



AUCH ZUM BEDIENEN  
VON **SMARTPHONES**  
UND TABLETS GEEIGNET



FÜR RUNDUM PERFECT  
GESCHÜTZTE HÄNDE

UNTERSUCHUNGS- UND SCHUTZHANDSCHUHE  
NITRYLEX® CLASSIC BLUE

# IHRE PERSÖNLICHE SCHUTZAUSRÜSTUNG

- UNIVERSELLES PRODUKT IN BLAU
- UN DURCHLÄSSIG FÜR BAKTERIEN, PILZE UND VIREN.



## EIGENSCHAFTEN DES MATERIALS:



### NITRIL:

Nitril oder Acrylnitril-Butadien-Kautschuk (NBR) ist ein Material, das aus organisch-chemischen Verbindungen hergestellt wird. Der Herstellungsprozess dieses Rohstoffs wurde so modifiziert, dass er mit Naturkautschuk konkurrieren kann. Nitrilhandschuhe sind eine ideale Alternative zu Handschuhen aus Naturstoff und werden oft als synthetische Latexhandschuhe bezeichnet.

Die Nitrilhandschuhe enthalten keine Latexproteine, haben nur einen minimalen Gehalt an Vulkanisationsbeschleunigern (Substanzen, die das Erstarren des Rohstoffs unter Temperatureinfluss beschleunigen). Der minimale Gehalt an chemischen Beschleunigern reduziert erheblich das Risiko von Typ-IV-Allergien.



**UNDURCHLÄSSIG**  
FÜR BAKTERIEN,  
PILZE UND VIREN

## DIE SPEZIFIKATIONEN IM SCHNELLCHECK:

- Produkttyp: Medizin- und Schutzhandschuh
- Medizinprodukte-Klasse: I
- Schutztyp: III
- Marke: nitrylex®
- Material: Nitril
- Sterilität: nicht steril
- Textur: Mikrotextrur mit zusätzlich texturierten Fingerspitzen
- Innenfläche: puderfrei - polymerisiert
- Dichtheit AQL:  $\leq 1,5$
- Form: universell
- Manschette: gerollt
- Länge des Handschuhs: normal
- Dicke: Standardhandschuhe
- Geeignet für empfindliche Haut: ja,
- Handschuhe ohne Latex
- Antistatisch: nein

## WÄHLEN SIE DIE RICHTIGE GRÖSSE:

Handschuhe sollten von der Größe her perfekt passen. Dadurch werden Sicherheit und Arbeitskomfort optimiert.

Um Ihre Größe zu ermitteln, messen Sie die Breite Ihrer Hand knapp über dem Daumen (breiteste Stelle der Hand).

**S**

Breite: 70–90 mm  
Länge:  $\geq 240$  mm

**M**

Breite: 85–105 mm  
Länge:  $\geq 240$  mm

**L**

Breite: 100–120 mm  
Länge:  $\geq 240$  mm

**XL**

Breite:  $\geq 110$  mm  
Länge:  $\geq 240$  mm



Richtiges Vermessen

# GENORMT UND ZERTIFIZIERT

EIN KLEINER ÜBERBLICK:

NORMENKONFORMITÄT:

EN ISO 13485:2016

EN 16523-1

EN ISO 15223

EN 1041

EN ISO 374-1

EN 420

EN ISO 374-2

EN 455(1-4)

EN ISO 374-4

VERORDNUNG (EU) 2017/745

EN ISO 374-5

VERORDNUNG (EU) 2016/425

**EU DECLARATION OF CONFORMITY**

Manufacturer: **MERCATOR MEDICAL S.A.**  
 UL. H.MODRZEJEWSKIEJ 30  
 31-327 KRAKÓW, POLSKA

Declares under its sole responsibility that non-sterile examination and protective gloves:

Brand	Type	Sizes	Reference Numbers
nitrilex® classic	nitrile, powder-free, blue, for single use	XS (5-6) - XL (9-10)	a°100: RD30019001-05 a°200: RD30095001-05
	nitrile, powder-free, white, for single use	XS (5-6) - XL (9-10)	a°50: RD30174001-05 a°100: RD30143001-05 a°200: RD30097001-05
	nitrile, powder-free, violet, for single use	XS (5-6) - XL (9-10)	a°100: RD30169001-05 a°200: RD30168001-05

Basic UDI-DE: 5906615 RD NS N PF 9C

meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices, are classified as medical device class I according to Annex VIII of the Regulation (EU) 2017/745 and comply with European harmonized standards: EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006, EN 455-4:2009, EN ISO 15223-1:2016, EN 1041:2008.

