meditec
GERMANY
DENTAL | CAD/CAM

VELVET GRIP

Disposable NITRILE GLOVES

www.meditec-germany.de
www.cerec4smile.de
www.cad-cam-dental.de

Für weitere Infos kontaktieren Sie uns gern unter

Meditec Germany GmbH
Hans-Böckler-Str. 43-45
30851 Langenhagen
Tel: 0511 165 908 0
cadcam@meditec-germany.de

Scan mich

INTRODUCTION CURADEN:

Curaden AG (www.CURADEN.com) - better health for you - is a public limited company from Switzerland and has been in **existence** for **more** than **60 years** (foundation).

Our main field of activity is **medical devices (dentists)** and as a result we **would be glad** to cooperate with your company to deliver you premium Nitrile gloves!

GENERAL INFORMATION:

- **Model:** Nitrile **VELVET GRIP blue** (Premium)
- **Country of Origin:** China
- **Material:** 99,99% pure nitrile
- **Color:** blue (more colors available!)
- **Packaging: GLOVES PACKED FLAT**
  - **Pieces per box:** 100
  - **1 Carton**: 10 boxes (1.000 pcs)
  - **1 pallet:** 120x100cm
    - 1.400 boxes
  - **40 HQ Container**
    - 33.600.500 boxes
- **Sizes:** S, M, L, XL
- **Thickness (material):** min 0.05 mm
- **AQL:** 1.5
- **Dimension (Length x Width):**
  - **Small:** 240 mm x 85 +/- 5mm
  - **Medium**: 240mm x 95 +/- 5mm
  - **Large**: 240mm x 105 +/- 5mm
  - **X-Large**: 240mm x 114 +/- 5mm
- **Features:**
  - **Powder-free:** Yes
  - **Latex-free:** Yes
  - Ambidextrous, textured fingertips
  - Medical grade
  - Non-sterile
- **Storage conditions**: 25C
- **Shelf-life**: 3 years from date of manufacture with the above storage conditions

CERTIFICATION: *(See page 5)*

Manufacturing Accreditation	Declaration of Conformity
ISO 9001:2015, ISO 13485:2016	EC-REP
International Standards	
EN 455:1-4; EN 374:1,2,4,5; EN 374-3 (EN 16523-1:2015); EG-Type certification, EN ISO 21420, EN 1186	
Regulation Compliance	
CE Marked, FDA 510K	



MANUFACTURING ACCREDITATIONS

ISO 9001: 2015

MANUFACTURING ACCREDITATIONS

ISO 13485:2016

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.:

Organization:

Scope: Design and Development, Manufacture and Distribution of Patient Examination Gloves

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.:
Effective date: 2021-04-15
Expiry date: 2024-04-14
Issue date: 2021-04-13

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

DAkkS

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.:

Organization:

The scope of certification also covers the following:

No.	Facility	Scope
/01		Distribution of Patent Examination Gloves
/02		Design and Development, Manufacture of Patient Examination Gloves

Report No.:
Effective date: 2021-04-15
Expiry date: 2024-04-14
Issue date: 2021-04-13

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

DAkkS

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.:

Organization:

The scope of certification also covers the following:

/03	Design and Development, Manufacture of Patient Examination Gloves
/04	Design and Development, Manufacture of Patient Examination Gloves

Report No.:
Effective date: 2021-04-15
Expiry date: 2024-04-14
Issue date: 2021-04-13

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

DAkkS

Business Stream Products
Certification Department

TÜVRheinland LGA
Precisely Right.

Application for:
Certificate No.:
Requirement: EN ISO 13485:2016

Dear Madam or Sir,

Enclosed please find the new certificate [illegible] replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,

Zing Zhang
Certification body

INTERNATIONAL STANDARDS

EN 455: 1-4

Test Report No.
dated 20 Oct 2020

SUBJECT:
Testing of Gloves submitted by
on 21 Jul 2020

TESTED FOR:

TEST DATE:
22 Jul 2020 to 14 Aug 2020, 20 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Blue		S	400	

Lot size as specified by client: 150,001 to 500,000 pieces

METHOD OF TEST:
1. EN 455-1:2020 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes
2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties
3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation
   - Clause 4.4 Powder-free gloves
   - Clause 4.6 Labelling

Test Report No.
dated 20 Oct 2020

RESULTS:
Sample: Nitrile Disposable Exam Gloves, Lot No: Size S

Table 1: Results for EN 455-1:2020

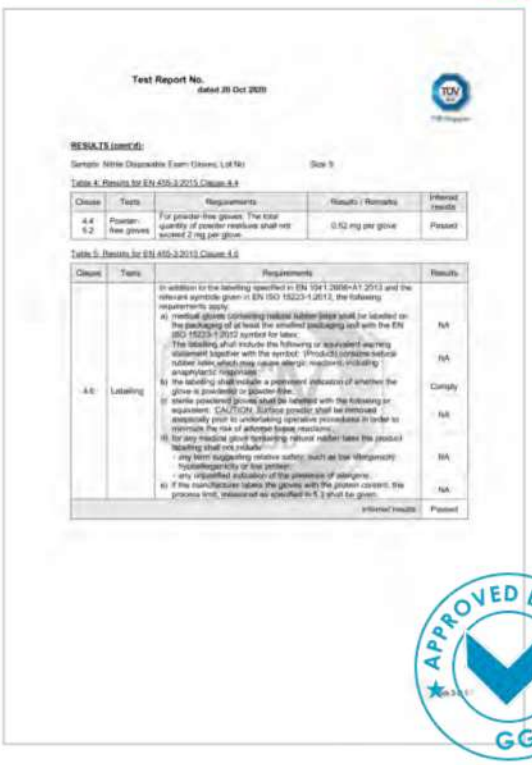
Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	10	315	0	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	≥ 240	10	246	Passed
	b) Width (mm)	For Size S: 80 ± 10	10	83	Passed
5	Strength a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	10	7.8	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	10	7.4	Passed

Table 3: Results for EN 455-3:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed



Test Report No.
dated 20 Oct 2020

RESULTS (cont'd):
Sample: Nitrile Disposable Exam Gloves, Lot No: Size S

Table 4: Results for EN 455-3:2015 Clause 4.4

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.52 mg per glove	Passed

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply: a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex; The labelling shall include the following or equivalent warning statement together with the symbol: 'Product contains natural rubber latex which may cause allergic reactions, including anaphylactic responses.' b) the labelling shall indicate a prominent indication of whether the glove is powdered or powder-free; c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed especially prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions.'; d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens; e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.1 shall be given.	NA NA Comply NA NA NA
		Inferred results	Passed

Test Report No.
dated 20 Oct 2020

REMARKS:
1. Labelling requirements are assessed based on submitted packaging artwork by client on 20 Oct 2020.
2. NA: Not applicable for the submitted sample

Yeo Poh Kwang
Associate Engineer

Engineer
Medical Health Services (NAM)

APPENDIX:

Photo 1: Nitrile Disposable Exam Gloves, Lot No: Blue

Photo 2: Packaging Artwork for Nitrile Disposable Lot No: Blue

INTERNATIONAL STANDARDS

EN 455: 1-4

Test Report No.
dated 20 Oct 2020

Please note that this Report is issued under the following terms:

1. This report applies to the sample of the specific product/equipment given at the time of its testing/submission. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB or any way "guarantees" the safe performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long-term effects of using the specific product/equipment.
2. The sample(s) mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any assessment or marks from any other testing authority or bodies that may be found on that sample.
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5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.
6. The tests carried out by TÜV SÜD PSB and this report are subject to TÜV SÜD PSB's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SÜD Group.

Effective 01 September 2020

Test Report No.
dated 20 Oct 2020

SUBJECT:
Testing of Gloves submitted by
on 21 Jul 2020.

TESTED FOR:

TEST DATE:
22 Jul 2020 to 14 Aug 2020, 20 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No	Size	Sample received (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Blue		M	400	

Lot size as specified by client: 150,001 to 500,000 pieces

METHOD OF TEST:

1. EN 455-1:2020 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes
2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties
3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation
   - Clause 4.4 Powder free gloves
   - Clause 4.6 Labelling

Test Report No.
dated 20 Oct 2020

RESULTS:

Sample: Nitrile Disposable Exam Gloves;

Table 1: Results for EN 455-1:2020

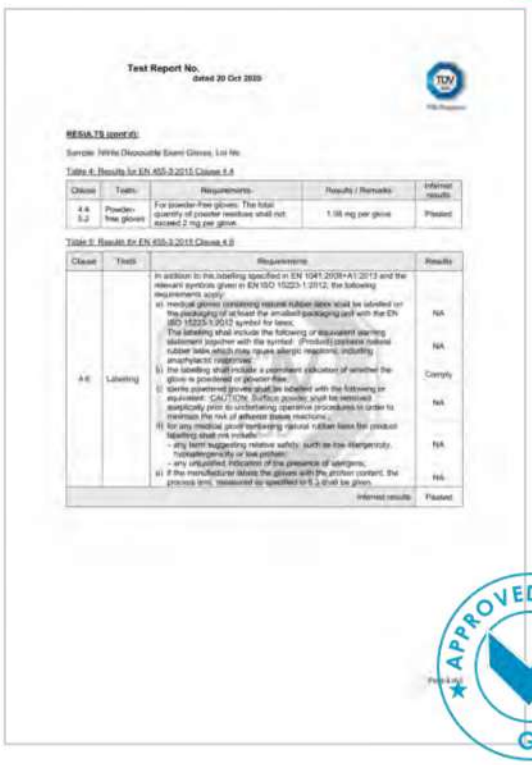
Clause	Tests	Requirements	No. of non-compliant allowed (pieces)	Number tested (pieces)	Actual no. of non-compliant found (pieces)	Interest results
4 5	Freedom from holes	Shall not leak	16	315	3	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Interest results
4	Dimensions a)Length (mm)	≥ 240	15	245	Passed
	b)Width (mm)	For Size M 90 ± 10	15	93	Passed
5	Strength a)Force at break (N)	For nitrile examination gloves: ≥ 6.0	15	8.6	Passed
	b)Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	15	7.1	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Interest results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed



Test Report No.
dated 20 Oct 2020

RESULTS (cont'd):

Sample: Nitrile Disposable Exam Gloves, Lot No.

Table 4: Results for EN 455-3:2015 Clause 4.4

Clause	Tests	Requirements	Results / Remarks	Interest results
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	1.08 mg per glove	Passed

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply: a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex. The labelling shall include the following or equivalent warning statement together with the symbol: (Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic reactions. b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free; c) sterile powdered gloves shall be labelled with the following or equivalent: CAUTION: Surface powder shall be removed analytically prior to undertaking operative procedures in order to minimize the risk of adhesion tissue reactions.; d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low-allergenicity, hypoallergenicity or low protein; - any unqualified indication of the presence of allergens; e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3, shall be given.	NA NA Comply NA NA NA
		Interest results:		Passed

INTERNATIONAL STANDARDS

EN 455: 1-4

Test Report No.
dated 20 Oct 2020

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2. The sample(s) mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
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Effective 01 September 2020

Test Report No.
dated 20 Oct 2020

SUBJECT:
Testing of Gloves submitted by
on 21 Jul 2020.

TESTED FOR:

TEST DATE:
22 Jul 2020 to 14 Aug 2020, 20 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No	Size	Sample received (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Blue		M	400	

Lot size as specified by client: 150,001 to 500,000 pieces

METHOD OF TEST:

1. EN 455-1:2020 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes
2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties
3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation
   - Clause 4.4 Powder free gloves
   - Clause 4.6 Labelling

Test Report No.
dated 20 Oct 2020

RESULTS:

Sample: Nitrile Disposable Exam Gloves;

Table 1: Results for EN 455-1:2020

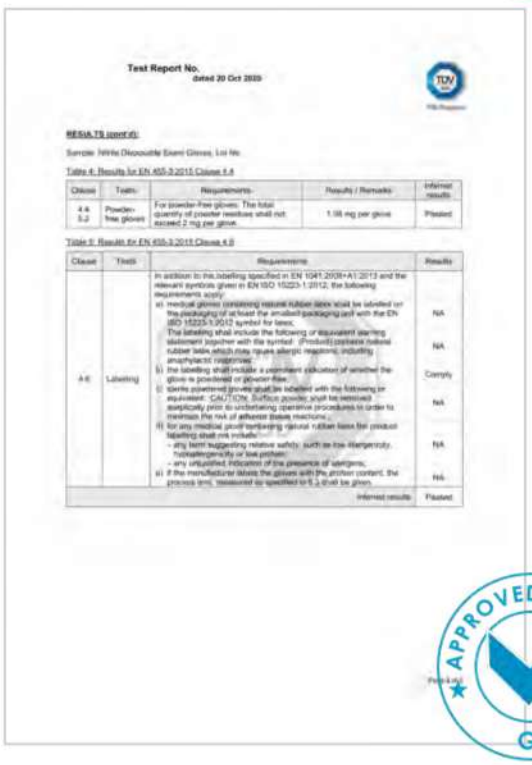
Clause	Tests	Requirements	No. of non-compliant allowed (pieces)	Number tested (pieces)	Actual no. of non-compliant found (pieces)	Interest results
4 5	Freedom from holes	Shall not leak	16	315	3	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Interest results
4	Dimensions a)Length (mm)	≥ 240	15	245	Passed
	b)Width (mm)	For Size M 90 ± 10	15	93	Passed
5	Strength a)Force at break (N)	For nitrile examination gloves: ≥ 6.0	15	8.6	Passed
	b)Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	15	7.1	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Interest results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed



Test Report No.
dated 20 Oct 2020

RESULTS (cont'd):

Sample: Nitrile Disposable Exam Gloves, Lot No.

Table 4: Results for EN 455-3:2015 Clause 4.4

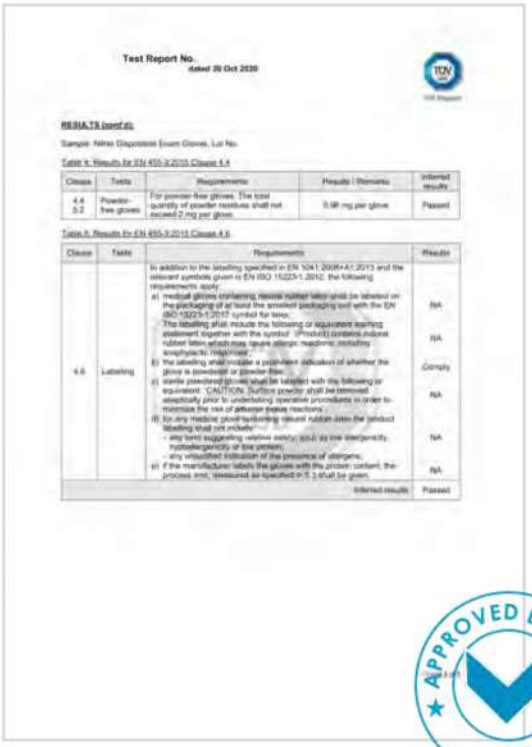
Clause	Tests	Requirements	Results / Remarks	Interest results
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	1.08 mg per glove	Passed

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply: a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex. The labelling shall include the following or equivalent warning statement together with the symbol: (Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic reactions. b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free; c) sterile powdered gloves shall be labelled with the following or equivalent: CAUTION: Surface powder shall be removed analytically prior to undertaking operative procedures in order to minimize the risk of adhesion tissue reactions.; d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low-allergenicity, hypoallergenicity or low protein; - any unqualified indication of the presence of allergens; e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3, shall be given.	NA NA Comply NA NA NA
		Interest results:		Passed

INTERNATIONAL STANDARDS

EN 455:1-4



Test Report No.
dated 20 Oct 2020

REGULATION (EU) 2017/745

Sample: Nitrile Disposable Exam Gloves, Lot No.

Table 4: Results for EN 455-3:2015 Clause 4.4

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.4 5.2	Powder-free gloves	For powder-free gloves. The total quantity of powder residues shall not exceed 2 mg per glove.	0.98 mg per glove	Passed

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply: a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex. The labelling shall include the following or equivalent warning statement together with the symbol: "Product(s) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses"; b) The labelling shall indicate a prominent indication of whether the glove is powdered or powder-free; c) sterile powdered gloves shall be labelled with the following or equivalent: "CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions"; d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unqualified indication of the presence of allergens; e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA NA Comply NA NA NA
			Inferred results: Passed

Test Report No.
dated 20 Oct 2020

REMARKS:

1. Labelling requirements are assessed based on submitted packaging artwork by client on 20 Oct 2020.
2. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate Engineer

Eve Ooi Yi
Engineer
Medical Health Services (NAM)

APPENDIX:

Photo 1: Nitrile Disposable Exam Gloves, Lot No. Blue

Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No.

