

Atemschutzmaske

FFP2 NR

Modell CDP201B



EU-Konformitätserklärung



EU-Konformitätserklärung EU-Declaration of Conformity

Dokumenten-Nr. / Document No. **DOC_CEO598_DOC-NFC**

Wir / We **NEOLITHIC TECH CO., LTD.**
Building 1, No. 13, Shinan Road Nansha District, Guangzhou (China)

erklären in alleiniger Verantwortung, dass das Produkt
declare under our sole responsibility that the product

Partikelfiltrierende Halbmaske: FFP2 NR, Modell DOC-NFC
Particle filtering half mask: FFP2 NR, Modell DOC-NFC

mit der EU-Baumusterprüfbescheinigung
is in conformity with the EU-Type Examination Certificate

A18/000046

ausgestellt von der notifizierten Stelle
mit der Kenn-Nr. **0099**
issued by the Notified Body with Identification
No. 0099

AENOR INTERNACIONAL S.A.U.
Adresse: Génova, 6. 28004 Madrid. España

und mit der folgenden Harmonisierungsrechtsvorschrift der EU unter Anwendung der
aufgeführten Norm übereinstimmt:
and is in compliance with the following EU harmonisation legislation by application of the listed
standard

Bestimmungen der Verordnung <i>provisions of regulation</i>		Nummer sowie Ausgabedatum der Norm <i>Number and date of issue of standard</i>
Verordnung (EU) 2016/ 425	Verordnung über persönliche Schutzausrüstungen <i>Personal Protective Equipment Regulation</i>	EN 149: 2001 + A1:2009

Überwachung der Konformität mit der
Bauart auf der Grundlage einer internen
Fertigungskontrolle mit überwachten
Produktprüfungen in unregelmäßigen
Abständen (Modul D) durch:

Surveillance of conformity to type based on
Internal production control plus supervised
product checks at random intervals (Module
D) by:

SGS FIMKO OY, Notified Body 0598
Adresse: Takomotie 8, FI-00380, Helsinki, Finland

Zertifikat-No. **CN20/42172**
Certi

EU-Importeur: **Gesundheitsrondell GmbH, Austraße 30,**
EU-Importer: **74336 Brackenheim**

NEOLITHIC TECH CO., LTD.

Guangzhou / 11.01.2021

Ort und Datum
Place and date

李军 总经理

Name, Position, Stempel
Name, Function, Stamp

AENOR

Certificado de Examen UE de Tipo EU Type-Examination Certificate

A18/000046

AENOR, como organismo notificado (n° 0099) para el Reglamento (UE) 2016/425, ha emitido este certificado a favor de
In compliance with Regulation (EU) 2016/425, the notified body AENOR (n° 0099) has issued this certificate to

NEOLITHIC TECH CO., LTD.

Domicilio social / Registered office Building 1, No. 13, Shinan Road Nansha District, Guangzhou (China)

para el producto / for the product Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. / Respiratory protection devices. Half filter masks to protect against particles.

conforme con el Reglamento in compliance with Regulation Reglamento UE 2016/425 de Equipos de Protección Individual (Regulation EU 2016/425 on Personal Protective Equipment)

Norma armonizada / Harmonized standard EN 149:2001+A1:2009

Más información en el anexo / See annex for more information.

Centro de producción / Production site Building 1, No. 13, Shinan Road Nansha District, Guangzhou (China)

Esquema de evaluación Assessment scheme Anexo V (Examen UE de Tipo – Módulo B) del Reglamento (UE) 2016/425.

Annex V (EU Type-examination – Module B) of Regulation (EU) 2016/425.