The products described above are also classified as Personal Protective Equipment Category III and comply with Regulation (EU) 2016/425 of the European Parliament and the Council of 9 March 2016 on Personal Protective Equipment and resolution of the Council Directive 89/686/EEC and European standards: EN 420:2003+A1:2009, EN ISO 374-1:2016, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016.

The products described above are identical to the Personal Protective Equipment, which is the subject to the EU Type Examination (Module B) under certificate No. 2777/12470-04/E00-00 issued by notified body:

**Satra Technology Europe Limited (2777)**  
 Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

and are subject to the conformity to type procedure based on the internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body:

**Satra Technology Europe Limited (2777)**  
 Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

Date and place of issue:  
 05.05.2020, Kraków

**MERCATOR MEDICAL S.A.**  
 ul. Heccey Modrzejewskiego 30, 31-327 Kraków  
 tel. +48 66 55 450, fax +48 66 55 415  
 Rejestracja Sąd Rejonowy dla M. St. w Krakowie, XII Wydział Gospodarczy KRS, KRS: 0000936244  
 Kapitał zakładowy (w całości opłacony): 10 580 100 PLN  
 NIP: 677-19-36-426, REGON: 350967107  
 Numer BDO: 00056663

Signed on the behalf of the Manufacturer:

*Wojciech Hercka*  
 Wojciech Hercka  
 Product Documentation Manager

**EU DECLARATION OF CONFORMITY**

Manufacturer: **Mercator Medical (Thailand) Ltd.**  
 88/8 Moo.12 Tambon Kampaengphet,  
 Amphur Rattaphum, Songkhla 90180 Thailand

Declare under its sole responsibility that non-sterile examination and protective gloves:

Brand	Type	Sizes	Reference Numbers
nitrilex® classic	Nitrile, powder free, blue, for single use	XS (5-6) - XL (9-10)	a°100: RD30019001-05

classified as medical device class I according to Annex VIII of the MDR 2017/745/EU (Medical Device Regulation) meet the general safety and performance requirements set out in Annex I MDR 2017/745/EU (Medical Device Regulation) and comply with the latest version of all part of EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2016 and EN 1041:2008+A1:2013.

The products described above are in conformity with the provision of the PPE Regulation (EU) 2016/425 as a Category III product, Type B where such is the case, with the latest version of EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016, EN 16523-1:2015+A1:2018, EN 388:201 and EN ISO 21420:2020.

The products are identical to Personal Protective equipment, which is the subject to the EU Type Examination (Module B) and Module C2 On-going Conformity under certificate No. 2777/12470-04/E00-00 issued by notified body:

**SATRA Technology Europe Limited (Notified Body number 2777)**  
 Bracetown Business Park Clonee Dublin 15 D15 YN2P, Republic of Ireland

This declaration is supported by the Quality System approval to ISO13485:2016/EN ISO13485:2016 and ISO 9001:2015 issued by:

**SGS United Kingdom Ltd**  
 Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK

Date and place of issue:  
 02.12.2020, Thailand

Signed on the behalf of the Manufacturer:

*Pranee Intajak*  
 Mr. Pranee Intajak  
 Senior QA/RA  
 Mercator Medical (Thailand) Ltd  
 Mercator Medical (Thailand), Ltd

Mercator Medical (Thailand)Ltd.  
 88/8 Moo 12 Tambon Kampaengphet  
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 enquiry@mercator.co.th  
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 31-327 Krakow,Poland  
 ph:+48(12)66 55 480  
 fax: +48(12)66 55 415  
 medical@mercatormedical.eu  
 www.mercatormedical.eu



