módulo B) y ha expedido el certificado de examen UE de tipo:

Certificate nümero: 60221944-001
Fecha: 08.03.2019
Fecha de caducidad: 07.03.2024

El EPI está sujeto al procedimiento de evaluación de la conformidad (módulo C2 /módulo D) bajo la supervisión del organismo notificado antes mencionado.

..oOo..

La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante.

Firmado por y en nombre de Zhonghong Pulin Medical Products Co.,Ltd.

China, 11.06.2021:

Zhonghong Pulin Medical Products Co., Ltd.

Shawn Su, Deputy General Manager EMEA & Americas

Zhonghong Pulin Medical Products Co., Ltd.

Dichiarazione di Conformità UE

Fabbricante

Zhonghong Pulin Medical Products Co., Ltd.

West Industrial Park, Luannan County, Tangshan City, Hebei Province 063500, China

SRN: CN-MF-000001108

Mandatario

Lotus NL B.V

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hauge, Netherlands

SRN: NL-AR-000000121

Il fabbricante dichiara sotto la propria responsabilità che i prodotti specificati sono conformi a tutti i requisiti in/ai sensi del regolamento e degli standard dell'Unione Europea (UE) che si applicano al prodotto. I prodotti specificati sono quindi etichettati con la marcatura CE:

Nome del prodotto	Numero del prodotto	Descrizione del prodotto
Guanto da esplorazione in nitrile	NG002	Guanti protettivi, rischi chimici. Dispositivo medico, monouso. Contatto con alimenti. Dimensioni: XS, S, M, L, XL GMDN Code: 56286

UDI-DI de base
697040580ZHPFN02XY

Classe / categoria di rischio
Dispositivi medici, classe I
Dispositivi di protezione individuale (DPI), categoria III

Il prodotto è conforme al seguente Regolamento Europeo:

Numero del regolamento	Nome del regolamento
2017/745	Regolamento (UE) del Parlamento europeo e del Consiglio del 5 aprile 2017 relativo ai dispositivi medici
2016/425	Regolamento (UE) del Parlamento europeo e del Consiglio del 9 marzo 2016 sui dispositivi di protezione individuale

Il prodotto è conforme alle seguenti norme armonizzate dell'Unione:

Numero del norme	Nome del norme
EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms
EN 420:2003 +A1:2009	Protective gloves - General requirements and test methods
EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009	Medical gloves for single use
ISO 188:2011	Rubber, vulcanized or thermoplastic – Accelerated ageing and heat resistance tests
ISO 21171:2006	Medical gloves – Determination of removable surface powder
ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010	Biological evaluation of medical devices
EN ISO 15223-1:2016	Symbols to be used with medical device labelling and information to be supplied
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 62366-1:2015+AC:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 13485:2016	Medical devices - Quality management systems
Resolution ResAP (2004) 4	Food Contact Material – Rubber

Il prodotto è conforme alle seguenti specifiche comuni (SC):

SC	
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l'organismo notificato

TÜV Rheinland LGA Products GmbH

Tillystraße 2, 90431 Nürnberg, Germany

Numero identificativo: 0197

ha svolto l'esame UE del tipo (modulo B) e ha rilasciato il certificato di esame UE del tipo:

Numero di certificato: 60221944-001

Data: 08.03.2019

Data di scadenza: 07.03.2024

Il DPI è oggetto della procedura di valutazione della conformità (modulo C2 / modulo D) sotto la sorveglianza del suddetto organismo notificato.

..oOo..

La presente dichiarazione di conformità è rilasciata sotto l'esclusiva responsabilità del fabbricante.

Firmato a nome e per conto di Zhonghong Pulin Medical Products Co.,Ltd.

China, 11.06.2021:

Zhonghong Pulin Medical Products Co., Ltd.

Shawn Su, Deputy General Manager EMEA & Americas

Zhonghong Pulin Medical Products Co., Ltd.

EU-Conformiteitsverklaring

Fabrikant

Zhonghong Pulin Medical Products Co., Ltd.