Test Report No.
dated 20 Oct 2020

Please note that this Report is issued under the following terms :

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Effective 01 September 2020

Test Report No.
dated 20 Oct 2020

SUBJECT:

Testing of Gloves submitted by
on 21 Jul 2020.

TESTED FOR:

TEST DATE:

22 Jul 2020 to 14 Aug 2020, 20 Oct 2020

DESCRIPTION OF SAMPLE(S):

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Blue		XL	401	

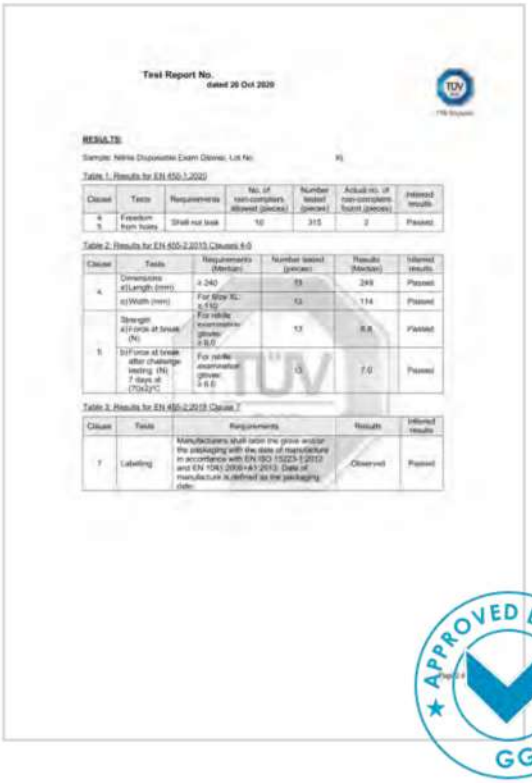
Lot size as specified by client: 150,001 to 500,000 pieces.

METHOD OF TEST:

1. EN 455-1:2020 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes
2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties
3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation
   - Clause 4.4 Powder-free gloves
   - Clause 4.6 Labelling

INTERNATIONAL STANDARDS

EN 455:1-4



Test Report No.
dated 20 Oct 2020

RESULTS:

Sample: Nitrile Disposable Exam Gloves, Lot No. XL

Table 1: Results for EN 455-1:2020

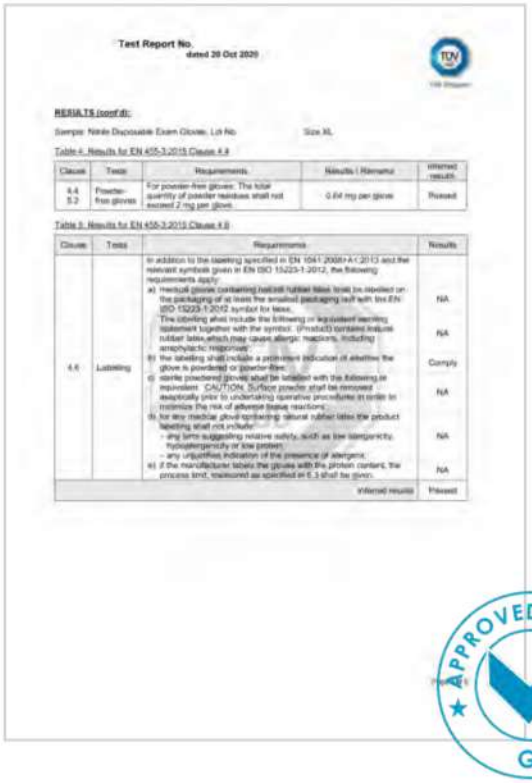
Clause	Tests	Requirements	No. of non-compliant allowed (pieces)	Number tested (pieces)	Actual no. of non-compliant found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	10	315	2	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-6

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a)Length (mm)	≥ 240	13	249	Passed
	c) Width (mm)	For size XL: ± 10	13	114	Passed
5	Strength a)Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	8.8	Passed
	b)Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	7.0	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed



Test Report No.
dated 20 Oct 2020

RESULTS (cont'd):

Sample: Nitrile Disposable Exam Gloves, Lot No. Size XL

Table 4: Results for EN 455-3:2015 Clause 4.4

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.64 mg per glove	Passed

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) Medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex. The labelling shall include the following or equivalent warning statement together with the symbol: "Product contains natural rubber latex which may cause allergic reactions, including anaphylactic responses".	NA
		b) The labelling shall include a prominent indication of whether the glove is powdered or powder-free.	NA
		c) sterile powdered gloves shall be labelled with the following or equivalent: CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions.	Comply
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens.	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
			Inferred results: Passed

Test Report No.
dated 20 Oct 2020

REMARKS:

1. Labelling requirements are assessed based on submitted packaging artwork by client on 20 Oct 2020.
2. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate Engineer

Ewe Chi Yi
Engineer
Medical Health Services (NAM)

APPENDIX:

Photo 1: Nitrile Disposable Exam Gloves, Lot No. Blue

Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No. Blue

Test Report No.
dated 20 Oct 2020

Please note that this Report is issued under the following terms:

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way 'guarantees' the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long-term effects of using the specific product/equipment.
2. The samples mentioned in this report were submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.
4. This report shall not be reproduced wholly or in parts and its reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisement or sales promotion.
5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.
6. The tests carried out by TÜV SÜD PSB and this report are subject to TÜV SÜD PSB's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SÜD Group.

Electrical & Electronics (EE)

INTERNATIONAL STANDARDS

EN 374 1,5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Prüfbericht-Nr.: / Test Report No.: — Auftrags-Nr.: / Order No.: — Seite 1 von 24 / Page 1 of 24

Kunden-Referenz-Nr.: / Client Reference No.: N/A — Auftragsdatum: / Order date: 14.05.2019

Auftraggeber: / Client:

Prüfgegenstand: / Test item: Schutzhandschuhe / Protective gloves

Bezeichnung / Typ-Nr.: / Identification / Type No.: Nitrilhandschuhe / Nitrile gloves

Auftrags-Inhalt: / Order content: Produktüberwachung PSA Kategorie III / Product surveillance PPE category III

Prüfgrundlage: / Test specification: EN ISO 374-1:2016 + A1:2018 — Schutzhandschuhe gegen gefährliche Chemikalien und Mikroorganismen / Protective gloves against dangerous chemicals and micro-organisms

Wareneingangsdatum: / Date of receipt: 22.05.2019

Prüfmuster-Nr.: / Test sample No.:

Prüfzeitraum: / Testing period: 11.07.2019 – 19.07.2019

Ort der Prüfung: / Place of testing: Prüflabore für Textilien und PSA Leipzig

Prüflaboratorium: / Testing laboratory: TÜV Rheinland LGA Products GmbH

Prüfergebnis*) / Test result*: Pass

geprüft von / tested by: 23.07.2019 — kontrolliert von / checked by: 23.07.2019

Sonstiges / Other:

Zustand des Prüfgegenstandes bei Anlieferung: / Condition of the test item at delivery: Prüfmuster vollständig und unbeschädigt / Test item complete and undamaged

Dieser Prüfbericht besteht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens. / This test report only relates to the a. m. test sample. Without permission of the test center this test report is not to be duplicated in extracts. This test report does not entitle to carry any test mark.

TÜV Rheinland LGA Products GmbH · Tillystraße 2 · D - 90431 Nürnberg · Tel.: +49 911 655 5225 · Fax: +49 911 655 5226 · Mail: service@tuv-lga.com · Web: www.tuv-lga.com

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Prüfbericht-Nr.: / Test Report No.: — Seite 2 von 24 / Page 2 of 24

Liste der verwendeten Prüfmittel / List of used test equipment

Prüfmittel / Test equipment	Prüfmittel-Nr. / ID-Nr. / Equipment No. / ID-No.	Nächste Kalibrierung / Next calibration
siehe Anlage zu diesem Prüfbericht		
see attachment to this test report		


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Prüfbericht-Nr.: / Test Report No.: — Seite 3 von 24 / Page 3 of 24

Produktbeschreibung / Product description

1	Produktdetails / Product details	5-Finger-Handschuh / 5 finger gloves
2	Artikel / Modell / Article / Model	Nitrilhandschuhe / Nitrile gloves
3	Größe / Länge / Size / Length	S (8,5), M (7,5), L(8,5), XL(9)
4	Leistungsstufen / Performance levels	Chemikalie K NaOH 40% — Permeation: Klasse/ level 6 — Degradation: -4,3 % — Typ /Type C
5	Verwendete Materialien / Used materials	Nitril Farbe blau / Nitrile colour blue — ≥ 0,05 mm — ≥ 0,05 mm
6	Chargennr. / Charge no.	—
7	Sonstiges / Other	Vorhersehbare Verwendung wurde betrachtet. Zurzeit liegen für derzeitige Produkte weiter Schutzklassenverfahren an, noch ist ein etwaiges Unfallaufkommen bekannt. / Foreseeable use was considered. Currently neither a safeguard clause procedure has been invoked nor is an increase in accidents known for this / these product (s).
8	Mitgeltende Dokumente / Prüfberichte / Further applicable documents / test reports	/*1 Prüfbericht Permeation. / Test report permeation: Bericht-Nr. / report nr.: 19.07.2019) TÜV Rheinland LGA /*2 Prüfbericht Permeation. Degradation / Test report permeation; degradation Bericht-Nr. / report nr.: (10.08.2017) TÜV Rheinland LGA /*3 Prüfbericht / Test report Bericht-Nr. / report nr.: (28.01.2019) TÜV Rheinland LGA

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Prüfbericht-Nr.: / Test Report No.: — Seite 4 von 24 / Page 4 of 24

Anlage	EN ISO 374-1:2016 + A1:2018	Messergebnisse - Bemerkungen	Bewertung
Clause	Anforderungen - Prüfungen / Requirements - Tests	Measuring results - Remarks	Evaluation
	Der Originaltext wird nur auszugsweise wieder gegeben. Details sind dem Original-Dokument zu entnehmen. / The original text is reproduced only in part. For details, be refffered to the original document.		
	Schutzhandschuhe gegen gefährliche Chemikalien und Mikroorganismen / Protective gloves against dangerous chemicals and micro-organisms		
1	Anwendungsbereich / Scope		
2	Normative Verweisungen / Normative references		
3	Begriffe / Terms and definition		
4	Probenahme / Sampling		
5	Leistungsanforderung / Performance requirements		
5.1	Allgemeine Anforderungen / General requirements		
	Schutzhandschuhe gegen gefährliche Chemikalien müssen die Anforderungen in EN 420:2006, Abschnitt 4, Abschnitt 5 und Abschnitt 7, erfüllen / Protective gloves against dangerous chemicals shall comply with the requirements given in EN 420:2006, Clause 4, Clause 5 and Clause 7.		
EN 420: 4.1	Gestaltungsgrundsätze und Handschuh-Anpassungsnummer — Allgemeines / Glove design and construction — General		
	- bei normalen Tätigkeiten Schutz auf der höchstmöglichen Leistungsstufe - minimale Zeit zum Ein-/ Ausziehen - gewerbe Leistung nicht wesentlich herabgesetzt durch Hände - in foreseeable conditions of use, protection at highest possible level - minimal time for put on/take off - overall not significantly decreased by seems	/*3 gegeben / given	P F NA NT
EN 420: 4.2	Widerstand des Handschuhmaterials gegen Wasserdurchdringung / Resistance of glove materials to water penetration		
	wenn gefordert, muss der Widerstand des Handschuhmaterials gegen Wasserdurchdringung nach folgenden Prüfverfahren geprüft werden: - Lederhandschuhe nach EN 344-1 - Textile Erzeugnisse nach EN 20811 If required, the gloves materials where resistance to water penetration have to tested according follow test methods: - leather gloves according to EN 344-1 - textile products according to EN 20811	—	

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INTERNATIONAL STANDARDS

EN 374 1,5

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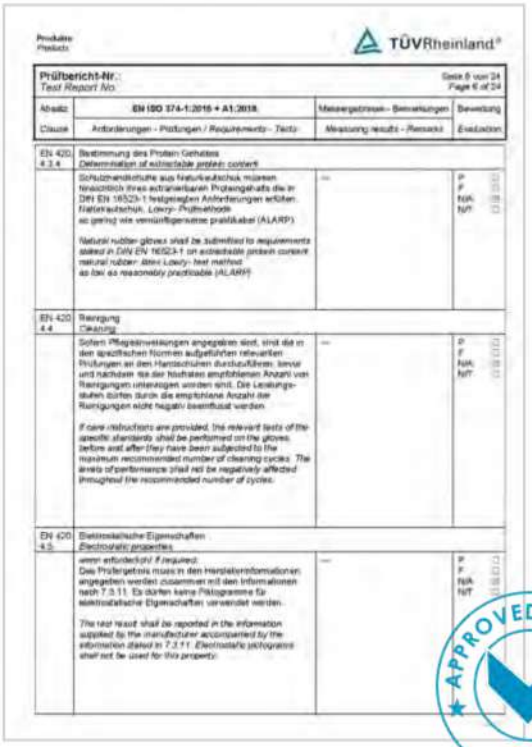
Prüfbericht-Nr.: / Test Report No.: — Seite 5 von 24 / Page 5 of 24

Absatz / Clause	EN ISO 374-1:2016 + A1:2018 Anforderungen - Prüfungen / Requirements - Tests	Messergebnisse - Bemerkungen / Measuring results - Remarks	Bewertung / Evaluation
EN 420 4.3	Unschädlichkeit von Schutzhandschuhen / *Innocuousness of protective gloves*		
EN 420 4.3.1	Allgemeines / *General*		
	- beim Gebrauch Schutz ohne gesundheitliche Schädigung - alle enthaltenen Substanzen, die bekannt sind, Allergien zu verursachen, sind anzugeben *- protection at use without harm to user* *- all substances contained which are known to cause allergies are named*	P3 gegeben *given*	P F N/A N/T
	Azo-Farbstoffe *Azo dye stuff*		
	< 30 mg/kg nach / according to 1907/2006/EU	—	P F N/A N/T
EN 420 4.3.2	Bestimmung des pH-Wertes / *Determination of pH-value*		
	Der pH-Wert für Handschuhe muss größer als 3,5 und kleiner als 9,5 sein. *The pH value for all gloves shall be greater than 3,5 and less than 9,5*	P3 — pH-Wert / *pH- value* Innenhand / *Palm* — 5,9	P F N/A N/T
EN 420 4.3.3	Bestimmung des Chrom(VI)-Gehaltes / *Determination of chromium (VI) content*		
	Der Chrom(VI)-Gehalt von Handschuhen, die Leder enthalten, darf bei der Bestimmung nach dem Prüfverfahren nach EN ISO 17075:2007 3,0 mg/kg nicht übersteigen. Enthält der Handschuh verschiedene Arten von Leder, muss jede Leder Art, unabhängig davon, ob sie mit der Haut in Berührung kommt oder nicht, separat geprüft werden und die vorgenannte Anforderung erfüllen. *The quantity of Chromium VI in gloves containing leather shall not exceed 3,0 mg/kg when determined according to the test method as specified in EN ISO 17075:2007. If the glove includes different types of leather, whether in contact with the skin or not, each leather type shall be tested separately and comply with the above requirement.*	—	P F N/A N/T



