

## PRODUCT DATA SHEET

### IDEAL MED PRO NITRIL SURGICAL GLOVES

**1. DESCRIPTION** : High-quality Nitrile Latex-Free surgical gloves style 12" (290mm) over the cuff fit. Come Left / Right fit. Powder free with 12 mil thickness. Disposable for single use.

**2. COLORS** : Mixed

**3. SIZES** : See below for Surgical glove sizes compared to exam

Size	Min Length (mm)	Width (mm)	Thickness, Cuff, Palm & Finger
Small / 6	>=12" (290)	80 +/-10	Min 0.05 mm for all sizes
Med / 6.5-7	>=12" (290)	95 +/-10	
Large / 7.5-8	>=12" (290)	110 +/-10	
XLarge / 8.5	>=12" (290)	>=110	

Size Guide	
Exam Glove Size	Surgical Glove Size
XS	5.5
S	6
M	6.5
	7
L	7.5
	8
XL	8.5
XXL	9

**4. PACKED** : 50ea gloves per box. Packed in Left and Right.

**5. BOX SIZE** : 165mmx100mmx17.5mm or 6.5"x4"x0.6"

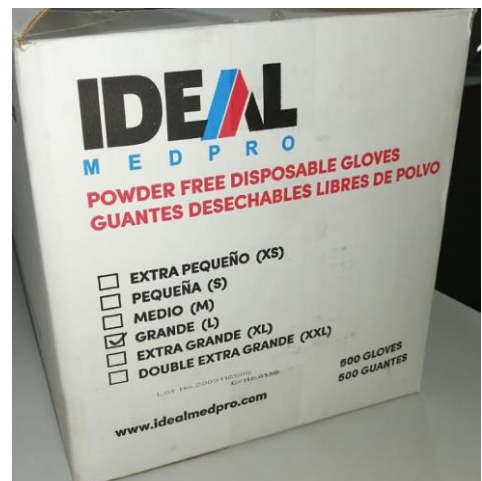
**7. USAGE & APPLICATIONS** : Single use, disposable. Medical, Dentistry, Janitorial , Laboratory Technician, Nursing Home Care, Painting, Veterinarian, Utilities, Clinical Laboratories, EMS, EMT, First Aid, First responder, Funeral Home, Hospital, Patient Examinations, Pharmaceutical, Tattoo and Piercing

**9. ORIGIN** : Made in Indonesia | Import code HTC 4015.19.1010

**10. MASTER CASE 37x26.7x24cm** : White corrugated with 10 Boxes / 500 ea gloves (250 Left / 250 Right) | GW 6.5kg



## GIFT BOX & MASTER CASE



Inside master case packed  
5 boxes Left hand / 5 boxes Right hand





## **Manufacture OEM Info**

PT. MEDISAFE TECHNOLOGIES

### **Factory location**

Sumatera Utara, Indonesia

### **See next pages:**

Certifications  
FDA Registration  
510k

# ZERTIFIKAT / Certificate

**DIN EN ISO / EN ISO 13485 : 2016**

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

**PT. MediSafe Technologies**  
**Jl. Batang Kuis gg. Tambak Rejo/Pasar IX**  
**Desa Buntu Bedimbar, Tanjung Morawa**  
**Medan - 20362, Sumatera Utara**  
**Indonesia**

ein Qualitätsmanagementsystem nach der Norm DIN EN ISO 13485 : 2016 / EN ISO 13485 : 2016 - Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke - eingeführt hat und aufrechterhält. Dieses Zertifikat stellt nicht den erforderlichen Nachweis zur Anbringung der CE-Kennzeichnung dar.