Issued to: **Mercator Medical (Thailand) Ltd**  
 88/8 Moo.12  
 Tambon Kampaengphet  
 Amphur Rattaphum  
 Songkhla 90180  
 Thailand

Notified Body: 2777 SATRA customer number: P19011

**EU Type-Examination Certificate**

Certificate number: 2777/12470-04/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:	Description:
Nitrilex Classic Nitrilex Classic + Nitrilex Basic Nitrilex Black Nitrilex Mcare	Powder Free Nitrile Examination Gloves in Black, Blue, Violet Blue, Cobalt Blue, Green, Magenta, Pink and White
<b>Sizes:</b> XS – 4101 S – 4102 M – 4103 L – 4104 XL – 4105 XXL – 4106	<b>Classification:</b> <b>EN ISO 374-1:2016 Type B</b> 40% Sodium hydroxide (K) 0 2.0% 30% Hydrogen peroxide (P) 2 52.8% 37% Formaldehyde (T) 5 20.0%
	<b>EN ISO 374-5:2016</b> Protection against bacteria and fungi – pass Protection against viruses – pass
	<b>EN 388:2016</b> Abrasion resistance 0 Blade cut resistance 0 Tear resistance 0 Puncture resistance 0 TDM cut resistance X

Standards/Technical specifications applied:  
 EN ISO 374-1:2016+A1:2018, EN 420: 2003+A1: 2009, EN ISO 374-5:2016, EN 388:2016

Technical reports/Approval documents:  
 SATRA: CHM0278315/1840LHP, CHM0278273/1847LH, CHM0278315/1840LHO, CHM0278315/1840LHN,  
 CHM0278315/1840LHP, CHM0278315/1840LHM, CHM0278273/1847LH, SPC0278178/18473/SPT, CHM0283478/1914/G,  
 SPC0284096/2003, CHM0287967/2020/SPT

Signed on behalf of SATRA: *Tara Holly* Tara Holly Quincy Brown  
 Date first issued: 29/03/2019  
 Date of issue: 29/06/2020 Expiry date: 29/03/2024



**PPE REGULATION (EU) 2016/425  
 MODULE C2 CERTIFICATE**

Issued to:  
**Mercator Medical (Thailand) Ltd**  
 88/8 Moo. 12  
 Tambon Kampaengphet  
 Amphur Rattaphum  
 Songkhla 90180  
 Thailand

This is to certify that the following products tested under SATRA reports referenced: STE0298488 & CHM0299220/2025/LH have been found to satisfy the requirement of PPE Regulation (EU) 2016/425 Module C2 EU quality control system for the final product for and on behalf of SATRA Technology Europe Limited

EU TYPE EXAMINATION CERTIFICATE NUMBER	PRODUCT GROUP REFERENCE	PRODUCT TYPE	CLASSIFICATION
2777/12470-04/E00-00	Nitrilex Classic Nitrilex Classic + Nitrilex Black Nitrilex Mcare	Powder free Nitrile Examination glove in various colours	EN ISO 374-1:2016 Type B

Dated: 6<sup>th</sup> July 2020 This certificate is valid until: July 2021

*Alan Weston*  
 Signed By (Alan Weston)

For and on behalf of SATRA Technology Europe Limited



The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standards.  
 SATRA Technology Europe Limited, Bracetown Business Park Clonee Dublin 15 D15 YN2P, Republic of Ireland.  
 (Notified Body number 2777)  
 Tel: +353 (0) 1 437 2484 Web: [www.satrapeurope.com](http://www.satrapeurope.com)

# MEDIZINISCHE NITRILHANDSCHUHE

IN HÖCHSTER QUALITÄT

## NITRYLEX® CLASSIC BLUE

- AUCH ZUM BEDIENEN VON SMARTPHONES UND TABLETS GEEIGNET
- MEDIZINISCHES PRODUKT
- KLASSISCHE, PUDERFREIE, MEDIZINISCHE NITRILHANDSCHUHE
- NICHT STERIL
- UN DURCHLÄSSIG FÜR BAKTERIEN, PILZE UND VIREN

SIE HABEN  
FRAGEN?

RUFEN SIE UNS  
EINFACH AN!