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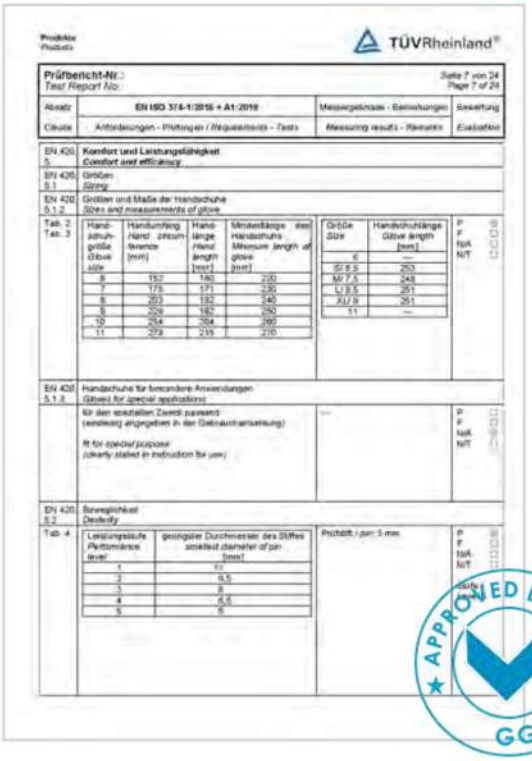
Absatz / Clause	EN ISO 374-1:2016 + A1:2018 Anforderungen - Prüfungen / Requirements - Tests	Messergebnisse - Bemerkungen / Measuring results - Remarks	Bewertung / Evaluation
EN 420 4.3.4	Bestimmung des Protein Gehaltes / *Determination of extractable protein content*		
	Schutzhandschuhe aus Naturkautschuk müssen hinsichtlich ihres extrahierbaren Proteingehalts die in DIN EN 16523-1 festgelegten Anforderungen erfüllen. Naturkautschuk, Lowry- Prüfmethode so gering wie vernünftigerweise praktikabel (ALARP) *Natural rubber gloves shall be submitted to requirements stated in DIN EN 16523-1 on extractable protein content natural rubber- Modi Lowry- test method* *as low as reasonably practicable (ALARP)*	—	P F N/A N/T
EN 420 4.4	Reinigung / *Cleaning*		
	Sofern Pflegeinweisungen angegeben sind, sind die in den spezifischen Normen aufgeführten relevanten Prüfungen an den Handschuhen durchzuführen, sowie und nachdem sie der höchsten empfohlenen Anzahl von Reinigungen unterzogen worden sind. Die Leistungsstufen dürfen durch die empfohlene Anzahl der Reinigungen nicht negativ beeinflusst werden. *If care instructions are provided, the relevant tests of the specific standards shall be performed on the gloves, before and after they have been subjected to the maximum recommended number of cleaning cycles. The levels of performance shall not be negatively affected throughout the recommended number of cycles.*	—	P F N/A N/T
EN 420 4.5	Elektrostatische Eigenschaften / *Electrostatic properties*		
	wenn erforderlich/ *if required:* Das Prüfergebnis muss in den Herstellerinformationen angegeben werden zusammen mit den Informationen nach 7.3.11. Es dürfen keine Piktogramme für elektrostatische Eigenschaften verwendet werden. *The test result shall be reported in the information supplied by the manufacturer accompanied by the information stated in 7.3.11. Electrostatic pictograms shall not be used for this property.*	—	P F N/A N/T



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Absatz / Clause	EN ISO 374-1:2016 + A1:2018 Anforderungen - Prüfungen / Requirements - Tests	Messergebnisse - Bemerkungen / Measuring results - Remarks	Bewertung / Evaluation
EN 420 5	**Komfort und Leistungsfähigkeit** / ***Comfort and efficiency***		
EN 420 5.1	Größen / *Sizing*		
EN 420 5.1.2	Größen und Maße der Handschuhe / *Sizes and measurements of glove*		

Tab. 2 / Tab. 3

Handschuhgröße / Glove size	Handumfang / *Hand circumference* (mm)	Handlänge / *Hand length* [mm]	Mittelfinger / *Middle finger length* [mm]
6	152	160	220
7	178	171	230
8	203	182	240
9	229	182	250
10	254	204	260
11	279	215	270

Größe / *Size*	Handschuhlänge / *Glove length* [mm]
6	—
S/ 8 S	253
M/ 7,5	248
L/ 9,5	261
XL/ 9	261
11	—

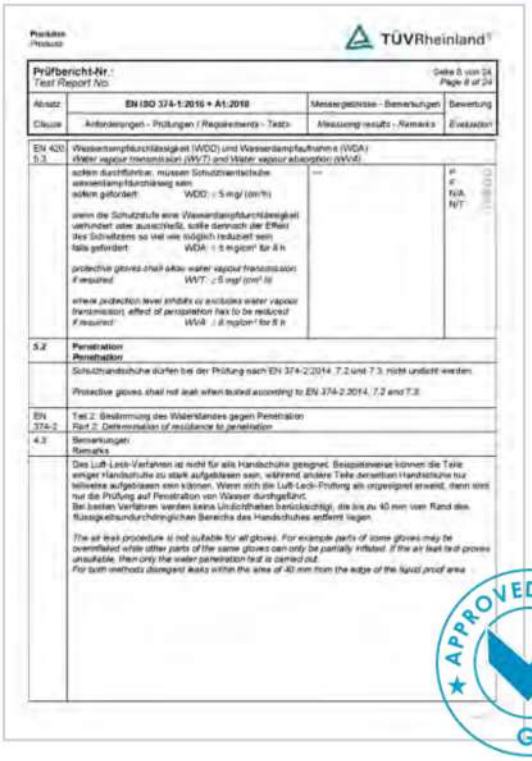
P F N/A N/T

EN 420 5.1.3	Handschuhe für besondere Anwendungen / *Gloves for special applications*		
	für den spezifischen Zweck passend (entsprechend angegeben in der Gebrauchsanweisung) *fit for special purpose (clearly stated in instruction for use)*	—	P F N/A N/T
EN 420 5.2	Beweglichkeit / *Dexterity*		

Tab. 4

Leistungsstufe / *Performance level*	geringster Durchmesser des Stiftes / *smallest diameter of pin* [mm]
1	12
2	9,5
3	8
4	6,5
5	5

Prüfstift / *pin:* 5 mm — P F N/A N/T



Produkte / Products — TÜVRheinland®

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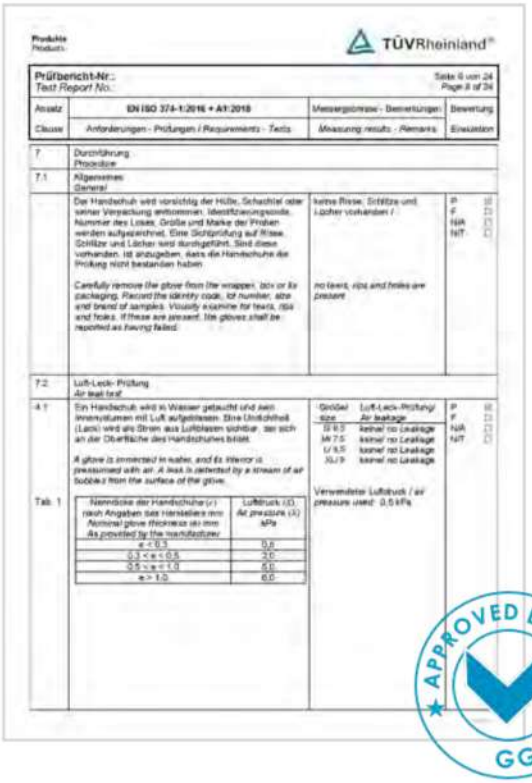
Absatz / Clause	EN ISO 374-1:2016 + A1:2018 Anforderungen - Prüfungen / Requirements - Tests	Messergebnisse - Bemerkungen / Measuring results - Remarks	Bewertung / Evaluation
EN 420 5.3	Wasserdampfdurchlässigkeit (WDD) und Wasserdampfaufnahme (WDA) / *Water vapour transmission (WVT) and Water vapour absorption (WVA)*		
	sofern durchführbar, müssen Schutzhandschuhe wasserdampfdurchlässig sein sofern gefordert: WDD: ≥ 5 mg/ (cm²h) wenn die Schutzstufe eine Wasserdampfdurchlässigkeit verhindert oder ausschließt, sollte dennoch der Effekt des Schwitzens so viel wie möglich reduziert sein falls gefordert: WDA: ≥ 6 mg/cm² für 8 h *protective gloves shall allow water vapour transmission if required: WVT: ≥ 5 mg/ (cm² h)* *where protection level inhibits or excludes water vapour transmission, effect of perspiration has to be reduced if required: WVA : ≥ 6 mg/cm² for 8 h*	—	P F N/A N/T
5.2	**Penetration** / ***Penetration***		
	Schutzhandschuhe dürfen bei der Prüfung nach EN 374-2:2014, 7.2 und 7.3, nicht undicht werden. *Protective gloves shall not leak when tested according to EN 374-2:2014, 7.2 and 7.3.*		
EN 374-2	Teil 2: Bestimmung des Widerstandes gegen Penetration / *Part 2: Determination of resistance to penetration*		
4.3	Bemerkungen / *Remarks*		
	Das Luft-Leck-Verfahren ist nicht für alle Handschuhe geeignet. Beispielsweise können die Teile einiger Handschuhe zu stark aufgeblasen sein, während andere Teile derselben Handschuhe nur teilweise aufgeblasen sein können. Wenn sich die Luft-Leck-Prüfung als ungeeignet erweist, dann wird nur die Prüfung auf Penetration von Wasser durchgeführt. Bei beiden Verfahren werden keine Undichtheiten berücksichtigt, die bis zu 40 mm vom Rand des flüssigkeitsundurchdringlichen Bereichs des Handschuhes entfernt liegen. *The air leak procedure is not suitable for all gloves. For example parts of some gloves may be overinflated while other parts of the same gloves can only be partially inflated. If the air leak test proves unsuitable, then only the water penetration test is carried out.* *For both methods disregard leaks within the area of 40 mm from the edge of the liquid proof area.*		

INTERNATIONAL STANDARDS

EN 374 1,5



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Prüfbericht-Nr.: / Test Report No.: Seite 6 von 24 / Page 6 of 24

Absatz / Clause	EN ISO 374-1:2016 + A1:2018 Anforderungen - Prüfungen / Requirements - Tests	Messergebnisse - Bemerkungen / Measuring results - Remarks	Bewertung / Evaluation
7	Durchführung / Procedure		
7.1	Allgemeines / General		
	Der Handschuh wird vorsichtig der Hülle, Schachtel oder seiner Verpackung entnommen. Identifizierungsmarke, Nummer des Loses, Größe und Marke der Proben werden aufgezeichnet. Eine Sichtprüfung auf Risse, Schlitze und Löcher wird durchgeführt. Sind diese vorhanden, ist anzugeben, dass die Handschuhe die Prüfung nicht bestanden haben / *Carefully remove the glove from the wrapper, box or its packaging. Record the identity code, lot number, size and brand of samples. Visually examine for tears, slits and holes. If these are present, the gloves shall be reported as having failed.*	keine Risse, Schlitze und Löcher vorhanden / / *no tears, slits and holes are present*	P ☒ F ☐ N/A ☐ N/T ☐
7.2	Luft-Leck- Prüfung / *Air leak test*		
4.1	Ein Handschuh wird in Wasser getaucht und sein Innenvolumen mit Luft aufgeblasen. Eine Undichtheit (Leck) wird als Strom aus Luftblasen sichtbar, der sich an der Oberfläche des Handschuhes bildet. / *A glove is immersed in water, and its interior is pressurised with air. A leak is detected by a stream of air bubbles from the surface of the glove.*	Größe / size: Luft-Leck-Prüfung / Air leakage 6 8,5 keine/ no Leakage M 7,5 keine/ no Leakage L/ 9,5 keine/ no Leakage XL/ 9 keine/ no Leakage	P ☒ F ☐ N/A ☐ N/T ☐
Tab. 1	Nennstärke der Handschuhe (r) nach Angaben des Herstellers mm / *Nominal glove thickness (a) mm As provided by the manufacturer* / Luftdruck (d) / *Air pressure (d)* kPa a < 0,1 — 5,8 0,1 < a < 0,5 — 20 0,5 < a < 1,0 — 60 a > 1,0 — 60	Verwendeter Luftdruck / *air pressure used*: 0,5 kPa	

Produkte / Products:

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Absatz / Clause	EN ISO 374-1:2016 + A1:2018 Anforderungen - Prüfungen / Requirements - Tests	Messergebnisse - Bemerkungen / Measuring results - Remarks	Bewertung / Evaluation
7.3	Wasser-Leck-Prüfung / *Water leak test*		
4.2	Ein Handschuh wird mit Wasser gefüllt. Eine Undichtheit wird durch das Auftreten von Wassertropfen an der Außenseite des Handschuhes festgestellt. / *A glove is filled with water. A leak is detected by the appearance of water droplets on the outside of the glove.*	Größe/ size: Luft-Leck-Prüfung/ Air leakage M 7,5: keine/ no Leakage L/ 9,5: keine/ no Leakage XL/ 9: keine/ no Leakage	P ☒ F ☐ N/A ☐ N/T ☐
5.3	**Degradation: / Degradation**		
	Die Degradation (DR) ist nach EN 374-4 für jede Chemikalie, die in der Kennzeichnung angegeben und in der Benutzerinformation aufgeführt wird, zu bestimmen. Für den Handschuh, der länger als 480 min ist, muss die zu dem gewählten Permeationsergebnis gehörende Degradation zusätzlich angegeben werden. / *The degradation (DR) shall be determined according to EN 374-4 for each chemical claimed in the marking and reported in the user instruction. For the glove longer than 480 min, the degradation corresponding to the lowest permeation results shall at least be reported.*		
EN 374-4	Teil 4: Bestimmung des Widerstandes gegen Degradation durch Chemikalien / *Part 4: Determination of resistance to degradation by chemicals*		
4	Prüfprinzip / *Test principles*		
	Der Widerstand eines Werkstoffes für Schutzhandschuhe gegen Degradation durch eine flüssige Chemikalie wird bestimmt, indem die Veränderung der Durchdringfestigkeit des Werkstoffes für Handschuhe nach ständigem Kontakt der Außenfläche mit der beanspruchenden Prüfchemikalie gemessen wird. Die Prüfung gilt für Handschuhe aus natürlichem oder synthetischem Polymer. Gefettete Handschuhe können unbrauchbare Messergebnisse liefern. / *The resistance of a protective glove material to degradation by a liquid chemical is determined by measuring the puncture resistance change of the glove material after a continuous contact of the external surface with the challenge test chemical. The test is applicable to gloves made of natural or synthetic polymer. Lined gloves may produce unusable measurement results.*		

Produkte / Products:

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Prüfbericht-Nr.: / Test Report No.: Seite 11 von 24 / Page 11 of 24

Absatz / Clause	EN ISO 374-1:2016 + A1:2018 Anforderungen - Prüfungen / Requirements - Tests	Messergebnisse - Bemerkungen / Measuring results - Remarks	Bewertung / Evaluation
5	Prüfverfahren für die Prüfung der Durchdringfestigkeit / *Test methods: Puncture resistance test*		
5.3.4	Darstellung der Ergebnisse / *Expression of results*		
	Die Degradation ist an jeden der drei Handschuhprüfmuster gegen jede spezifische Chemikalie oder jedes Chemikliengemisch zu bestimmen. / *Determine the degradation for each of the three glove specimens against each specific chemical or chemical mixture.* Die Degradation des Prüfmusters durch die beanspruchende Chemikalie ist zu ermitteln. / *Determine the degradation of the sample against the challenge chemical.* Die Standardabweichung (SD) der Degradation der drei Handschuhe ist zu bestimmen. / *Determine the standard deviation (SD) of the degradation for the three gloves.* Veränderungen wie Aufquellen, Schrumpfen, Versprödung, Verhärtung, Erweichung, Schuppenbildung, Auflösung, Farbveränderung/ Ausbleichen, Delaminieren sind anzugeben. / *Any changes such as swelling, shrinking, brittleness, hardening, softening, flaking, disintegration, colour change/bleeding, delaminating shall be noted and described for information*	P2 Chemikalie/ chemical: NaOH Reinheit/ purity: 40% DR1: -12,5 DR2: -11,9 DR3: 11,6 **DR: -4,5** SD: 14,6 Veränderungen / *changes*: keine / *none* Prüfdatum / *date of the test*: 10.08.2017	P ☒ F ☐ N/A ☐ N/T ☐ **DR = - 4%**

Produkte / Products:

TÜVRheinland®

Prüfbericht-Nr.: / Test Report No.: Seite 12 von 24 / Page 12 of 24

Absatz / Clause	EN ISO 374-1:2016 + A1:2018 Anforderungen - Prüfungen / Requirements - Tests	Messergebnisse - Bemerkungen / Measuring results - Remarks	Bewertung / Evaluation
5.4	**Permeation / Permeation**		
5.4.1	Allgemeines / *General*		
	Für den Handschuh, der länger als 400 mm ist, und bei dem die Handinnenfläche und die Stulpe unterschiedliche Leistungsstufen erreichen muss für jede Chemikalie die geringere Leistungsstufe in der Kennzeichnung angegeben werden. Alle Ergebnisse sollten in der Benutzeranleitung angegeben sein. / Jede Kombination von Schutzhandschuh/Prüfchemikalie ist nach Tabelle 1 zu klassifizieren, wobei die in EN 16523-1:2015, 8.5.1.1 oder 8.5.1.3, angegebene Ergebnisse für die normalisierte Durchbruchszeit anzuwenden sind. / *For the glove longer than 400 mm, where the palm and cuff achieve different performance levels, the lowest performance level shall be claimed in the marking for each chemical. All the results should be reported in the user instruction. Each combination of protective glove/test chemical shall be classified according to Table 1, using the results as given in EN 16523-1:2015, 8.5.1.1 or 8.5.1.3 for the normalized breakthrough time.*		
5.4.2	Typ A: Die Permeationsleistung muss mindestens Stufe 2 gegen wenigstens sechs Prüfchemikalien entsprechen, die in Tabelle 2 gelistet sind. / *Type A: The permeation performance shall be at least level 2 against a minimum of six test chemicals listed in Table 2.*		
5.4.3	Typ B: Die Permeationsleistung muss mindestens Stufe 2 gegen wenigstens drei Prüfchemikalien entsprechen, die in Tabelle 2 gelistet sind. / *Type B: The permeation performance shall be at least level 2 against minimum of three test chemicals listed in Table 2.*		
5.4.3	Typ C: Die Permeationsleistung muss mindestens Stufe 1 gegen wenigstens eine Prüfchemikalie entsprechen, die in Tabelle 2 gelistet ist. / *Type C: The permeation performance shall be at least level 1 against minimum of one test chemical listed in Table 2.*		
Tab. 2	Kennbuchstabe / *Code Letter* — Prüfchemikalie / *Chemical* — CAS-Nr. / *CAS Number* A — Methanol / *Methanol* — 67-56-1 B — Aceton / *Acetone* — 67-64-1 C — Acetonitril / *Acetonitrile* — 75-05-8 D — Dichlormethan / *Dichloromethane* — 75-09-2 E — Kohlenwasserstoffe / *Carbon disulphide* — 75-15-0 F — Toluol / *Toluene* — 108-88-3 G — Diethylamin / *Diethylamine* — 109-89-7 H — Tetrahydrofuran / *Tetrahydrofuran* — 109-99-9 I — Ethylacetat / *Ethyl acetate* — 141-78-6 J — n-Heptan / *n-Heptane* — 142-82-5 K — Natriumhydroxid 40 % / *Sodium hydroxide 40 %* — 1310-73-2 L — Schwefelsäure 95 % / *Sulphuric acid 95 %* — 7664-93-9 M — Salpetersäure 65 % / *Nitric acid 65 %* — 7697-37-2 N — Essigsäure 99 % / *Acetic acid 99 %* — 64-19-7 O — Ammoniakwasser 25 % / *Ammonium hydroxide 25 %* — 1336-21-6 P — Wasserstoffperoxid 30 % / *Hydrogen peroxide 30 %* — 7722-84-1 S — Flusssäure 40 % / *Hydrofluoric acid 40 %* — 7664-39-3 T — Formaldehyd 37 % / *Formaldehyde 37 %* — 50-00-0		

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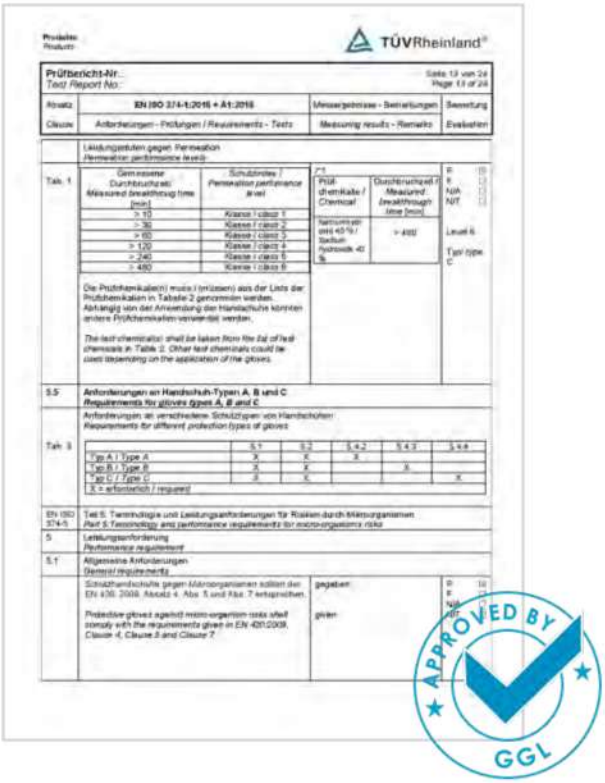
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EN ISO 374-1:2016 + A1:2018
Messergebnisse - Bemerkungen / Measuring results - Remarks
Bewertung / Evaluation
Leistungsstufen gegen Permeation / Permeation performance levels
Tab. 1
Gemessene Durchbruchzeit / Measured breakthrough time [min]
Schutzniveau / Permeation performance level
Prüf-chemikalie / Chemical
Durchbruchzeit / Measured breakthrough time [min]
> 10 Klasse / class 1
> 30 Klasse / class 2
> 60 Klasse / class 3
> 120 Klasse / class 4
> 240 Klasse / class 5
> 480 Klasse / class 6
Natriumhydroxid 40 % / Sodium hydroxide 40 %
> 480
Level 6
Typ / type C
Die Prüfchemikalie(n) muss / müssen aus der Liste der Prüfchemikalien in Tabelle 2 genommen werden. Abhängig von der Anwendung der Handschuhe können andere Prüfchemikalien verwendet werden.
The test chemical(s) shall be taken from the list of test chemicals in Table 2. Other test chemicals could be used depending on the application of the gloves.
5.5 Anforderungen an Handschuh-Typen A, B und C / Requirements for gloves types A, B and C
Anforderungen an verschiedene Schutztypen von Handschuhen / Requirements for different protection types of gloves
Tab. 3
Typ A / Type A
Typ B / Type B
Typ C / Type C
X = erforderlich / required
EN ISO 374-5 Teil 5: Terminologie und Leistungsanforderungen für Risiken durch Mikroorganismen / Part 5: Terminology and performance requirements for micro-organisms risks
5 Leistungsanforderung / Performance requirement
5.1 Allgemeine Anforderungen / General requirements
Schutzhandschuhe gegen Mikroorganismen müssen der EN 420: 2009, Absatz 4, Abs. 5 und Abs. 7 entsprechen.
Protective gloves against micro-organism risks shall comply with the requirements given in EN 420:2009, Clause 4, Clause 5 and Clause 7.
gegeben / given
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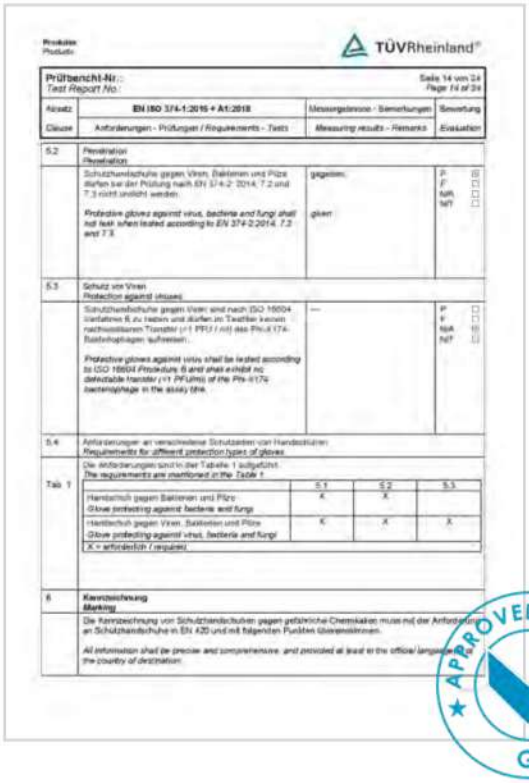
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Bewertung / Evaluation
5.2 Penetration / Penetration
Schutzhandschuhe gegen Viren, Bakterien und Pilze dürfen bei der Prüfung nach EN 374-2: 2014, 7.2 und 7.3 nicht undicht werden.
Protective gloves against virus, bacteria and fungi shall not leak when tested according to EN 374-2:2014, 7.2 and 7.3.
gegeben / given
5.3 Schutz vor Viren / Protection against viruses
Schutzhandschuhe gegen Viren sind nach ISO 16604 Verfahren B zu testen und dürfen im Testfilm keinen nachweisbaren Transfer (< 1 PFU / ml) des Phi-X174-Basteriophagen aufweisen.
Protective gloves against virus shall be tested according to ISO 16604 Procedure B and shall exhibit no detectable transfer (< 1 PFU/ml) of the Phi-X174 bacteriophage in the assay film.
5.4 Anforderungen an verschiedene Schutzarten von Handschuhen / Requirements for different protection types of gloves
Die Anforderungen sind in der Tabelle 1 aufgeführt. / The requirements are mentioned in the Table 1
Tab. 1
Handschutz gegen Bakterien und Pilze / Glove protecting against bacteria and fungi
Hantlschutz gegen Viren, Bakterien und Pilze / Glove protecting against virus, bacteria and fungi
X = erforderlich / required
6 Kennzeichnung / Marking
Die Kennzeichnung von Schutzhandschuhen gegen gefährliche Chemikalien muss mit der Anforderung an Schutzhandschuhe in EN 420 und mit folgenden Punkten übereinstimmen.
All information shall be precise and comprehensive, and provided at least in the official language of the country of destination.
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Bewertung / Evaluation
EN 420 Kennzeichnung und Information – Allgemeines / Marking and information – General
EN 420 7.1 Allgemeines / General
Alle Informationen müssen präzise und umfassend sein. Sie sind mindestens in der (den) offiziellen Sprache(n) des Bestimmungslandes anzugeben.
All details have to be precise and in official language of country of destination.
gegeben, in Englisch / given, in english
EN 420 7.2 Kennzeichnung / Marking
7.2.1 Jeder Schutzhandschuh muss mit folgenden Angaben gekennzeichnet sein:
- Name, Handelsmarke oder andere Kennzeichnungsmittel des Herstellers oder seines Repräsentanten
- Handschuhbezeichnung (Handelsname oder Code, der dem Anwender die eindeutige Identifizierung des Produkts innerhalb des Sortiments des Herstellers oder seines bevollmächtigten Repräsentanten erlaubt)
- Größenbezeichnung
- Kennzeichnung mit Verfallsdatum, das Piktogramm mit der Nennmaß der Norm und die Leistungsstufen
Each protective glove shall be marked with the following information:
- Name, trade mark or other means of identification of manufacturer or his authorized representative
- Glove designation (commercial name or code allowing the user to identify clearly the product within the manufacturer's/authorized representative's range)
- Size designation
- Marking with date of obsolescence
- Pictogram with number of standard and performance levels
gegeben, z.B.: S (6,5) / given, e.g.: S (6,5)
gegeben / given
gegeben / given
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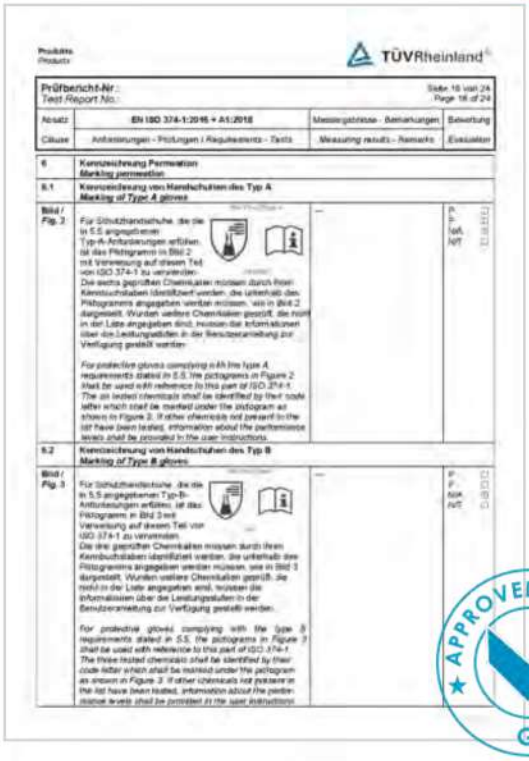
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Bewertung / Evaluation
6 Kennzeichnung Permeation / Marking permeation
6.1 Kennzeichnung von Handschuhen des Typ A / Marking of Type A gloves
Bild / Fig. 2
Für Schutzhandschuhe, die die in 5.5 angegebenen Typ-A-Anforderungen erfüllen, ist das Piktogramm in Bild 2 mit Verweisung auf diesen Teil von ISO 374-1 zu verwenden.
Die drei geprüften Chemikalien müssen durch ihren Kennbuchstaben identifiziert werden, die unterhalb des Piktogramms angegeben werden müssen, wie in Bild 3 dargestellt. Wurden weitere Chemikalien geprüft, die nicht in der Liste angegeben sind, müssen die Informationen über die Leistungsstufen in der Benutzeranleitung zur Verfügung gestellt werden.
For protective gloves complying with the type A requirements stated in 5.5, the pictograms in Figure 2 shall be used with reference to this part of ISO 374-1.
The six tested chemicals shall be identified by their code letter which shall be marked under the pictogram as shown in Figure 3. If other chemicals not present in the list have been tested, information about the performance levels shall be provided in the user instructions.
6.2 Kennzeichnung von Handschuhen des Typ B / Marking of Type B gloves
Bild / Fig. 3
Für Schutzhandschuhe, die die in 5.5 angegebenen Typ-B-Anforderungen erfüllen, ist das Piktogramm in Bild 3 mit Verweisung auf diesen Teil von ISO 374-1 zu verwenden.
Die drei geprüften Chemikalien müssen durch ihren Kennbuchstaben identifiziert werden, die unterhalb des Piktogramms angegeben werden müssen, wie in Bild 3 dargestellt. Wurden weitere Chemikalien geprüft, die nicht in der Liste angegeben sind, müssen die Informationen über die Leistungsstufen in der Benutzeranleitung zur Verfügung gestellt werden.
For protective gloves complying with the type B requirements stated in 5.5, the pictograms in Figure 3 shall be used with reference to this part of ISO 374-1.
The three tested chemicals shall be identified by their code letter which shall be marked under the pictogram as shown in Figure 3. If other chemicals not present in the list have been tested, information about the performance levels shall be provided in the user instructions.
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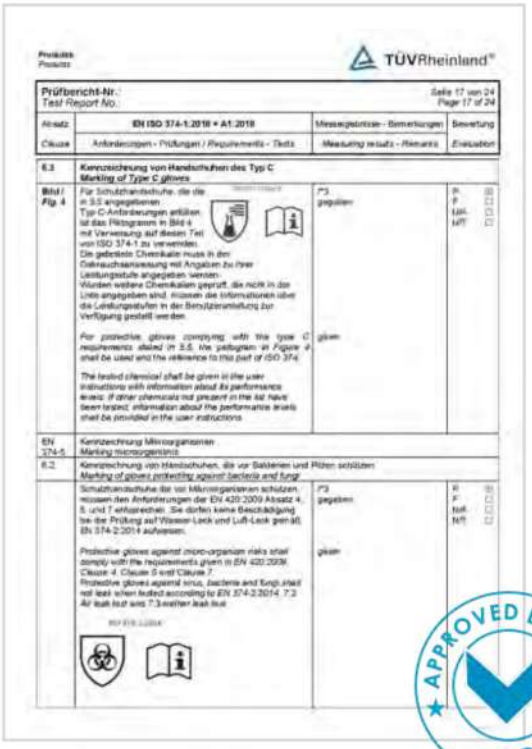

