

Technical Sheet

Product: Latex Free-Powdered Examination Gloves
Manufacturer: Vogt Medical Vertrieb GmbH (Germany)



Product Description

Latex examination gloves are non-sterile medical gloves, intended for conducting medical checkups, diagnostic and therapeutic procedures and for handling contaminated medical material.

Material: 100% natural rubber latex
Colour: White to pale yellow
Cuff: Beaded cuff
Shape: Ambidextrous fitting
External surface: Textured

Quality and safety

Compliance standards: EN 455-1, 2, 3, 4
ASTM D3578
Quality certificates: ISO 9001, ISO 13485
Medical device classification: I (acc. to MDD 93/42/EEC)
Water-tightness: max. AQL 1,5

Packaging

Box: 100 gloves (in dispenser box)*
Carton: 1000 gloves*

Storage

Shelf life: 5 years

Requirements: Store in dark, dry conditions in the original packaging at temperatures between +10° C and +30° C.

Caution: This product contains natural rubber latex which may cause allergic reactions.

* quantity of XL size in box/carton: 95/950

Art. No.	Size	Glove dimensions (mm)		Single wall thickness (min. mm)	
		Length (min)	Width	Finger	Palm
1314349	XS	240	≤ 80	0,08	0,08
1314350	S	240	80 ± 10	0,08	0,08
1314351	M	240	95 ± 10	0,08	0,08
1314352	L	240	110 ± 10	0,08	0,08
1314353	XL	240	≥ 110	0,08	0,08



Declaration of Conformity



EC-Declaration of conformity

Manufacturer: Vogt Medical Vertrieb GmbH
Address: Rüppurrer Str. 1A, Haus B, 76137 Karlsruhe, Germany
Product: Examination gloves, non-sterile, for single use
Classification: Class I

We declare on our own responsibility that the medical devices specified above, complies with the relevant Essential Requirement of the Directive 93/42/EEC, taking in the account the state of art.

This declaration concerns all denoted medical devices until the date **2023-10-31**.

The manufacturer is solely responsible for issuance of the declaration of conformity.

Place, Date of Issue: Karlsruhe, 2020-11-01
Signature: Michael Vogt, Managing Director
(Name, Function)



Filename with revision : DoC_VM_examination gloves, Rev.4
Created by : ob
Created at : 14.02.12
Modified by : ak
Modified at : 01.11.20



Annex to EC-Declaration of conformity

Product

- VM STANDARD Latex Examination Gloves, POWDERED, smooth
- VM STANDARD Latex Examination Gloves, POWDERED, textured
- VM STANDARD Latex Examination Gloves, POWDER FREE, textured
- VM PREMIUM Latex Examination Gloves, POWDERED, textured
- VM PREMIUM Latex Examination Gloves, POWDERED, smooth
- VM PREMIUM Latex Examination Gloves, POWDER FREE, textured
- VM HIGH RISK Latex Examination Gloves, POWDER FREE, textured
- VM HIGH RISK PLUS Latex Examination Gloves, POWDER FREE, textured
- VM STANDARD Nitrile Examination Gloves, POWDER FREE, textured
- VM EkoFreund Nitrile Examination Gloves, POWDER FREE, textured
- VM PREMIUM Nitrile Examination Gloves, POWDER FREE, textured
- VM PREMIUM PLUS Nitrile Examination Gloves, POWDER FREE, textured

Place, Date of Issue: Karlsruhe, 2020-11-01
Signature: Michael Vogt, Managing Director
(Name, Function)



Filename with revision : DoC_VM_examination gloves, Rev.4
Created by : ob
Created at : 14.02.12
Modified by : ak
Modified at : 01.11.20

3. TUV Certificate

ZERTIFIKAT • CERTIFICATE • CERTIFICADO • CERTIFICAT


Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH
certifies that


Vogt Medical Vertrieb GmbH
Rüppurrer Str. 1A Haus B
76137 Karlsruhe
Germany

has established and applies
a Quality Management System for

**Design and Development, Production and Distribution of
sterile and non-sterile medical disposable products
and surgical instruments.**

An audit was performed, Order No. **70106912**
Proof has been furnished that the requirements
according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2020-11-01** until **2023-10-31**.
Certificate Registration No.: **12 100 26693 TMS**


Product Compliance Management
Munich, 2020-09-08



TÜV SÜD Management Service GmbH • Zertifizierungsstelle • Rüdigerstrasse 57 • 80339 München • Germany
www.tuv-sud.de/certificate-validation-check



ZERTIFIKAT • CERTIFICATE • CERTIFICADO • CERTIFICAT



Certificate

No. Q5 057451 0040 Rev. 02

Holder of Certificate: **Vogt Medical Vertrieb GmbH**

Rüppurrer Str. 1A, Haus B
76137 Karlsruhe
GERMANY

Facility(ies):

Vogt Medical Vertrieb GmbH
Rüppurrer Str. 1A, Haus B, 76137 Karlsruhe, GERMANY

Certification Mark:



Scope of Certificate:

Design and development, manufacturing and distribution of sterile and non sterile disposables: surgical clothes, gynecology sets, urinal bags, syringes with/ without needles, scalp vein sets, transfusion sets, infusion sets, surgical gloves, examinations gloves, vaginal specula, micro infusion pumps for general purpose, endotracheal tubes, catheter Foley, injection needles, blood bags, central venous catheter and kits, spinal needles, I.V. cannula, insulin pen needles, laryngeal masks, spikes, 3-way stopcocks, extension sets

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuv-sud.com/ps-cert?cert=Q5.057451.0040.Rev.02

Report No.: 713192629

Valid from: 2020-11-27

Valid until: 2023-10-31

Date: 2020-11-27

Christoph Dicks
Head of Certification/Notified Body

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TÜV SÜD Product Service GmbH • Certification Body • Rüdigerstrasse 65 • 80339 Munich • Germany



4. Certificate of Quality

 Certificate of Quality					
PRODUCT: VM STANDARD LATEX EXAMINATION GLOVE					
LOT:	S	8818			
	M	8818			
	L	8818			
MFG. Date:	10.2020				
EXP. Date:	10.2025				
INSPECTION Date:	04.11.2020				
Sizes Breakdown	Extra-	Small	Medium	Large	TOTAL
No. of gloves		720.000	1.800.000	1.200.000	3.720.000
Sampling plan acc. to ISO 2859-1					
Inspection level: GI, AQL 2.5, Multiple Sampling for normal					
A. Barrier properties					
No. of gloves tested		282	650	450	1382
No. of defect gloves		0	0	0	0
B. Major defects (cuts, tears)					
No. of defect gloves (cuts, tears)		0	0	0	0
Accepted :		YES	YES	YES	
C. Minor defects					
No. of gloves tested		282	650	450	1382
No. of defect gloves		2	4	1	7
Accepted :		YES	YES	YES	
Total conclusion by QC : PASS					
D. Dimension in mm	n = 13 pcs				
Width in mm : Minimum measured of this lot		81	95	107	
specification : +/- 10 mm		80	95	111	
Length in mm - Spec Min 230 mm		240	241	240	
Single-wall thickness					
- Finger in mm, Min 0.08 mm		0.10	0.11	0.11	
- Palm in mm, Min 0.08 mm		0.09	0.08	0.09	
E. Physical Properties	Inspection level S 2, AQL 4.0				
Force at break in N, unaged -		-	-	-	
Force at break in N, aged -		-	-	-	
Tensile Strength in MPa, unaged - 18 MPa min		19,1	20,2	19,3	
Elongation in %, unaged - 650 % min		673	732	715	
Tensile Strength in MPa, aged - 14 MPa min		19,1	18,2	19,5	
Elongation in %, aged - 500 % min		682	663	677	
F. Biocompatibility	No Talcum (Magnesiumsilicate)				
☒ Residual powdered (Spec: Max 10 mg/dm2)		8	8	7	
☐ Residual powdered (Spec: Max 2.0 mg/glove)					
Protein content (ug/g), mean spec : 200 ug/g max)		127	100	114	
Total conclusion by LAB : PASS					
Conclusion: We hereby certify that glove consignment of goods were determined to meet the acceptable limit of the specifications as referring to the above findings of randomly selected samples.					

VOGT MEDICAL
VERTRIEB GMBH
 Rüppurrer Straße 1 A, Haus B
 76137 Karlsruhe
 Tel. 07 21 / 98 23 50 - Fax: 07 21 / 98 23 52

Date: 14.12.2021

4. NAMMDR Notice 1/2



MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu nr. 48, sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anmm.ro

ANEXA din data 06.04.2021
LA AVIZUL DE FUNCȚIONARE
Nr. 7111/19.08.2020 al MEDPLAZA HEALTH SRL

În conformitate cu art. 926 din Legea nr. 95/2006 privind reforma în domeniul sănătății, republicată și în baza documentației înaintate, Avizul de funcționare nr. 7111/19.08.2020 se completează după cum urmează:

Unitatea este distribuitor al producătorilor:

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Pagina 1 de la Anexa din 06.04.2021 de la Avizul de funcționare nr. 7111/19.08.2020



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Pagina 2 de la Anexa din 06.04.2021 de la Avizul de functionare nr. 7111/19.08.2020

4. NAMMDR Notice 2/2



MINISTERUL SĂNĂTĂȚII
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Nume producător	Țară
PHARMABIO STARS ENTERPRISE LTD LTD	ROMANIA
PHARMABIO STARS SRL	ROMANIA

Prezentul document este valabil numai însoțit de avizul inițial.

PREȘEDINTE

Agencia Națională a Medicamentului și a
Dispozitivelor Medicale din România
Roxana Stefania STROE



MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
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Str. Av. Sănătescu nr. 48, sector 1, 011478 București
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Către,

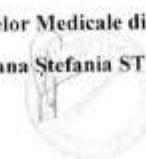
MEDPLAZA HEALTH SRL
Tel: 0737552756

Prin prezenta vă înaintăm anexa avizului de funcționare aferentă cererii cu numărul
DM 2125/26.03.2021.

Cu stimă,

PREȘEDINTE

Agencia Națională a Medicamentului și a
Dispozitivelor Medicale din România
Roxana Stefania STROE





Thank you!

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