



AUCH ZUM BEDIENEN
VON SMARTPHONES
UND TABLETS GEEIGNET



FÜR RUNDUM PERFEKT
GESCHÜTZTE HÄNDE

UNTERSUCHUNGS- UND SCHUTZHANDSCHUHE
NITRYLEX® CLASSIC BLUE

IHRE PERSÖNLICHE SCHUTZAUSRÜSTUNG

- UNIVERSELLES PRODUKT IN BLAU
- UNDURCHLÄSSIG 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.



DIE SPEZIFIKATIONEN IM SCHNELLCHECK:

- Produkttyp: Medizin- und Schutzhandschuh
- Medizinprodukte-Klasse: I
- Schutztyp: III
- Marke: nitrylex®
- Material: Nitril
- Sterilität: nicht steril
- Textur: Mikrotextur mit zusätzlich texturierten Fingerspitzen
- Innenfläche: puderfrei - polymerisiert
- Dictheit AQL: <1,5
- Form: universell
- Manschette: gerollt
- Länge des Handschuhs: normal
- Dicke: Standardhandschuh
- 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: > 240 mm

M

Breite: 85–105 mm
Länge: > 240 mm

L

Breite: 100–120 mm
Länge: > 240 mm

XL

Breite: > 110 mm
Länge: > 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

MERCATOR MEDICAL

EU DECLARATION OF CONFORMITY

Manufacturer: MERCATOR MEDICAL S.A.
ul. H.MODRZEJEWSKIEJ 30
31-327 KRAKOW, POLSKA

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

Brand	Type	Sizes	Reference Numbers
nitrylex® classic	nitrile, powder-free, blue, for single use	XS (5-6) - XL (9-10)	a'100: RD30019001-05 a'200: RD30096001-05
	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-DI: 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 ISO 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. 2777/10015-03/E17-01 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. Henry Modrejewskiego 30, 31-327 Kraków
tel. 12 66 55 40 00 fax 12 66 55 40 01
Rejestracja podmiotów gospodarki cywilnej w Krakowie
X Wydział Gospodarczy KRS, KRS: 0000036244
Kapitał zakładowy: 1000000 PLN, 1000000 PLN
NIP: 527-19-36-424, REGON: 350967107
Numer BDO: 0000560633
Sp.

Signed on the behalf of the Manufacturer:

Wojciech Herka
Product Documentation Manager

MERCATOR

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
nitrylex® 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 455-3:2009, 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
Rossnow Business Park Ellesmere Port Cheshire CH65 3EN UK

Date and place of issue:
02.12.2020, Thailand

Signed on the behalf of the Manufacturer:



Mr. Praneet Inthajak
Senior QA/QC Manager
Mercator Medical (Thailand) Ltd

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

ph.+66 74 584 222
Fax+66 74 584 223

enquiry@mercator.co.th

Sales Office
MERCATOR MEDICAL S.A.
ul. H. Modrejewskiego 30
31-327 Krakow, Poland

ph.: +48 12 66 55 480
fax: +48 12 66 55 415
medical@mercatormedical.eu
www.mercatormedical.eu

Rev.2.0

SATRA TECHNOLOGY			
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:		
Nitrylex Classic	Powder Free Nitrile Examination Gloves in Black, Blue, Violet Blue, Cobalt Blue, Green, Magenta, Pink and White		
Nitrylex Classic +			
Nitrylex Basic			
Nitrylex Black			
Nitrylex			
Mcare			
Sizes:	Classification:		
XS – 4101	EN ISO 374-1:2016 Type B	Level	EN 374-4:2013
S – 4102	40% Sodium hydroxide (K)	6	2.0%
M – 4103	30% Hydrogen peroxide (P)	2	62.8%
L – 4104	37% Formaldehyde (T)	5	20.0%
XL – 4105			
XXL – 4106			
EN ISO 374-5:2016			
Protection against bacteria and fungi – pass			
Protection against viruses – pass			
EN 388:2016			
Abrasion resistance	Level		
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/LH/02/2018/04/CHM0278273/1847/LH, CHM0278315/1840/LH/O, CHM0278315/1840/LH/N, CHM0278315/1841/LH/P, CHM0278315/1840/LH/M, CHM0278273/1847/LH, SPC027819/1847/S/PT, CHM02834798/1914/JG, SPC0294088/2003, CHM0297987/2020/S/PT			
Signed on behalf of SATRA:		Tara Holly	
Date first issued: 29/03/2019		Expiry date: 29/03/2024	Quincy Brown
Page 1 of 2			

SATRA TECHNOLOGY			
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	Nitrylex Classic Nitrylex Classic + Nitrylex Basic Nitrylex Black Nitrylex Mcare	Powder free Nitrile Examination glove in various colours	EN ISO 374-1:2016 Type B
Dated: 6 th July 2020		This certificate is valid until: July 2021	
Signed By (Alan Weston) 			
For and on behalf of SATRA Technology Europe Limited			
CE			
The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard. SATRA Technology Europe Limited, Bracetown Business Park Clonee Dublin 15 D15 YN2P, Republic of Ireland. (Notified Body number 2777) Tel: +353 (0) 1 437 2424 Web: www.satrabeurope.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
- UNDURCHLÄSSIG FÜR BAKTERIEN, PILZE UND VIREN

SIE HABEN
FRAGEN?

RUFEN SIE UNS
EINFACH AN!