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6.3	**Kennzeichnung von Handschuhen des Typ C** ***Marking of Type C gloves***		
Bild / Fig. 4	Für Schutzhandschuhe, die die in 3.5 angegebenen Typ-C-Anforderungen erfüllen, ist das Piktogramm in Bild 4 mit Verweisung auf diesen Teil von ISO 374-1 zu verwenden. Die getestete Chemikalie muss in der Ozonrauchsanerwasung mit Angaben zu ihrer Leistungsstufe angegeben werden. Wurden weitere Chemikalien geprüft, die nicht in der Liste angegeben sind, müssen die Informationen über die Leistungsstufen in der Benutzerunterlage zur Verfügung gestellt werden. *For protective gloves complying with the type C requirements stated in 3.5, the pictogram in Figure 4 shall be used and the reference to this part of ISO 374.* *The tested chemical shall be given in the user instructions with information about its performance levels. If other chemicals not present in the list have been tested, information about the performance levels shall be provided in the user instructions.*	/*3 gegeben given	P F N/A N/T
EN 374-5	Kennzeichnung Mikroorganismen *Marking microorganisms*		
6.2	Kennzeichnung von Handschuhen, die vor Bakterien und Pilzen schützen *Marking of gloves protecting against bacteria and fungi*		
	Schutzhandschuhe die vor Mikroorganismen schützen, müssen den Anforderungen der EN 420:2009 Absatz 4, 5 und 7 entsprechen. Sie dürfen keine Beschädigung bei der Prüfung auf Wasser-Leck und Luft-Leck gem. EN 374-2:2014 aufweisen. *Protective gloves against micro-organism risks shall comply with the requirements given in EN 420:2009, Clause 4, Clause 5 and Clause 7. Protective gloves against virus, bacteria and fungi shall not leak when tested according to EN 374-2:2014, 7.3 Air leak test and 7.3 water leak test.*	/*3 gegeben given	P F N/A N/T

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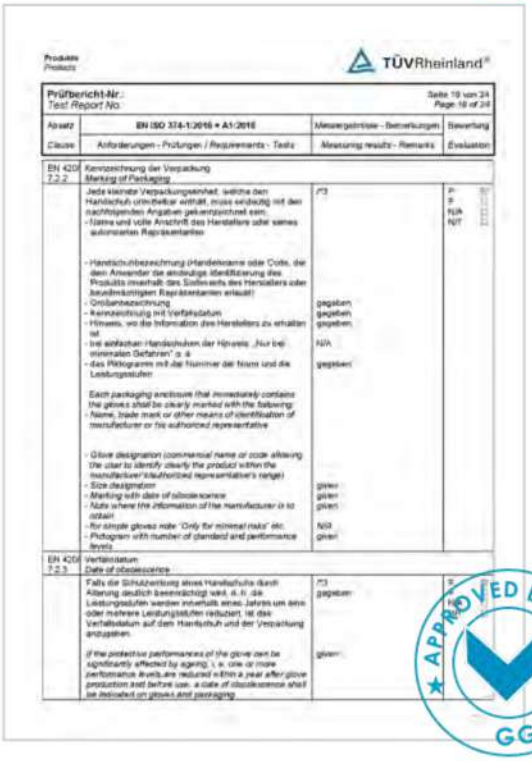
6.3	Kennzeichnung von Handschuhen, die vor Viren, Bakterien und Pilze schützen *Marking of gloves protecting against viruses, bacteria and fungi*		
	Schutzhandschuhe die vor Viren schützen, müssen den Anforderungen aus EN 374-5:6.2 entsprechen und dürfen gemäß ISO 16604 Verfahren B kein nachweisbares Transfer (<1 PFU/ml) des Phi-X174 Bakteriophagen bei der Titer Untersuchung aufweisen. *Protective gloves against virus have to comply with the requirements of EN 374-5:6.2 and shall be tested according to ISO 16604 Procedure B and shall exhibit no detectable transfer (<1 PFU/ml) of the Phi-X174 bacteriophage in the assay titre.*	—	P F N/A N/T
7	**Information des Herstellers** ***Information supplied by the manufacturer***		
	Die Informationen des Herstellers müssen in Übereinstimmung mit den Anforderungen an die Informationen stehen, die in EN 420 festgelegt sind. Sie müssen außerdem die Ergebnisse von 5.2, 5.3, 5.4 enthalten, die Liste sämtlicher Chemikalien, auf die die Schutzhandschuhe geprüft wurden und die Leistungsstufen, die bei der Permeationsprüfung erreicht wurden. *The information supplied by the manufacturer shall be in accordance with the requirements for information as defined in EN 420. It shall also include the results of 5.2, 5.3, 5.4, the list of all the chemicals to which the protective gloves have been tested and the performance levels obtained in permeation testing.*	/*3 gegeben given	P F N/A N/T



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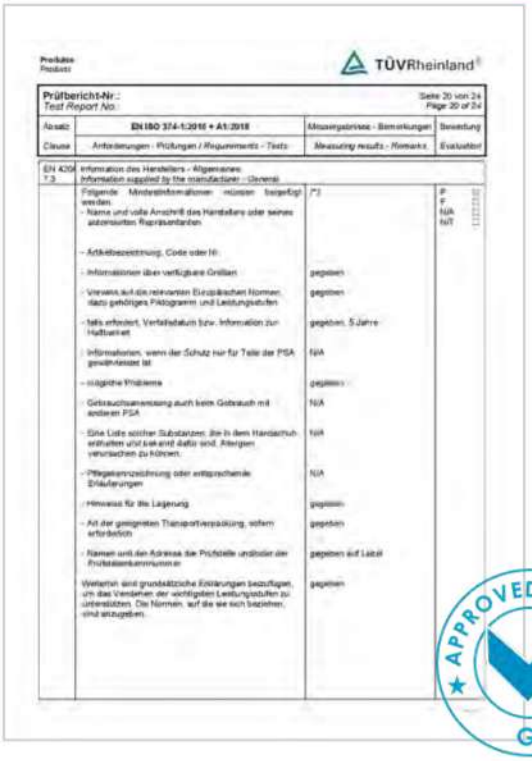
EN 420 7.2.2	Kennzeichnung der Verpackung *Marking of Packaging*		
	Jede kleinste Verpackungseinheit, welche den Handschuh unmittelbar enthält, muss einbezug mit den nachfolgenden Angaben gekennzeichnet sein. - Name und volle Anschrift des Herstellers oder seines autorisierten Repräsentanten - Handschuhbezeichnung (Handelsname oder Code, die dem Anwender die eindeutige Identifizierung des Produkts innerhalb des Sortiments des Herstellers oder bevollmächtigten Repräsentanten erlaubt) - Größenbezeichnung - Kennzeichnung mit Verfallsdatum - Hinweis, wo die Information des Herstellers zu erhalten ist - bei einfachen Handschuhen der Hinweis „Nur bei minimalen Gefahren" o. ä. - das Piktogramm mit der Nummer der Norm und die Leistungsstufen *Each packaging enclosure that immediately contains the gloves shall be clearly marked with the following:* *- Name, trade mark or other means of identification of manufacturer or his authorized representative* *- Glove designation (commercial name or code allowing the user to identify clearly the product within the manufacturer's/authorized representative's range)* *- Size designation* *- Marking with date of obsolescence* *- Note where the information of the manufacturer is to obtain* *- For simple gloves note 'Only for minimal risks' etc.* *- Pictogram with number of standard and performance levels*	/*3 gegeben gegeben gegeben N/A gegeben given given given N/A given	P F N/A N/T
EN 420 7.2.3	Verfallsdatum *Date of obsolescence*		
	Falls die Schutzwirkung eines Handschuhs durch Alterung deutlich beeinträchtigt wird, d. h. die Leistungsstufen werden innerhalb eines Jahres um eine oder mehrere Leistungsstufen reduziert, ist das Verfallsdatum auf dem Handschuh und der Verpackung anzugeben. *If the protective performances of the glove can be significantly affected by ageing, i. e. one or more performance levels are reduced within a year after glove production test before use, a date of obsolescence shall be indicated on gloves and packaging.*	/*3 gegeben given	P F N/A N/T



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EN 420 7.3	Information des Herstellers - Allgemeines *Information supplied by the manufacturer - General*		
	Folgende Mindestinformationen müssen beigefügt werden: - Name und volle Anschrift des Herstellers oder seines autorisierten Repräsentanten - Artikelbezeichnung, Code oder Nr. - Informationen über verfügbare Größen - Verweis auf die relevanten Europäischen Normen, falls gültigen Piktogramm und Leistungsstufen - falls erforderl, Verfallsdatum bzw. Information zur Haltbarkeit - Informationen, wenn der Schutz nur für Teile der PSA gewährleistet ist - mögliche Probleme - Gebrauchsanweisung auch beim Gebrauch mit anderen PSA - Eine Liste solcher Substanzen, die in dem Handschuh enthalten sind bekannt sind, Allergien verursachen zu können. - Pflegekennzeichnung oder entsprechende Erläuterungen - Hinweise für die Lagerung - Art der geeigneten Transportverpackung, sofern erforderlich - Namen und die Adresse der Prüfstelle und/oder der Prüfstellenkennnummer Weiterhin sind grundsätzliche Erklärungen beizufügen, um das Verstehen der wichtigsten Leistungsstufen zu unterstützen. Die Normen, auf die sie sich beziehen, sind anzugeben.	/*1 gegeben gegeben gegeben, 5 Jahre N/A gegeben N/A N/A gegeben gegeben gegeben auf Label gegeben	P F N/A N/T

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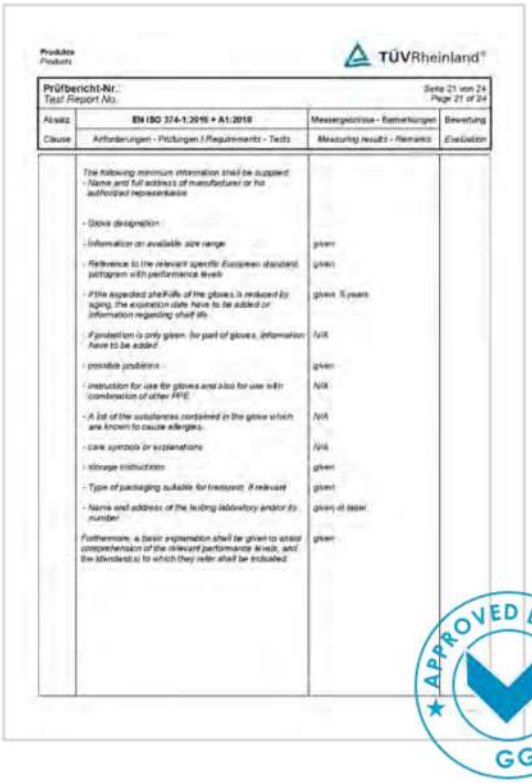
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Absatz / Clause | EN ISO 374-1:2016 + A1:2018 | Messergebnisse - Bemerkungen / Measuring results - Remarks | Bewertung / Evaluation
Anforderungen - Prüfungen / Requirements - Tests
The following minimum information shall be supplied:
- Name and full address of manufacturer or his authorized representative
- Glove designation
- Information on available size range: given
- Reference to the relevant specific European standard pictogram with performance levels: given
- If the expected shelf-life of the gloves is reduced by aging, the expiration date have to be added or information regarding shelf life: given: 5 years
- If protection is only given for part of gloves, information have to be added: N/A
- possible problems: given
- instruction for use for gloves and also for use with combination of other PPE: N/A
- A list of the substances contained in the glove which are known to cause allergies: N/A
- care symbols or explanations: N/A
- storage instruction: given
- Type of packaging suitable for treatment, if relevant: given
- Name and address of the testing laboratory and/or its number: given at least
Furthermore, a basic explanation shall be given to assist comprehension of the relevant performance levels and the standard(s) to which they refer shall be indicated: given
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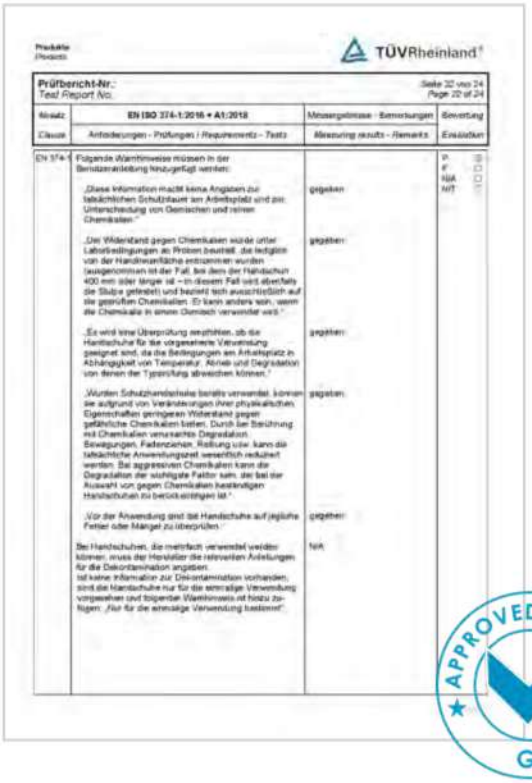
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Anforderungen - Prüfungen / Requirements - Tests
EN 374-1
Folgende Warnhinweise müssen in der Benutzeranleitung hinzugefügt werden:
„Diese Information macht keine Angaben zur tatsächlichen Schutzdauer am Arbeitsplatz und zur Unterscheidung von Gemischen und reinen Chemikalien.“ gegeben
„Der Widerstand gegen Chemikalien wurde unter Laborbedingungen an Proben bestimmt, die festgelegt von der Handinnenfläche entnommen wurden (ausgenommen ist der Fall, bei dem der Handschuh 400 mm oder länger ist – in diesem Fall wird abwechselnd die Stulpe getestet) und bezieht sich ausschließlich auf die geprüften Chemikalien. Er kann anders sein, wenn die Chemikalie in einem Gemisch verwendet wird.“ gegeben
„Es wird eine Überprüfung empfohlen, ob die Handschuhe für die vorgesehene Verwendung geeignet sind, da die Bedingungen am Arbeitsplatz in Abhängigkeit von Temperatur, Abrieb und Degradation von denen der Typprüfung abweichen können.“ gegeben
„Wurden Schutzhandschuhe bereits verwendet, können sie aufgrund von Veränderungen ihrer physikalischen Eigenschaften geringeren Widerstand gegen gefährliche Chemikalien bieten. Durch bei Berührung mit Chemikalien verursachte Degradation, Bewegungen, Fadenziehen, Reibung usw. kann die tatsächliche Anwendungszeit wesentlich reduziert werden. Bei aggressiven Chemikalien kann die Degradation der wichtigste Faktor sein, der bei der Auswahl von gegen Chemikalien bestimmten Handschuhen zu berücksichtigen ist.“ gegeben
„Vor der Anwendung sind die Handschuhe auf jegliche Fehler oder Mängel zu überprüfen.“ gegeben
Bei Handschuhen, die mehrfach verwendet werden können, muss der Hersteller die relevanten Anleitungen für die Dekontamination angeben.
Ist keine Information zur Dekontamination vorhanden, sind die Handschuhe nur für die einmalige Verwendung vorgesehen und folgender Warnhinweis ist hinzuzufügen: „Nur für die einmalige Verwendung bestimmt“. N/A
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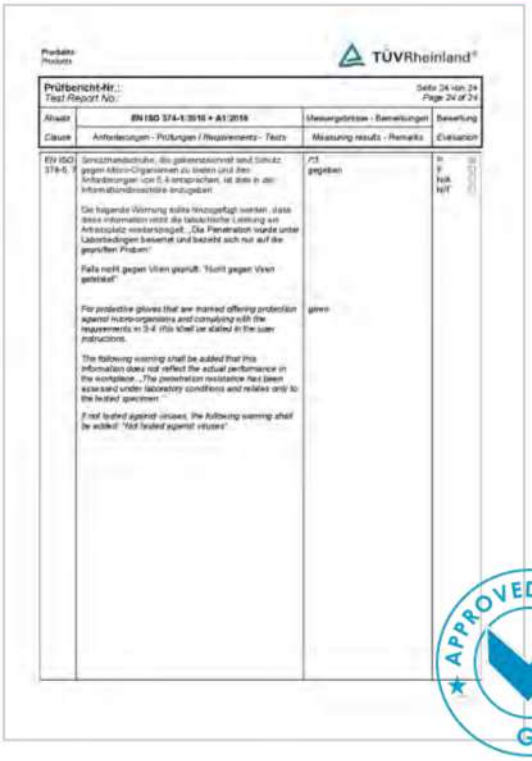
Anforderungen - Prüfungen / Requirements - Tests
Following information shall be added in user instructions:
- the results of Penetration, Degradation, Permeation
- the list of all the chemicals to which the protective gloves have been tested
- the performance levels obtained in permeation testing
The following warnings shall be added in the user instructions: given
"This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals." given
"The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400 mm - where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture." given
"It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation." given
"When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves" given
"Before usage, inspect the gloves for any defect or imperfections." given
For reusable gloves, the manufacturer shall provide the relevant instructions for decontamination. If there is no information about decontamination, then it is intended for single use only and the following warning shall be added: "For single use only". N/A
APPROVED BY GGL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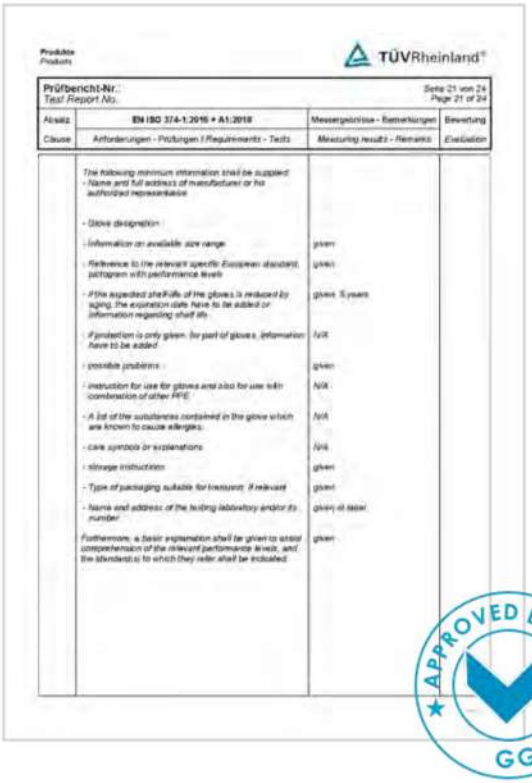
Absatz / Clause | EN ISO 374-1:2016 + A1:2018 | Messergebnisse - Bemerkungen / Measuring results - Remarks | Bewertung / Evaluation
Anforderungen - Prüfungen / Requirements - Tests
EN ISO 374-5, T
Spritzmembranhandschuh, das gekennzeichnet sind Schutz gegen Mikro-Organismen zu bieten und den Anforderungen von 5.4 entsprechen, ist dies in der Informationsbroschüre anzugeben. /5 gegeben
Die folgende Warnung sollte hinzugefügt werden, dass diese Information nicht die tatsächliche Leistung am Arbeitsplatz widerspiegelt: „Die Penetration wurde unter Laborbedingungen bewertet und bezieht sich nur auf die geprüften Proben.“
Falls nicht gegen Viren geprüft: "Nicht gegen Viren getestet"
For protective gloves that are marked offering protection against micro-organisms and complying with the requirements in 5.4 this shall be stated in the user instructions. given
The following warning shall be added that this information does not reflect the actual performance in the workplace: „The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.“
If not tested against viruses, the following warning shall be added: "Not tested against viruses".
APPROVED BY GGL