Fecha de emisión / First issued on 2020-06-29
Fecha de expiración / Validity date 2025-06-29



Rafael GARCÍA MEIRO
Director General / CEO

Original Electronic Certificate

AENOR INTERNACIONAL S.A.U.
Génova, 6. 28004 Madrid. España
Tel. 91 432 60 00 - www.aenor.com

Organismo de control acreditado por ENAC con acreditación N° 1/C-PR354
Control body accredited by ENAC. Accreditation number 1/C-PR354

AENOR

Certificado de Examen UE de Tipo EU Type-Examination Certificate

A18/000046

Anexo al Certificado Annex to Certificate

Norma armonizada / Harmonized standard EN 149:2001+A1:2009

Marca Comercial / Trade Mark	Referencia / Reference	Clasificación / Classification	Descripción / Description
DOC	DOC-NFC	FFP2 NR	MEDIA MASCARILLA, DE CINCO CAPAS DE FILTRADO, DOS LAZOS FIJOS DE SUJECIÓN A OREJAS, DE TIPO PLEGABLE. DISEÑADA PARA PROTEGER CONTRA PARTÍCULAS SÓLIDAS O LÍQUIDAS SUSPENDIDAS EN EL AIRE. NO REUTILIZABLE / FILTERING HALF MASK, FIVE FILTERING LAYERS, TWO EARLOOPS, FOLDING STYLE. DESIGNED TO PROTECT AGAINST AIRBORNE SOLID OR LIQUID PARTICLES. NON-REUSABLE.

Fecha de emisión / First issued on 2020-06-29
Fecha de expiración / Validity date 2025-06-29

AENOR INTERNACIONAL S.A.U.
Génova, 6. 28004 Madrid. España
Tel. 91 432 60 00.- www.aenor.com

Organismo de control acreditado por ENAC con acreditación N° 1/C-PR354
Control body accredited by ENAC. Accreditation number 1/C-PR354

Original Electronic Certificate

SGS

Certificate CN20/42172

The management system of

NEOLITHIC TECH CO., LTD.

Building 1, No. 13, Shinan Road, Nansha District,
Guangzhou, Guangdong Province, 511400, P.R. China

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425

Module D

For the following activities

Manufacture of FFP1/FFP2 /FFP3 Protective Respirators
(Note: all products marked CE0598 must have a valid EU Type
Examination Certificates issued under Module B or a valid EC type-
examination certificate issued under Article 10 of the PPE Directive
89/686/EEC.)

This certificate is valid from 4 August 2020 until 3 August 2023
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 24 July 2023

Issue 1. Certified since 4 August 2020

Authorised by

Tom Toim

SGS FIMKO OY, Notified Body 0598

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FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

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extent of the law.

Testbericht zur Baumusterprüfung



国检检测
CHINA COMPONENTS TEST

Test Report

Report No.: [2020] WSZ FHL NO.5329

Product Name Filtering half mask

Applicant NEOLITHIC TECH CO.,LTD.

Manufacturer NEOLITHIC TECH CO.,LTD.

Test Type Entrusted inspection

Jiangsu Guojian Testing Technology Co., Ltd.
3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China

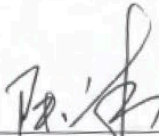
检验专用章

Testbericht zur Baumusterprüfung

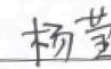
Report No.: [2020] WSZ FHL NO.5329

Test Report

Product name	Filtering half mask	Model name	Doc-NFC
		Brand	Doc
Laboratory/ Add.	Jiangsu Guojian Testing Technology Co., Ltd./ 3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China		
Applicant/ Add/Tel	NEOLITHIC TECH CO.,LTD./Room 108, Building 1, No. 13, Shinan Road, Nansha District, Guangzhou, China/18928760666		
Manufacturer/ Add/Tel	NEOLITHIC TECH CO.,LTD./Room 108, Building 1, No. 13, Shinan Road, Nansha District, Guangzhou, China/18928760666		
Sample classification	FFP2	Sample number	GW5329-2020
Sample quantity	110 pcs	Date of receipt of sample	08/05/2020
Test type	Entrusted inspection	Article/Batch/Style number	Doc-NFC
Date (s) of performance of tests	10/05/2020~22/05/2020	Testing location	Same as the Laboratory
Sample state	Meeting the requirements of testing	Sample description	Refer to page 3
Test standard(s)	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking		
Test items	Packaging, material, practical performance, finish of parts, compatibility with skin, flammability, carbon dioxide content of the inhalation air, head harness, field of vision, penetration of filter material, breathing resistance, total inward leakage		
Test conclusion	The samples upon testing comply with FFP2 classification requirements according to the standard EN 149:2001+A1:2009. The details of test results see on Pages 3-11. Date of issue: 13/06/2020		
Note	The test results presented in this report relate only to the submitted sample as received.		