West Industrial Park, Luannan County, Tangshan City, Hebei Province 063500, China

SRN: CN-MF-000001108

Gemachtigde

Lotus NL B.V

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hauge, Netherlands

SRN: NL-AR-000000121

De fabrikant verklaart hierbij onder onze verantwoordelijkheid dat het/de gespecificeerde product(en) voldoet aan alle eisen in/volgens de regelgeving en normen in de Europese Unie (EU) die van toepassing zijn op het product. Het/de gespecificeerde product(en) zijn daarom gelabeld met de CE-markering:

Productnaam	Productnummer	Product beschrijving
Nitril onderzoekshandschoenen	NG002	Beschermende handschoenen, chemische risico's. Medische hulpmiddelen, voor eenmalig gebruik. Voedselcontact. Grootte: XS, S, M, L, XL GMDN Code: 56286

Basic UDI-DI
697040580ZHPFN02XY

Risicoklasse / categorie
Medische hulpmiddelen, klasse I
Persoonlijke beschermingsmiddelen (PBM), categorie III

Het product is conform met de volgende Europese verordening:

Verordening nummer	Verordening naam
2017/745	Verordening (EU) van het Europees Parlement en de Raad van 5 april 2017 betreffende medische hulpmiddelen
2016/425	Verordening (EU) van het Europees Parlement en de Raad van 9 maart 2016 betreffende persoonlijke beschermingsmiddelen

Het product is conform met de volgende geharmoniseerde normen van de Unie:

Norm nummer	Norm naam
EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms
EN 420:2003 +A1:2009	Protective gloves - General requirements and test methods
EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009	Medical gloves for single use
ISO 188:2011	Rubber, vulcanized or thermoplastic – Accelerated ageing and heat resistance tests
ISO 21171:2006	Medical gloves – Determination of removable surface powder
ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010	Biological evaluation of medical devices
EN ISO 15223-1:2016	Symbols to be used with medical device labelling and information to be supplied
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 62366-1:2015+AC:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 13485:2016	Medical devices - Quality management systems
Resolution ResAP (2004) 4	Food Contact Material – Rubber

Het product is conform met de volgende gemeenschappelijke specificaties (GS):

GS	
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De aangemelde instantie

TÜV Rheinland LGA Products GmbH

Tillystraße 2, 90431 Nürnberg, Germany

Identificatie nummer: 0197

heeft het EU-typeonderzoek (module B) verricht en het certificaat van EU-typeonderzoek afgegeven:

Certificaat nummer: 60221944-001

Datum: 08.03.2019

Vervaldatum: 07.03.2024

Het persoonlijk beschermingsmiddel is onderworpen aan de conformiteitsbeoordelingsprocedure (module C2 / module D) onder toezicht van de bovengenoemde aangemelde instantie.

..oOo..

Deze conformiteitsverklaring wordt op eigen verantwoording van de fabrikant verstrekt.

Ondertekend voor en namens Zhonghong Pulin Medical Products Co.,Ltd.

China, 11.06.2021:

Zhonghong Pulin Medical Products Co.,Ltd.

Shawn Su, Deputy General Manager EMEA & Americas

Zhonghong Pulin Medical Products Co., Ltd.

EU-Samsvarserklæring

Produsent

Zhonghong Pulin Medical Products Co., Ltd.

West Industrial Park, Luannan County, Tangshan City, Hebei Province 063500, China

SRN: CN-MF-000001108

Representant

Lotus NL B.V

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hauge, Netherlands

SRN: NL-AR-000000121

Produsenten erklærer herved på eneansvar at det eller de spesifiserte produktene er i samsvar med alle krav i/under forskrift og standarder i EU som gjelder for produktet. De spesifiserte produktene er derfor merket med CE-merking:

Produktnavn	Produktnummer	Produktbeskrivelse
Nitril undersøktshansker	NG002	Vernehansker mot farlige kjemikalier. Medisinsk utstyr, engangsbruk. Matforedling. Størrelse: XS, S, M, L, XL GMDN Code: 56286

Grunnleggende UDI-DI
697040580ZHPFN02XY

Risikoklasse / kategori
Medisinsk utstyr, klasse I
Personlig verneutstyr (PVU), kategori III

Produktet er i samsvar med følgende europeiske forskrifter:

Forskrift nummer	Forskrift navn
2017/745	Europaparlaments- og rådsforordning (EU) av 5. april 2017 om medisinsk utstyr
2016/425	Europaparlaments- og rådsforordning (EU) av 9. mars 2016 om personlig verneutstyr

Produktet er i samsvar med følgende EU-harmoniserte standarder:

Standard nummer	Standard navn
EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms
EN 420:2003 +A1:2009	Protective gloves - General requirements and test methods
EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009	Medical gloves for single use
ISO 188:2011	Rubber, vulcanized or thermoplastic – Accelerated ageing and heat resistance tests
ISO 21171:2006	Medical gloves – Determination of removable surface powder
ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010	Biological evaluation of medical devices
EN ISO 15223-1:2016	Symbols to be used with medical device labelling and information to be supplied
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 62366-1:2015+AC:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 13485:2016	Medical devices - Quality management systems
Resolution ResAP (2004) 4	Food Contact Material – Rubber

Produktet er i samsvar med følgende felles spesifikasjoner (CS):

CS	
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Det meldte organet

TÜV Rheinland LGA Products GmbH

Tillystraße 2, 90431 Nürnberg, Germany

identifikasjonsnummer: 0197

har utført EU-typeprøving (modul B) og utstedt EU-typeprøvingssertifikat:

Sertifikat nummer.: 60221944-001

Dato: 08.03.2019

Utløpsdato: 07.03.2024

PVU-et omfattes av framgangsmåten for samsvarsvurdering (modul C2 / modul D) under tilsyn av det ovennevnte meldte organet.

..oOo..

Denne samsvarserklæringen utstedes på produsentens eneansvar.

Undertegnet for og på vegne av Zhonghong Pulin Medical Products Co.,Ltd.

China, 11.06.2021:

Zhonghong Pulin Medical Products Co., Ltd.

Shawn Su, Deputy General Manager EMEA & Americas

Zhonghong Pulin Medical Products Co., Ltd.

EU-Försäkran om Överensstämmelse

Tillverkare

Zhonghong Pulin Medical Products Co., Ltd.

West Industrial Park, Luannan County, Tangshan City, Hebei Province 063500, China

SRN: CN-MF-000001108

Tillverkarens representant

Lotus NL B.V

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hauge, Netherlands

SRN: NL-AR-000000121

Tillverkaren försäkran härmed under eget ansvar att den eller de angivna produkterna uppfyller alla krav i/enligt föreskrifterna och standarderna i Europeiska unionen (EU) som gäller för produkten. De angivna produkterna är därför märkta med CE-märkning:

Produktnamn	Produktnummer	Produktbeskrivning
Nitril examination handskar	NG002	Skyddshandskar, kemiska risker. Medicintekniska produkten, engångsbruk. Kontakt med livsmedel. Storlek: XS, S, M, L, XL GMDN Code: 56286

Grundläggande UDI-DI
697040580ZHPFN02XY

Riskklass / kategori
Medicintekniska produkten, klass I
Personlig skyddsutrustning, kategori III

Produkten överensstämmer med följande europeiska förordning:

Förordning nummer	Förordning namn
2017/745	Europaparlamentets och rådets förordning (EU) av den 5 april 2017 om medicintekniske produkter
2016/425	Europaparlamentets och rådets förordning (EU) av den 9 mars 2016 om personlig skyddsutrustning

Produkten överensstämmer med följande unionsharmoniserade standarder:

Standard nummer	Standard namn
EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms
EN 420:2003 +A1:2009	Protective gloves - General requirements and test methods
EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009	Medical gloves for single use
ISO 188:2011	Rubber, vulcanized or thermoplastic – Accelerated ageing and heat resistance tests
ISO 21171:2006	Medical gloves – Determination of removable surface powder
ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010	Biological evaluation of medical devices
EN ISO 15223-1:2016	Symbols to be used with medical device labelling and information to be supplied
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 62366-1:2015+AC:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 13485:2016	Medical devices - Quality management systems
Resolution ResAP (2004) 4	Food Contact Material – Rubber

Produkten överensstämmer med följande gemensamma specifikationer (CS):

CS	
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Det anmälda organet

TÜV Rheinland LGA Products GmbH

Tillystraße 2, 90431 Nürnberg, Germany

Identifieringsnummer: 0197

har utfört EU-typkontrollen (modul B) och utfärdat EU-typintyget:

Intygsnummer.: 60221944-001

Datum: 08.03.2019

Sista giltighetsdag: 07.03.2024

Den personliga skyddsutrustningen omfattas av förfarandet för bedömning av överensstämmelse (modul C2 / modul D) under övervakning av ovan nämnda anmälda organet:

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Denna försäkran om överensstämmelse utfärdats på tillverkarens eget ansvar.

Undertecknad för Zhonghong Pulin Medical Products Co.,Ltd.

China, 11.06.2021:

Shawn Su, Deputy General Manager EMEA & Americas