INTERNATIONAL STANDARDS

EN 374 1,5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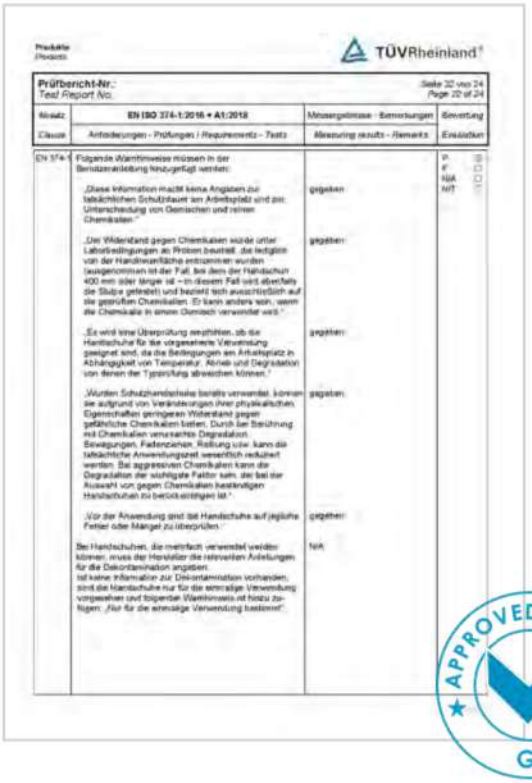
Anforderungen - Prüfungen / Requirements - Tests
The following minimum information shall be supplied:
- Name and full address of manufacturer or his authorized representative
- Glove designation
- Information on available size range: given
- Reference to the relevant specific European standard pictogram with performance levels: given
- If the expected shelf-life of the gloves is reduced by aging, the expiration date have to be added or information regarding shelf life: given: 5 years
- If protection is only given for part of gloves, information have to be added: N/A
- possible problems: given
- instruction for use for gloves and also for use with combination of other PPE: N/A
- A list of the substances contained in the glove which are known to cause allergies: N/A
- care symbols or explanations: N/A
- storage instruction: given
- Type of packaging suitable for treatment, if relevant: given
- Name and address of the testing laboratory and/or its number: given at least
Furthermore, a basic explanation shall be given to assist comprehension of the relevant performance levels and the standard(s) to which they refer shall be indicated: given
APPROVED BY GGL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Absatz / Clause | EN ISO 374-1:2016 + A1:2018 | Messergebnisse - Bemerkungen / Measuring results - Remarks | Bewertung / Evaluation
Anforderungen - Prüfungen / Requirements - Tests
EN 374-1
Folgende Warnhinweise müssen in der Benutzeranleitung hinzugefügt werden:
„Diese Information macht keine Angaben zur tatsächlichen Schutzdauer am Arbeitsplatz und zur Unterscheidung von Gemischen und reinen Chemikalien.“ gegeben
„Der Widerstand gegen Chemikalien wurde unter Laborbedingungen an Proben bestimmt, die festgelegt von der Handinnenfläche entnommen wurden (ausgenommen ist der Fall, bei dem der Handschuh 400 mm oder länger ist – in diesem Fall wird abwechselnd die Stulpe getestet) und bezieht sich ausschließlich auf die geprüften Chemikalien. Er kann anders sein, wenn die Chemikalie in einem Gemisch verwendet wird.“ gegeben
„Es wird eine Überprüfung empfohlen, ob die Handschuhe für die vorgesehene Verwendung geeignet sind, da die Bedingungen am Arbeitsplatz in Abhängigkeit von Temperatur, Abrieb und Degradation von denen der Typprüfung abweichen können.“ gegeben
„Wurden Schutzhandschuhe bereits verwendet, können sie aufgrund von Veränderungen ihrer physikalischen Eigenschaften geringeren Widerstand gegen gefährliche Chemikalien bieten. Durch bei Berührung mit Chemikalien verursachte Degradation, Bewegungen, Fadenziehen, Reibung usw. kann die tatsächliche Anwendungszeit wesentlich reduziert werden. Bei aggressiven Chemikalien kann die Degradation der wichtigste Faktor sein, der bei der Auswahl von gegen Chemikalien bestimmten Handschuhen zu berücksichtigen ist.“ gegeben
„Vor der Anwendung sind die Handschuhe auf jegliche Fehler oder Mängel zu überprüfen.“ gegeben
Bei Handschuhen, die mehrfach verwendet werden können, muss der Hersteller die relevanten Anleitungen für die Dekontamination angeben.
Ist keine Information zur Dekontamination vorhanden, sind die Handschuhe nur für die einmalige Verwendung vorgesehen und folgender Warnhinweis ist hinzuzufügen: „Nur für die einmalige Verwendung bestimmt“. N/A
APPROVED BY GGL


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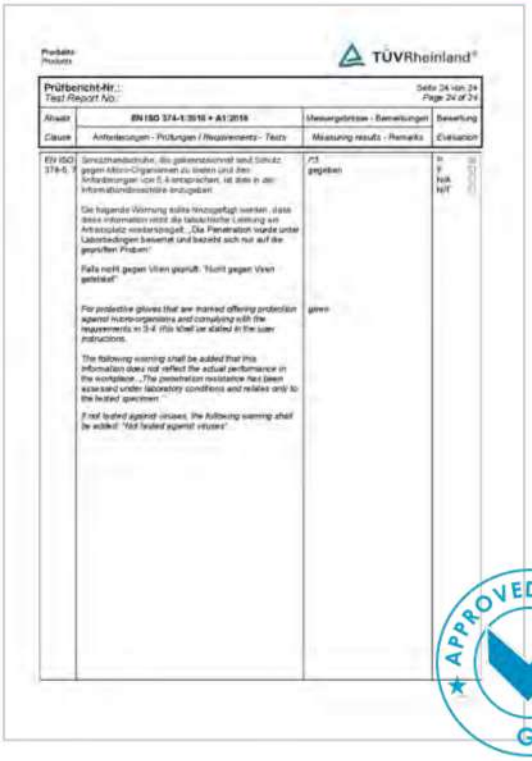
Anforderungen - Prüfungen / Requirements - Tests
Following information shall be added in user instructions:
- the results of Penetration, Degradation, Permeation
- the list of all the chemicals to which the protective gloves have been tested
- the performance levels obtained in permeation testing
The following warnings shall be added in the user instructions: given
"This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals." given
"The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400 mm - where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture." given
"It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation." given
"When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves" given
"Before usage, inspect the gloves for any defect or imperfections." given
For reusable gloves, the manufacturer shall provide the relevant instructions for decontamination. If there is no information about decontamination, then it is intended for single use only and the following warning shall be added: "For single use only". N/A
APPROVED BY GGL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Spritzmembranhandschuh, das gekennzeichnet sind Schutz gegen Mikro-Organismen zu bieten und den Anforderungen von 5.4 entsprechen, ist dies in der Informationsbroschüre anzugeben. /5 gegeben
Die folgende Warnung sollte hinzugefügt werden, dass diese Information nicht die tatsächliche Leistung am Arbeitsplatz widerspiegelt: „Die Penetration wurde unter Laborbedingungen bewertet und bezieht sich nur auf die geprüften Proben.“
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If not tested against viruses, the following warning shall be added: "Not tested against viruses".
APPROVED BY GGL

INTERNATIONAL STANDARDS

EN ISO 21420, EN ISO 374-2, EN 374-5

SATRA TECHNOLOGY

Customer details:

SATRA reference:

Your reference:

Date of report: 23 March 2021

Samples received: 1 March 2021

Date(s) work carried out: 4-22 March 2021

TECHNICAL REPORT

Subject: EN ISO 21420: 2020 size & dexterity & innocuousness test, EN ISO 374-2: 2019 air leak and water leak. EN ISO 374-5: 2016 viruses on Disposable Powder Free Nitrile Gloves referenced as , colour: blue, size: XS(5-6), S(6-7), M(7-8), L(8-9), XL(9-10).

Conditions of issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides a coverage probability of approximately 95%.

Report signed by: Gladys He
Position: Technologist
Department: China Testing

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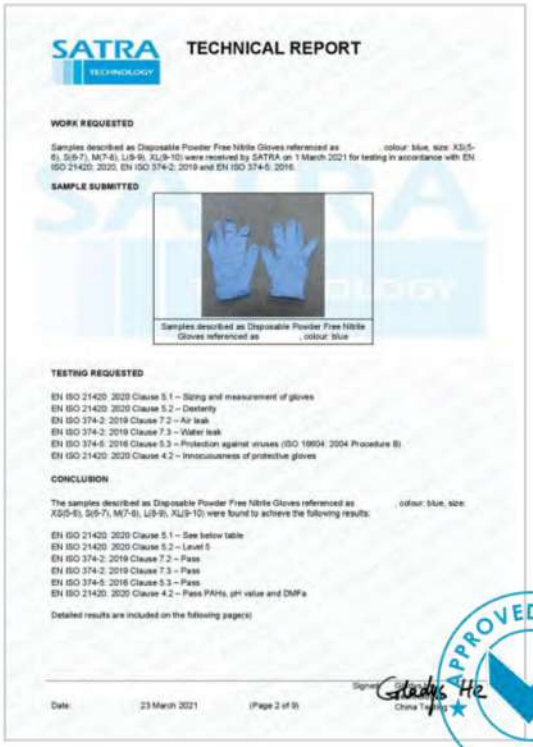

SATRA TECHNOLOGY

TECHNICAL REPORT

WORK REQUESTED

Samples described as Disposable Powder Free Nitrile Gloves referenced as colour: blue, size: XS(5-6), S(6-7), M(7-8), L(8-9), XL(9-10) were received by SATRA on 1 March 2021 for testing in accordance with EN ISO 21420: 2020, EN ISO 374-2: 2019 and EN ISO 374-5: 2016.

SAMPLE SUBMITTED

Samples described as Disposable Powder Free Nitrile Gloves referenced as , colour: blue

TESTING REQUESTED

EN ISO 21420: 2020 Clause 5.1 – Sizing and measurement of gloves
EN ISO 21420: 2020 Clause 5.2 – Dexterity
EN ISO 374-2: 2019 Clause 7.2 – Air leak
EN ISO 374-2: 2019 Clause 7.3 – Water leak
EN ISO 374-5: 2016 Clause 5.3 – Protection against viruses (ISO 16604: 2004 Procedure B)
EN ISO 21420: 2020 Clause 4.2 – Innocuousness of protective gloves

CONCLUSION

The samples described as Disposable Powder Free Nitrile Gloves referenced as colour: blue, size: XS(5-6), S(6-7), M(7-8), L(8-9), XL(9-10) were found to achieve the following results:

EN ISO 21420: 2020 Clause 5.1 – See below table
EN ISO 21420: 2020 Clause 5.2 – Level 5
EN ISO 374-2: 2019 Clause 7.2 – Pass
EN ISO 374-2: 2019 Clause 7.3 – Pass
EN ISO 374-5: 2016 Clause 5.3 – Pass
EN ISO 21420: 2020 Clause 4.2 – Pass PAHs, pH value and DMFa

Detailed results are included on the following page(s)

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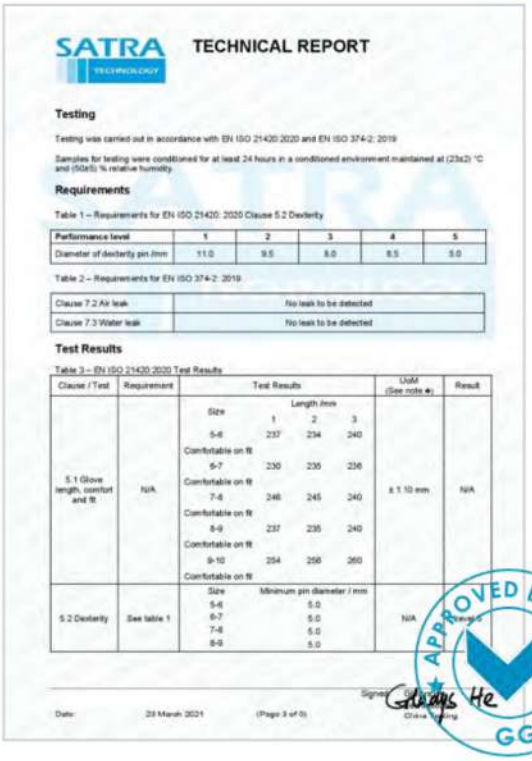

SATRA TECHNOLOGY

TECHNICAL REPORT

Testing

Testing was carried out in accordance with EN ISO 21420:2020 and EN ISO 374-2: 2019

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2) °C and (50±5) % relative humidity.