Lu Bing 
Approver (name, signature)

Wan Heng 
Reviewer (name, signature)

Yang Ying 
Chief Tester (name, signature)

Testbericht zur Baumusterprüfung

Report No.: [2020] WSZ FHL NO.5329

Sample description:	Doc-NFC
Test item particulars:	
Type of use	☐ re-useable particle filtering half mask ☒ single shift only particle filtering half mask
Classes of devices.....	☐ FFP1 ☒ FFP2 ☐ FFP3
Exhalation valve(s).....	☐ Yes ☒ No
Inhalation valve(s).....	☐ Yes ☒ No
Designed to protect against both solid & liquid aerosols. :	☒ Yes ☐ No
Possible test case verdicts:	
- Test case does not be required to the test object.....: NRq (Not required)	
- Test case does not apply to the test object.....: N/A (Not Applicable)	
- Test object does meet the requirement.....: P (Pass)	
- Test object does not meet the requirement.....: F (Fail)	
General remarks:	
The test results presented in this report relate only to the submitted sample as received. This report shall not be reproduced, except in full, without the written approval of the issuing Laboratory can provide assurance that parts of a report are not taken out of context. Determination of the test results includes consideration of measurement uncertainty from the test equipment and methods. Throughout this report a ☐ comma / ☒ point is used as the decimal separator.	
Environmental condition of the testing in this report:	
1) Unless otherwise specified, the ambient temperature for testing shall be 25 °C;	
2) T.C. Temperature conditioned:	
a) for 24 h to a dry atmosphere of 70 °C; b) for 24 h to a temperature of -30 °C;	
and return to room temperature 25 °C for 4 h between exposures and prior to subsequent testing.	

Testbericht zur Baumusterprüfung

Report No.: [2020] WSZ FHL NO.5329

S.No. (Cl.No.)	Test item		Unit	Technical requirements	Test result	Single item decision
1 (7.3)	Visual inspection	Marking/ information	—	Marking and the information supplied by the manufacturer, requirements refer to Cl.9 and Cl.10	The clause were not required	NRq
2 (7.4)	Packaging	Visual inspection	—	Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Particle filtering half masks packaged and protected against mechanical damage and contamination.	Pass
3 (7.5)	Material	Visual inspection	—	Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.	Materials were suitable withstand handling and wear.	Pass
			—	After undergoing S.W., none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Sample 1: neither facepiece nor straps have mechanical failure	
					Sample 2: neither facepiece nor straps have mechanical failure	
					Sample 3: neither facepiece nor straps have mechanical failure	
			—	After undergoing S.W. and T.C., none of the particle filtering half masks shall not collapse.	Sample 4: no collapse	
					Sample 5: no collapse	
			—	Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Sample 6: no collapse	
					Not constitute a hazard or nuisance for the wearer	
4 (7.6)	Cleaning and disinfecting		—	Particle filtering half mask designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. Testing shall be done in accordance with 8.4 and 8.5.	☐ Fulfil the requirements after testing, or ☒ The Particle filtering half mask is NOT re-usable according to information supplied by manufacturer	N/A
			—	With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class. Testing shall be done in accordance with 8.11.	☐ Tests results refer to S. No. 7(7.9.2), or ☒ The Particle filtering half mask is NOT re-usable according to information supplied by manufacturer	