*has established and maintains a quality management system that meets the requirements of DIN EN ISO 13485 : 2016 / EN ISO 13485 : 2016 - Medical devices - Quality management systems - Requirements for regulatory purposes. This certificate is not an authorisation to affix the CE mark.*

Geltungsbereich / *Scope*

**Manufacturing of Powder Free Nitrile Examination Gloves, Powder Free Polychloroprene Examination Gloves, Powder Free Polychloroprene Surgical Gloves, Powder Free Polyisoprene Surgical Gloves**

Reg.-Nr. / *Reg.-No.* 44 221 117840  
Bericht Nr. / *Report No.* 3522 0444

Gültigkeit / *Validity*  
von / *from* 2018-07-10  
bis / *until* 2020-04-22  
Edition 5



Zertifizierungsstelle für Medizinprodukte  
*Certification body for medical devices*

Essen, 2018-07-10

TÜV NORD CERT GmbH    Langemarckstraße 20    45141 Essen    [www.tuev-nord-cert.de](http://www.tuev-nord-cert.de)    [medical@tuev-nord.de](mailto:medical@tuev-nord.de)

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*



*Certificate*  
OF REGISTRATION

This is to certify that

**PT. Medisafe Technologies**

Address: Jl. Batang Kuis, Gg. Tambak Rejo/Psr.IX Desa Buntu Bedimbar,  
Kecamatan Tanjung Morawa Medan 20362, Sumatera Utara, Indonesia

has been assessed and found to be conforming to the requirements

**HACCP Codex Alimentarius (2003)**

For the Scope of

**Manufacture and Supply of Powder Free Nitrile Examination Gloves, Powder Free Polychloroprene Examination Gloves, Powder Free Polychloroprene Surgical Gloves, Powder Free Polyisoprene Surgical Gloves and Powder Free Natural Rubber Latex Surgical Gloves.**

By QSA International, UK

This certificate is valid from April 03, 2020 until April 02, 2021

**Registration Number: QSA-17041289**

**Initial Certification Date: 03-04-2017**

**Re-Certification Date: 03-04-2020**

**Certification Expiry Date: 02-04-2023**



**QSA INTERNATIONAL  
LIMITED**  
27, Old Gloucester Street,  
London, WC1N3AX, ENGLAND

*Startford Ray*

Certification Manager



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PT. MEDISAFE TECHNOLOGIES

Jl. Batang Kuis Gg. Tambak Rejo / PSR IX, Desa Buntu Bedimbar, Tanjung Morawa  
Medan Sumatera Utara, ID 20362**Registration Number:** 9616501**FEI Number\*:** 3002955419**Status:** Active**Date Of Registration Status:** 2021**Owner/Operator:**[PT. MEDISAFE TECHNOLOGIES<sup>6</sup>](#)Jl. Batang Kuis Gg. Tambak Rejo / PSR IX  
Medan, Sumatera Utara ID 20362**Owner/Operator Number:** [9019595<sup>7</sup>](#)**Official Correspondent:**

Deepak Bang

Jl. Batang Kuis Gg. Tambak Rejo / PSR IX  
Medan, Sumatera Utara ID 20362**Phone:** 62-61-3000-7134

\* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 01/04/2021

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<b>Device Classification Name</b>	<a href="#">Polymer Patient Examination Glove</a> <sup>22</sup>
<b>510(K) Number</b>	K082302
<b>Device Name</b>	POWDER FREE NITRILE PATIENT EXAMINATION GLOVES WITH CHEMO LABELING CLAIM
<b>Applicant</b>	PT. MEDISAFE TECHNOLOGIES JL.BATANG KUIS GG.TAMBAK REJO DESA BUNTU BEDIMBAR TJ. MORAWA Medan, North Sumatera, ID 20362
<b>Applicant Contact Correspondent</b>	Anil Taneja PT. MEDISAFE TECHNOLOGIES JL.BATANG KUIS GG.TAMBAK REJO DESA BUNTU BEDIMBAR TJ. MORAWA Medan, North Sumatera, ID 20362
<b>Correspondent Contact</b>	Anil Taneja
<b>Regulation Number</b>	<a href="#">880.6250</a> <sup>23</sup>
<b>Classification Product Code</b>	<a href="#">LZA</a> <sup>24</sup>
<b>Subsequent Product Code</b>	<a href="#">LZC</a> <sup>25</sup>
<b>Date Received</b>	08/12/2008
<b>Decision Date</b>	12/09/2008
<b>Decision</b>	Substantially Equivalent (SESE)
<b>Regulation Medical Specialty</b>	General Hospital
<b>510k Review Panel</b>	General Hospital
<b>Statement</b>	<a href="#">Statement</a> <sup>26</sup>
<b>Type</b>	Traditional
<b>Reviewed By Third Party</b>	No
<b>Combination Product</b>	No

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