Requirements

Table 1 – Requirements for EN ISO 21420: 2020 Clause 5.2 Dexterity

Performance level	1	2	3	4	5
Diameter of dexterity pin /mm	11.0	9.5	8.0	6.5	5.0

Table 2 – Requirements for EN ISO 374-2: 2019

Clause 7.2 Air leak	No leak to be detected
Clause 7.3 Water leak	No leak to be detected

Test Results

Table 3 – EN ISO 21420:2020 Test Results

Clause / Test	Requirement	Test Results				UoM (See note ♣)	Result
5.1 Glove length, comfort and fit	N/A	Size	Length /mm 1	2	3	± 1.10 mm	N/A
		5-6	237	234	240		
		Comfortable on fit					
		6-7	230	235	236		
		Comfortable on fit					
		7-8	246	245	240		
		Comfortable on fit					
		8-9	237	235	240		
		Comfortable on fit					
		9-10	254	258	260		
		Comfortable on fit					
5.2 Dexterity	See table 1	Size	Minimum pin diameter / mm			N/A	Level 5
		5-6	5.0				
		6-7	5.0				
		7-8	5.0				
		8-9	5.0				

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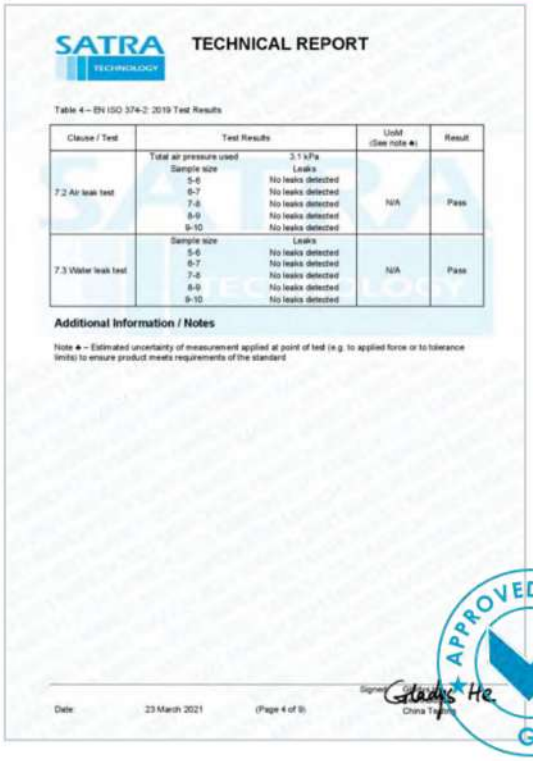

SATRA TECHNOLOGY

TECHNICAL REPORT

Table 4 – EN ISO 374-2: 2019 Test Results

Clause / Test	Test Results		UoM (See note ♣)	Result
7.2 Air leak test	Total air pressure used	3.1 kPa	N/A	Pass
	Sample size	Leaks		
	5-6	No leaks detected		
	6-7	No leaks detected		
	7-8	No leaks detected		
	8-9	No leaks detected		
	9-10	No leaks detected		
7.3 Water leak test	Sample size	Leaks	N/A	Pass
	5-6	No leaks detected		
	6-7	No leaks detected		
	7-8	No leaks detected		
	8-9	No leaks detected		
	9-10	No leaks detected		

Additional Information / Notes

Note ♣ – Estimated uncertainty of measurement applied at point of test (e.g. to applied force or to tolerance limits) to ensure product meets requirements of the standard

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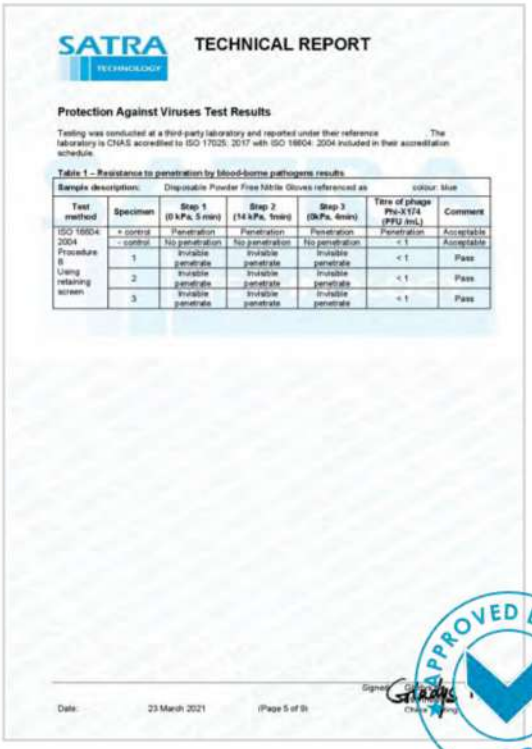
INTERNATIONAL STANDARDS

EN ISO 21420, EN ISO 374-2, EN 374-5



SATRA TECHNOLOGY

TECHNICAL REPORT

Protection Against Viruses Test Results

Testing was conducted at a third-party laboratory and reported under their reference . The laboratory is CNAS accredited to ISO 17025: 2017 with ISO 16604: 2004 included in their accreditation schedule.

Table 1 – Resistance to penetration by blood-borne pathogens results

Sample description:		Disposable Powder Free Nitrile Gloves referenced as			colour: blue	
Test method	Specimen	Step 1 (0 kPa, 5 min)	Step 2 (14 kPa, 1min)	Step 3 (0kPa, 4min)	Titre of phage Phi-X174 (PFU /mL)	Comment
ISO 16604: 2004 Procedure B Using retaining screen	+ control	Penetration	Penetration	Penetration	Penetration	Acceptable
	- control	No penetration	No penetration	No penetration	< 1	Acceptable
	1	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	2	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	3	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass

Date: 23 March 2021 (Page 5 of 9)

Signed: Gladys He China Testing

SATRA TECHNOLOGY

TECHNICAL REPORT

Innocuousness Test Results

Testing was conducted at a third-party laboratory and reported under their reference . The laboratory is CNAS accredited to ISO 17025: 2017.

Sample Item	Sample Description	Location	Style
/001	Disposable Powder Free Nitrile Gloves referenced as colour: Blue	Gloves	-

pH Value - EN ISO 21420:2020

Test Method I : With reference to EN ISO 4045:2018, analysed by pH meter.
Test Method II : With reference to ISO 3071:2020, analysed by pH meter.

Requirement:	3.5-9.5

-	Unit	Result
Test Item(s)	-	/001
Test Method	-	II
Parameter	-	-
pH Value of Extracting Solution	-	5.46
Temp. of Aqueous Extract	deg. C	25.1
pH Value of Aqueous Extract	-	7.4
Difference Figure	-	-
Conclusion	-	PASS

Note / Key : deg. C = degree Celsius (°C) Temp. = Temperature
Remark: Result(s) was (were) reported the average value from two trials.

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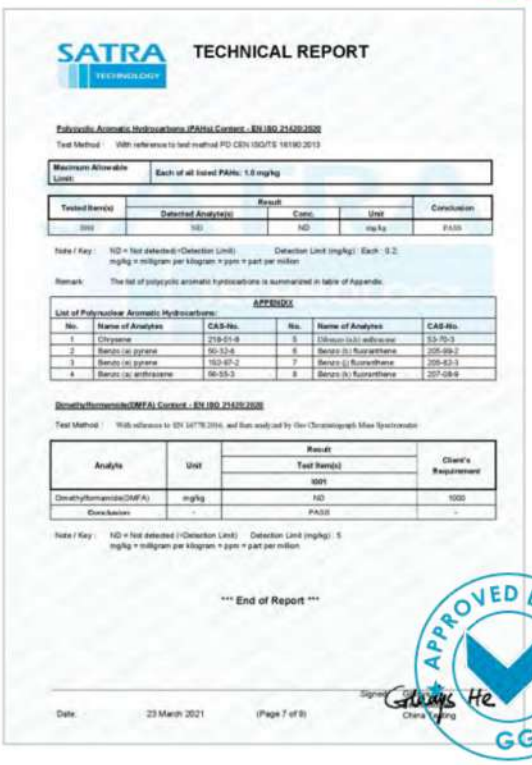
Signed: Gladys He China Testing



SATRA TECHNOLOGY

TECHNICAL REPORT

Polycyclic Aromatic Hydrocarbons (PAHs) Content - EN ISO 21420:2020

Test Method : With reference to test method PD CEN ISO/TS 16190:2013

Maximum Allowable Limit:	Each of all listed PAHs: 1.0 mg/kg

Tested Item(s)	Result			Conclusion
	Detected Analyte(s)	Conc.	Unit	
/001	ND	ND	mg/kg	PASS

Note / Key : ND = Not detected(=Detection Limit) Detection Limit (mg/kg): Each : 0.2
mg/kg = milligram per kilogram = ppm = part per million

Remark: The list of polycyclic aromatic hydrocarbons is summarized in table of Appendix.

APPENDIX

List of Polynuclear Aromatic Hydrocarbons:

No.	Name of Analytes	CAS-No.	No.	Name of Analytes	CAS-No.
1	Chrysene	218-01-9	5	Dibenzo (a,h) anthracene	53-70-3
2	Benzo (a) pyrene	50-32-8	6	Benzo (b,) fluoranthene	205-99-2
3	Benzo (e) pyrene	192-97-2	7	Benzo (j,) fluoranthene	205-82-3
4	Benzo (a) anthracene	56-55-3	8	Benzo (k) fluoranthene	207-08-9

Dimethylformamide(DMFA) Content - EN ISO 21420:2020

Test Method : With reference to EN 16778:2016, and then analyzed by Gas Chromatograph Mass Spectrometer.

Analyte	Unit	Result	Client's Requirement
		Test Item(s)	
		/001	
Dimethylformamide(DMFA)	mg/kg	ND	1000
Conclusion	-	PASS	-

Note / Key : ND = Not detected (=Detection Limit) Detection Limit (mg/kg): 5
mg/kg = milligram per kilogram = ppm = part per million

*** End of Report ***

Date: 23 March 2021 (Page 7 of 9)

Signed: Gladys He China Testing

SATRA TECHNOLOGY

TECHNICAL REPORT

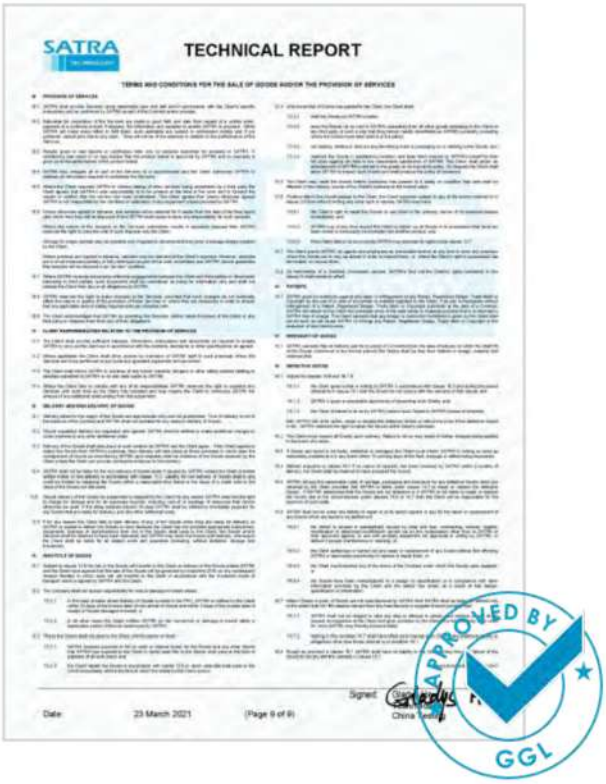
TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

Date: 23 March 2021 (Page 8 of 9)

Signed: Gladys He China Testing

INTERNATIONAL STANDARDS

EN ISO 21420, EN ISO 374-2, EN 374-5


SATRA

TECHNICAL REPORT

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

Date 23 March 2021 (Page 9 of 9)

Signed

China Testing

APPROVED BY GGL

INTERNATIONAL STANDARDS

EN 374-1,4 EN 16523

Produkte / Products: TÜVRheinland®

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Absatz / Clause	EN ISO 374-1:2016 + A1:2018 Anforderungen - Prüfungen / Requirements - Tests	Messergebnisse - Bemerkungen Measuring results - Remarks	Bewertung Evaluation
7	Durchführung / Procedure		
7.1	Allgemeines / General		
	Der Handschuh wird vorsichtig der Hülle, Schachtel oder seiner Verpackung entnommen, identifizierungsmittel, Nummer des Loses, Größe und Marke der Proben werden aufgezeichnet. Eine Sichtprüfung auf Risse, Schlitze und Löcher wird durchgeführt. Sind diese vorhanden, ist anzugeben, dass die Handschuhe die Prüfung nicht bestanden haben. / Carefully remove the glove from the wrapper, box or its packaging. Record the identity code, lot number, size and brand of samples. Visually examine for tears, rips and holes. If these are present, the gloves shall be reported as having failed.	keine Risse, Schlitze und Löcher vorhanden / no tears, rips and holes are present	P F N/A N/T
7.2	Luft-Leck- Prüfung / Air leak test		
4.1	Ein Handschuh wird in Wasser getaucht und sein Innenvolumen mit Luft aufgeblasen. Eine Undichtheit (Leck) wird als Strien aus Luftblasen sichtbar, die sich an der Oberfläche des Handschuhes bildet. / A glove is immersed in water, and its interior is pressurised with air. A leak is detected by a stream of air bubbles from the surface of the glove.	Größe/ size: M 7,5 – Luft-Leck-Prüfung/ Air leakage: keine/ no Leakage	P F N/A N/T
Tab. 1	Nennlänge der Handschuhe (z) nach Angaben des Herstellers mm / Nominal glove thickness as mm As provided by the manufacturer: ≤ 1,0 – 0,8; 1,0 < e ≤ 0,5 – 2,0; 0,5 < e ≤ 1,0 – 4,0; e > 1,0 – 6,0	Verwendeter Luftdruck / air pressure used: 0,5 kPa	

Produkte / Products: TÜVRheinland®

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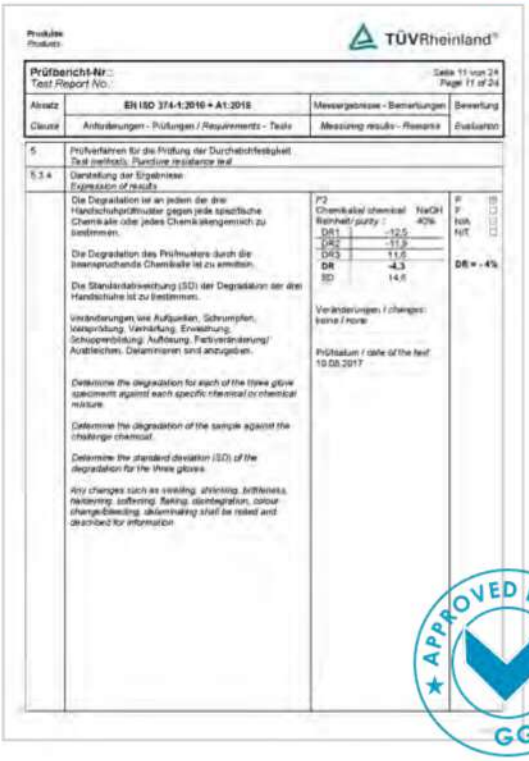
Absatz / Clause	EN ISO 374-1:2016 + A1:2018 Anforderungen - Prüfungen / Requirements - Tests	Messergebnisse - Bemerkungen Measuring results - Remarks	Bewertung Evaluation
7.3	Wasser-Leck-Prüfung / Water leak test		
4.2	Ein Handschuh wird mit Wasser gefüllt. Eine Undichtheit wird durch das Auftreten von Wassertropfchen an der Außenseite des Handschuhes festgestellt. / A glove is filled with water. A leak is detected by the appearance of water droplets on the outside of the glove.	Größe/ size: M 7,5 – Luft-Leck-Prüfung/ Air leakage: keine/ no Leakage	P F N/A N/T
5.3	Degradation / Degradation		
	Die Degradation (DR) ist nach EN 374-4 für jede Chemikalie, die in der Kennzeichnung angegeben und in der Benutzerinformation aufgeführt wird, zu bestimmen. Für den Handschuh, der länger als 400 mm ist, muss die zu dem geringsten Permeationsergebnis gehörende Degradation zusätzlich angegeben werden. / The degradation (DR) shall be determined according to EN 374-4 for each chemical claimed in the marking and reported in the user instruction. For the glove longer than 400 mm, the degradation corresponding to the lowest permeation results shall at least be reported.		
EN 374-4	Teil 4: Bestimmung des Widerstandes gegen Degradation durch Chemikalien / Part 4: Determination of resistance to degradation by chemicals		
4	Prüfprinzip / Test principles		
	Der Widerstand eines Werkstoffes für Schutzhandschuhe gegen Degradation durch eine flüssige Chemikalie wird bestimmt, indem die Veränderung der Durchrichtfestigkeit des Werkstoffes für Handschuhe nach ständigem Kontakt der Außenfläche mit der beanspruchenden Prüfchemikalie gemessen wird. Die Prüfung gilt für Handschuhe aus natürlichem oder synthetischem Polymer. Geflockte Handschuhe können unbrauchbare Messergebnisse liefern. / The resistance of a protective glove material to degradation by a liquid chemical is determined by measuring the puncture resistance change of the glove material after a continuous contact of the external surface with the challenge to be chemical. The test is applicable to gloves made of natural or synthetic polymer. Lined gloves may produce unusable measurement results.		



