

SRN: DE-MF-000006279

Declaration of Conformity

Manufacturer: Vogt Medical Vertrieb GmbH

Rüppurrer Str. 1A, Haus B 76137 Karlsruhe/ Germany

declares under sole responsibility that

the medical

Non-sterile Examination Gloves for Single Use

device

Basic UDI-DI 4066258NsExGISUBV

Art. No. According to Attachment

of class I under Rule 1 and 5

According to Annex VIII, Chapter III of Regulation 2017/745

meets the essential safety and performance requirements of Annex I to Regulation 2017/745.

Conformity assessment procedures in accordance with Annexes II and III.

This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of Regulation 2017/745 with:

Quality Management System certification to EN ISO 13485:2016 under the supervision of TÜV SÜD Product Service GmbH, Cert.-no. Q5 057451 0040 Rev. 02.

Availability of technical documentation per Annex II and III of Regulation 2017/745.

Valid from:

2021-05-26

Valid until:

2023-10-31



Attachment to Declaration of Conformity

Art. No.	Product Description
1314320T	VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, blue, Size XS
1314321T	VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, blue, Size S
1314322T	VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, blue, Size M
1314323T	VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, blue, Size L
1314324T	VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, blue, Size XL
1314320Q200	VM Non-sterile Nitrile Examination Gloves, powder free, finer textured, blue, Size XS
1314321Q200	VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, blue, Size S
1314322Q200 VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, I	
1314323Q200	VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, blue, Size L
1314324Q200	VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, blue, Size XL
1314320ST	VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, ocean blue, Size XS
1314321ST	VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, ocean blue, Size S
1314322ST	VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, ocean blue, Size M
1314323ST	VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, ocean blue, Size L
1314324ST	VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, ocean blue,
1314325T	Size XL
1314326T	VM Non-sterile Nitrile Examination Gloves, powder free, palm textured, blue, Size XS
	VM Non-sterile Nitrile Examination Gloves, powder free, palm textured, blue, Size S
1314327T	VM Non-sterile Nitrile Examination Gloves, powder free, palm textured, blue, Size M
1314328T 1314329T	VM Non-sterile Nitrile Examination Gloves, powder free, palm textured, blue, Size L
1314320D	VM Non-sterile Nitrile Examination Gloves, powder free, palm textured, blue, Size XL VM Non-sterile Nitrile Examination Gloves, EkoFreund, powder free, finger textured, pastel green, Size XS
1314321D	VM Non-sterile Nitrile Examination Gloves, EkoFreund, powder free, finger textured, pastel green, Size S
1314322D	VM Non-sterile Nitrile Examination Gloves, EkoFreund, powder free, finger textured, pastel green, Size M
1314323D	VM Non-sterile Nitrile Examination Gloves, EkoFreund, powder free, finger textured, pastel green, Size L
1314324D	VM Non-sterile Nitrile Examination Gloves, EkoFreund, powder free, finger textured, pastel green, Size XL
1314330T	VM Non-sterile Nitrile Examination Gloves, Premium, powder free, palm textured, black, Size XS
1314331T	VM Non-sterile Nitrile Examination Gloves, Premium, powder free, palm textured, black, Size S
1314332T	VM Non-sterile Nitrile Examination Gloves, Premium, powder free, palm textured, black, Size M
1314333T	VM Non-sterile Nitrile Examination Gloves, Premium, powder free, palm textured, black, Size L
1314334T	VM Non-sterile Nitrile Examination Gloves, Premium, powder free, palm textured, black, Size XL
1314224ST	
1314225ST	VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, blue, Size XS
1314226ST	VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, blue, Size S
1314227ST	VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, blue, Size M VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, blue, Size L
Filename, Revision:	
nename, Revision:	Created by: Created at: Modificated by: Modificated by: Page:

Filename, Revision: MDR DoC Examination Gloves VM, Rev. 1

Created by: ak

Created at: 26.05.2021

Modificated by:

Modificated by:

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1314228ST	VM Non-sterile Nitrile Examination Gloves, powder free, finger textured, blue, Size XL
1314339T	VM Non-sterile Latex Examination Gloves, powder free, finger textured, blue, size XL
1314340T	VM Non-sterile Latex Examination Gloves, powdered, smooth, natural, Size S
1314341T	VM Non-sterile Latex Examination Gloves, powdered, smooth, natural, Size S VM Non-sterile Latex Examination Gloves, powdered, smooth, natural, Size M
1314342T	
1314343T	VM Non-sterile Latex Examination Gloves, powdered, smooth, natural, Size L
	VM Non-sterile Latex Examination Gloves, powdered, smooth, natural, Size XL
1314349ST	VM Non-sterile Latex Examination Gloves, powdered, finger textured, white, Size XS
1314350ST	VM Non-sterile Latex Examination Gloves, powdered, finger textured, white, Size S
1314351ST	VM Non-sterile Latex Examination Gloves, powdered, finger textured, white, Size M
1314352ST	VM Non-sterile Latex Examination Gloves, powdered, finger textured, white, Size L
1314353ST	VM Non-sterile Latex Examination Gloves, powdered, finger textured, white, Size XL
124 4250	VM Non-sterile Latex Examination Gloves, powder free, palm textured, natural, Size
1314359T	XS
1314360T	VM Non-sterile Latex Examination Gloves, powder free, palm textured, natural, Size S
	VM Non-sterile Latex Examination Gloves, powder free, palm textured, natural, Size
1314361T	M
1314362T	VM Non-sterile Latex Examination Gloves, powder free, palm textured, natural, Size L
	VM Non-sterile Latex Examination Gloves, powder free, palm textured, natural, Size
1314363T	XL
101411	VM Non-sterile Latex Examination Gloves, Standard, powder free, palm textured,
1314115T	natural, Size XS
121411CT	VM Non-sterile Latex Examination Gloves, Standard, powder free, palm textured,
1314116T	natural, Size X
12141171	VM Non-sterile Latex Examination Gloves, Standard, powder free, palm textured,
1314117T	natural, Size M
121/110T	VM Non-sterile Latex Examination Gloves, Standard, powder free, palm textured,
_1314118T	natural, Size L
1314119T	VM Non-sterile Latex Examination Gloves, Standard, powder free, palm textured,
13141191	natural, Size XL
1314354T	VM Non-sterile Latex Examination Gloves, Premium, powder free, palm textured, natural, Size XS
131 133 11	VM Non-sterile Latex Examination Gloves, Premium, powder free, palm textured,
1314355T	natural, Size X
101 10001	VM Non-sterile Latex Examination Gloves, Premium, powder free, palm textured,
1314356T	natural, Size M
	VM Non-sterile Latex Examination Gloves, Premium, powder free, palm textured,
1314357T	natural, Size L
	VM Non-sterile Latex Examination Gloves, Premium, powder free, palm textured,
1314358T	natural, Size XL
101 10001	VM Non-sterile Latex Examination Gloves, powder free, finger textured, pale yellow,
1314359ST	Size XS
	VM Non-sterile Latex Examination Gloves, powder free, finger textured, pale yellow,
1314360ST	Size S
=	VM Non-sterile Latex Examination Gloves, powder free, finger textured, pale yellow,
1314361ST	Size M
1314362ST	VM Non-sterile Latex Examination Gloves, powder free, finger textured, pale yellow,
	Size L
1314363ST 1314432	VM Non-sterile Latex Examination Gloves, powder free, finger textured, pale yellow,
	Size XL
	VM Non-sterile Latex Examination Gloves, High Risk, powder free, palm textured,
	dark blue, Size S
1314433	VM Non-sterile Latex Examination Gloves, High Risk, powder free, palm textured,
	dark blue, Size M
4044404	VM Non-sterile Latex Examination Gloves, High Risk, powder free, palm textured,
1314434	dark blue, Size L
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Filename,	Revision:	
MDR DoC	Examination Gloves	VM,
Pov 1		



1314435	VM Non-sterile Latex Examination Gloves, High Risk, powder free, palm textured, dark blue, Size XL
1314436	VM Non-sterile Latex Examination Gloves, High Risk Plus, powder free, palm textured, dark blue, Size S
1314437	VM Non-sterile Latex Examination Gloves, High Risk Plus, powder free, palm textured, dark blue, Size M
1314438	VM Non-sterile Latex Examination Gloves, High Risk Plus, powder free, palm textured, dark blue, Size L
1314439	VM Non-sterile Latex Examination Gloves, High Risk Plus, powder free, palm textured, dark blue, Size XL

Place, Data of Issue:

Karlsruhe, 2021-05-26

Signature:

Michael Vogt, Managing Director

Haus R