Produkte / Products: TÜVRheinland®

Prüfbericht-Nr.: / Test Report No.: Seite 11 von 24 / Page 11 of 24

Absatz / Clause	EN ISO 374-1:2016 + A1:2018 Anforderungen - Prüfungen / Requirements - Tests	Messergebnisse - Bemerkungen Measuring results - Remarks	Bewertung Evaluation
5	Prüfverfahren für die Prüfung der Durchtrittfestigkeit / Test methods: Puncture resistance test		
5.3.4	Darstellung der Ergebnisse / Expression of results		
	Die Degradation ist an jedem der drei Handschuhprüfmuster gegen jede spezifische Chemikalie oder jedes Chemikalengemisch zu bestimmen. Die Degradation des Prüfmusters durch die beanspruchende Chemikalie ist zu ermitteln. Die Standardabweichung (SD) der Degradation der drei Handschuhe ist zu bestimmen. Veränderungen wie Aufquellen, Schrumpfen, Versprödung, Verhärtung, Erweichung, Schichtentrennung, Auflösung, Farbveränderung/ Ausbleichen, Delaminieren sind anzugeben. / Determine the degradation for each of the three glove specimens against each specific chemical or chemical mixture. Determine the degradation of the sample against the challenge chemical. Determine the standard deviation (SD) of the degradation for the three gloves. Any changes such as swelling, shrinking, brittleness, thickening, softening, flaking, disintegration, colour change/bleeding, delaminating shall be noted and described for information	P2 Chemikalie/ chemical: NaOH Reinheit/ purity: 40% DR1: -12,5 DR2: -11,9 DR3: 11,6 DR: -4,3 SD: 14,6 Veränderungen / changes: keine / none Prüfdatum / date of the test: 10.08.2017	P F N/A N/T DR = - 4%

Produkte / Product: TÜVRheinland®

Prüfbericht-Nr.: / Test Report No.: Seite 12 von 24 / Page 12 of 24

Absatz / Clause	EN ISO 374-1:2016 + A1:2018 Anforderungen - Prüfungen / Requirements - Tests	Messergebnisse - Bemerkungen Measuring results - Remarks	Bewertung Evaluation
5.4	Permeation / Permeation		
5.4.1	Allgemeines / General		
	Für den Handschuh, der länger als 400 mm ist, und bei dem die Handinnenfläche und die Stulpe unterschiedliche Leistungsstufen erreichen, muss für jede Chemikalie die geringere Leistungsstufe in der Kennzeichnung angegeben werden. Alle Ergebnisse sollten in die Benutzeranleitung angegeben sein. Jede Kombination von Schutzhandschuhs/Prüfmerkmale ist nach Tabelle 1 zu klassifizieren, wobei die in EN 16523-1:2015, 8.5.1.1 oder 8.5.1.3, angegebene Ergebnisse für die normalisierte Durchbruchszeit anzuwenden sind. / For the glove longer than 400 mm, where the palm and cuff achieve different performance levels, the lowest performance level shall be claimed in the marking for each chemical. All the results should be reported in the user instruction. Each combination of protective glove/test chemical shall be classified according to Table 1, using the results as given in EN 16523-1:2015, 8.5.1.1 or 8.5.1.3 for the normalized breakthrough time.		
5.4.2	Typ A: Die Permeationsleistung muss mindestens Stufe 2 gegen wenigstens sechs Prüfchemikalien entsprechen, die in Tabelle 2 gelistet sind. / Type A: The permeation performance shall be at least level 2 against a minimum of six test chemicals listed in Table 2.		
5.4.3	Typ B: Die Permeationsleistung muss mindestens Stufe 2 gegen wenigstens drei Prüfchemikalien entsprechen, die in Tabelle 2 gelistet sind. / Type B: The permeation performance shall be at least level 2 against minimum of three test chemicals listed in Table 2.		
5.4.3	Typ C: Die Permeationsleistung muss mindestens Stufe 1 gegen wenigstens eine Prüfchemikalie entsprechen, die in Tabelle 2 gelistet ist. / Type C: The permeation performance shall be at least level 1 against minimum of one test chemical listed in Table 2.		
Tab. 2	Kennbuchstabe / Code Letter: A Methanol / Methanol 67-56-1; B Aceton / Acetone 67-64-1; C Acetonitril / Acetonitrile 75-05-8; D Dichlormethan / Dichloromethane 75-09-2; E Kohlenstoffdisulfid / Carbon disulphide 75-15-0; F Toluol / Toluene 108-88-3; G Diethylamin / Diethylamine 109-89-7; H Tetrahydrofuran / Tetrahydrofuran 109-99-9; I Ethylacetat / Ethyl acetate 141-78-6; J n-Heptan / n-Heptane 142-82-5; K Natriumhydroxid 40 % / Sodium hydroxide 40 % 1310-73-2; L Schwefelsäure 96 % / Sulphuric acid 96 % 7664-93-9; M Salpetersäure 65 % / Nitric acid 65 % 7697-37-2; N Essigsäure 99 % / Acetic acid 99 % 64-19-7; O Ammoniumhydroxid 25 % / Ammonium hydroxide 25 % 1336-21-6; P Wasserstoffperoxid 30 % / Hydrogen peroxide 30 % 7722-84-1; S Flusssäure 40 % / Hydrofluoric acid 40 % 7664-39-3; T Formaldehyd 37 % / Formaldehyde 37 % 50-00-0		

MANUFACTURING ACCREDITATIONS

CE 0197

Business Stream Products
Certification Department

Application for : EU type-examination certificate PPE
Certificate No.
Device: Protective gloves against chemicals and micro-organisms according to EN ISO 374-1+A1:2016 and EN ISO 374-5:2016
Type
Test requirement: UE/reg-425/2016
EN ISO 374-1:2016+A1
EN ISO 374-5:2016

Dear Madame or Sir,

A specimen of above mentioned product has been tested and found to be technically in compliance with § 20 and § 21 of the ProdSG (= German Product Safety Law).

The certificate is issued with the reservation that the licence holder applies all information required in § 6 of the ProdSG related to name of the manufacturer and, if need be, the authorised representative / the importer including their respective addresses on the product, its packing and/or the user's manual prior to marketing the product in the European Economic Area.

Enclosed please find the certificate of approval No.

Kind regards

Certification body

Dipl.-Ing. C. Albrecht

Test sample: no. documentation available

CERTIFICATE
EU Type-Examination Certificate
Regulation 2016/425/EU
Personal Protective Equipment

Registration No.:

Report No.:

Holder:

Product: Protective gloves against chemicals and micro-organisms according to EN ISO 374-1+A1:2016 and EN ISO 374-5:2016

Identification: disposable gloves
Colour: blue
Material: nitrile, wall thickness 0,05 mm
Sizes: S (6,5) - XL (9)
Performance parameter: Type C, class 6, K: MaCH 409

- PPE Category III - obligatory monitoring module C2 -

The EU type-examination certificate refers to the above mentioned product. This is to certify that the product complies with the essential requirements of Annex II of the regulation 2016/425/EU. This certificate does not imply assessment of the production of the product and does not permit the use of a TÜV Rheinland mark of conformity. The holder is entitled to use this certificate in connection with the declaration of conformity in accordance with Annex IX.

valid till: 07.03.2024

Notified Body

Date 06.03.2019

Dipl.-Ing. C. Albrecht

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Notified by Zentralstelle der Länder für Sicherheitstechnik (ZLS).

Notified under No. 0197 to the EC Commission

CE The CE marking may be used if all relevant and effective EC Directives are complied with.

ZERTIFIKAT
EU-Baumusterprüfbescheinigung
Verordnung 2016/425/EU
Persönliche Schutzausrüstung

Registrier Nr.:

Bericht Nr.:

Inhaber:

Produkt: Schutzhandschuhe gegen Chemikalien und Mikroorganismen gemäß EN ISO 374-1+A1:2016 und EN ISO 374-5:2016

Identifikation: Einmalhandschuhe
Farbe: blau
Material: Nitril, Wandstärke 0,05 mm
Größen: S (6,5) - XL (9)
Leistungsparameter: Typ C, Klasse 6, K: MaCH 409

- PSA Kategorie III - Überwachungspflichtig Modul C2 -

Die EU-Baumusterbescheinigung bezieht sich auf das o.g. Produkt. Es wird bescheinigt, dass das Produkt den grundlegenden Anforderungen nach Anhang II der Verordnung 2016/425/EU entspricht. Das Zertifikat stellt kein allgemein gültiges Urteil über die Serienfertigung des Produktes dar und berechtigt nicht zur Nutzung einer TÜV Rheinland Prüfplakette. Der Inhaber ist berechtigt, diese Bescheinigung im Rahmen seiner EU-Konformitätserklärung gemäß Anhang IX zu verwenden.

Gültig bis: 07.03.2024

Benannte Stelle

Datum: 06.03.2019

Dipl.-Ing. C. Albrecht

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Benannt durch die Zentralstelle der Länder für Sicherheitstechnik (ZLS).

Notifiziert unter Nr. 0197 bei der Kommission der Europäischen Gemeinschaften

CE Die CE-Kennzeichnung darf bei Befolgung aller zutreffenden EU-Richtlinien angebracht werden. CE

INTERNATIONAL STANDARDS

EN 1186

Test Report No.:
Report Date: 11 April 2019

SUBJECT	Chemical Test
TEST LOCATION	TÜV SÜD China
	TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1588 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME CLIENT ADDRESS	
TEST PERIOD	01-Mar-2019~08-Mar-2019
TEST REQUEST	In accordance with Council of Europe Res AP (2004) 4
CONCLUSION	PASS The submitted sample was found to comply with the overall migration requirement(s) as stated in European Resolution Res AP (2004) 4 on rubber to be used for food contact applications.

Prepared By
(Cynthia Cao)
Report Drafter

Authorized By
(Leo Liu)
Authorized Signatory

Test Report No.:
Report Date: 11 April 2019

RECEIPT DATE / TEST DATE
01-Mar-2019/ 01-Mar-2019

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED BY/ ON BEHALF OF THE CLIENT/S AS
Sample Name: Powder free nitrile glove, blue
Sample Specification: Medium
Batch No./Date:
Manufacturer:

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
	Blue glove	

TEST METHOD(S)

1. For material : Rubber
- Overall migration test for compliance with Europe Resolution Res AP (2004) 4 on rubber to be used for food contact applications
- As specified in REGULATION (EU) No 10/2011 and its amendments; with reference to EN 1186: Part 2 (Test methods for overall migration into olive oil by total immersion) / EN 1186: Part 3 (Test methods for overall migration into aqueous food simulants by total immersion)/ EN 1186: Part 14 (substitute test)

TEST RESULT(S)

1. Overall Migration Test - with reference to EN 1186: Part 2, Part 3 & Part 14

Simulant(s) Used	Test Condition	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
10% Ethanol	70°C for 2 hours	<5.0	60
3% Acetic acid	70°C for 2 hours	<5.0	60
95% Ethanol	60°C for 2 hours	<5.0	60
Iso-octane	40°C for 0.5 hour	<5.0	60

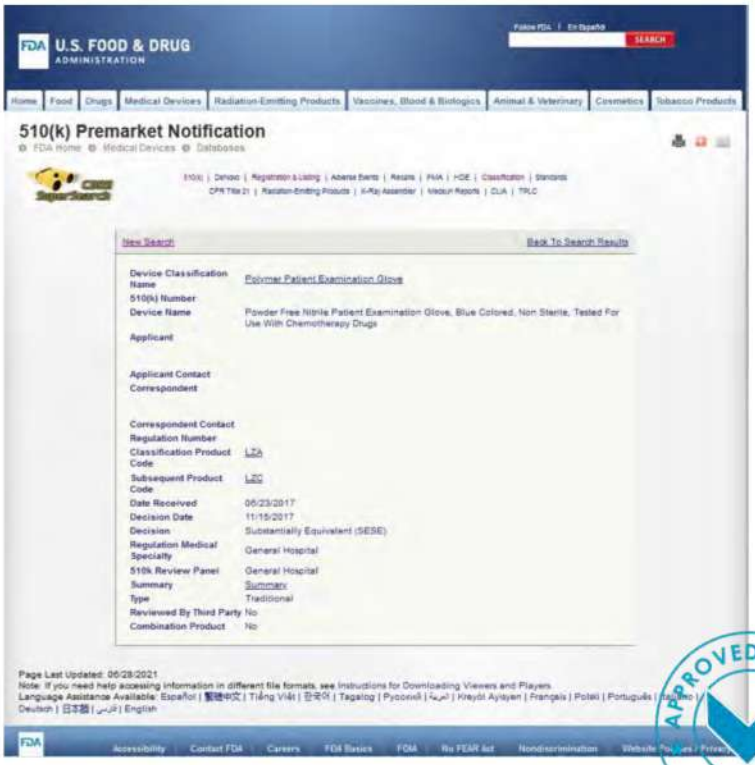
Note: 1. mg/kg denotes milligram per kilogram foodstuff
2. Specification is quoted from European Resolution Res AP (2004) 4 on rubber to be used for food contact applications
3. "<" denotes less than

Note: This report is for internal use only by the client.

-END OF THE TEST REPORT-

REGULATION COMPLIANCE

FDA 510K



DECLARATION OF CONFORMITY

Medical

Declaration of Conformity

Manufacturer:
Address:

Product: Disposable Nitrile Examination Gloves
Designation: X-Small, Small, Medium, Large, X-Large, XX-Large

We herewith declare that the above-mentioned devices comply with the European Medical Device Regulation (EU) MDR 2017/745 and PPE Regulation (EU) 2016/425. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

By formulating the products, the chemical substances selecting was rigorous, and compliance to REACH, RoHS, Halogen-Free, SVHC 181

We strict following the standard of U.S. and EU, no DEHP, BBP, DBP, and DIBP is using in any vinyl products.

STANDARDS

Standards Harmonized Standards applicable to this product are
EN455-1, EN455-2, EN455-3, EN455-4
EN374-1, EN374-2, EN374-3, EN374-5

Signature:

Date:
March 02, 2021

Medical

EU Declaration of Conformity

Manufacturer:
Address:
SRN:
European Representative: Lotus NL B.V. koningin Julianaplein10, 1e Verd, 2595AA The Hague, Netherlands
SRN:
Product: Disposable Medical nitrile exam glove
X-Small, Small, Medium, Large, X-Large
GMDN Code:
UMDN Code:
Basic UDI:

Classification (MDR, Annex VIII): Class I, Rule 1.
Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith declare that the above mentioned de products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.
is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
Applied standards, common specification, guidance:

EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009

Signature:

Date:
July 06, 2021

Chemical

EU Declaration of Conformity - PPE

The manufacturer

Representative (EU, Switzerland): CURADEN AG, Amlehnstrasse 22, 6010 Kriens, Switzerland

Declares under his sole responsibility, that the PPE reference : described hereafter:

Protective nitrile Glove
PPE to be used against Category III risks

EN ISO 374-1:2016/Type C EN ISO 374-5:2016

is in conformity with the provisions of Regulation (EU)2016/425 and with the European harmonized standards EN ISO 374-1+A1:2018, EN ISO 374-5:2016*, EN ISO 21420:2020* (*see SATRA test report) and is identical to the PPE which is subject to the EU-Type examination, under certificate number 0197, issued by the Notified Body:

TUV Rheinland LGA Products GmbH
Tillystrabe 2
90431 Nürnberg
Germany

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified body:

TUV Rheinland LGA Products GmbH
Tillystrabe 2
90431 Nürnberg
Germany

Signature:

Date: August 18, 2021

PACKAGING


VELVET GRIP
Examination NITRILE GLOVES
curaden
• Disposable Gloves
• Non-sterile
• Ambidextrous
• Powder-free and blue
• Latex-free
100
Size L
VELVET GRIP
GUANTI IN NITRILE
VELVET GRIP
GUANTES DE NITRILO
VELVET GRIP
Einweg-NITRILEHANDSCHUHE
• Untersuchungshandschuhe
• Nicht steril
• Beidseitig
• Puderfrei und blau
• Latexfrei
Größe L
VELVET GRIP
Examination NITRILE GLOVES
CURADEN AG
Ammerstraße 22, CH-6010 Kriens
LOTUS NL B.V.
The Hague, Netherlands
4 260740 980185
AQL 1.5

VELVET GRIP

Disposable **NITRILE GLOVES**

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