Testbericht zur Baumusterprüfung

Report No.: [2020] WSZ FHL NO.5329

S.No. (CLNo.)	Test item		Unit	Technical requirements	Test result				Single item decision
5 (7.7)	Practical performance	Head harness comfort	—	Head harness should be comfort.	Sample 1: has the feeling of comfortable wearing				Pass
					Sample 2: has the feeling of comfortable wearing				
		Security of fastenings	—	Fastenings are safe and reliable	Sample 1: All fastenings are firm				
					Sample 2: All fastenings are firm				
		Field of vision	—	Field of vision is acceptable	Sample 1: Having a wider visual field				
					Sample 2: Having a wider visual field				
6 (7.8)	Finish of parts	Visual inspection	—	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Parts of the device have no sharp edges and burrs				Pass
7 (7.9.2)	Leakage— Penetration of filter material	Sodium chloride	—	$\leq 6\%$	A.R. ¹⁾	0.1%	0.1%	0.1%	Pass
					S.W. ¹⁾	0.2%	0.1%	0.1%	
					M.S+ T.C. ²⁾	0.3%	0.3%	0.3%	
		Paraffin oil	—	$\leq 6\%$	A.R. ¹⁾	0.2%	0.2%	0.3%	Pass
					S.W. ¹⁾	0.2%	0.3%	0.3%	
					M.S+ T.C. ²⁾	1.2%	1.2%	1.4%	
		1) average penetration over a time of 30s, beginning 3 min after the start of the test reported							
		2) max. penetration during exposure test reported;							
		Note:							
		The penetration of the filter of the particle filtering half mask shall meet the requirements below:							
Maximum penetration of sodium chloride aerosol test 95 L/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%									
Maximum penetration of paraffin oil aerosol test 95 L/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%									

Testbericht zur Baumusterprüfung

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S.No. (Cl.No.)	Test item	Unit	Technical requirements	Test result		Single item decision
8 (7.10)	Compatibility with skin	—	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	A.R.	5 pcs all don't cause irritation	Pass
				T.C.	5 pcs all don't cause irritation	
9 (7.11)	Flammability	—	When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5s after removal from the flame.	A.R.	The Sample is burning. Burning time:0.1s	Pass
					The Sample is burning. Burning time:0.1s	
				T.C.	The Sample is burning. Burning time:0.1s	
					The Sample is burning. Burning time:0.1s	
10 (7.12)	Carbon dioxide content of the inhalation air	—	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume). Remark: 3 half masks (S1, S2 and S3) A.R. tested.	Sample 1	0.6370%	Pass
				Sample 2	0.6330%	
				Sample 3	0.6340%	
				average	0.63%	
11 (7.13)	Head harness	—	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position	A.R.	All of 5 pieces particle filtering half mask meet the requirements	Pass
				T.C.	All of 5 pieces particle filtering half mask meet the requirements	
12 (7.14)	Field of vision	—	The field of vision is acceptable if determined so in practical performance tests.	The two samples both have a wider visual field		Pass

Testbericht zur Baumusterprüfung

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S.No (Cl.No.)	Test item		Unit	Technical requirements	Test result	Single item decision
13 (7.15)	Exhalation valve(s)	Visual inspection	—	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	No exhalation valve(s)	N/A
			—	If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage, and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.	No exhalation valve(s)	
		Flow conditioning	—	Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.	No exhalation valve(s)	
		Strength of attachment of exhalation valve housing	—	When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.	No exhalation valve(s)	
14 (7.17)	Clogging— Breathing resistance & Penetration of filter material		—	Optional for single shift use devices, mandatory for re-usable devices. Tested by Cl. 7.17.1/2/3.	☐ Tests results refer to Table C&D, or ☒ Tests not requested for single shift use face mask	N/A
15 (7.18)	Demountable parts		—	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	No demountable parts	N/A

Testbericht zur Baumusterprüfung

Report No.: [2020] WSZ FHL NO.5329

Table A- Leakage—Total Inward Leakage

S.No. (CLNo.)	Test item	Unit	Technical requirements ¹⁾	Test result							Single item decision
16 (7.9.1)	Leakage— Total inward leakage	—	At least 46 out of the 50 individual exercise results shall be not greater than 11% ; And in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 8%.	Exercises	E1 (%)	E2 (%)	E3 (%)	E4 (%)	E5 (%)	TIL (%)	Pass
				A.R.	6.2	6.9	6.8	6.7	6.2	6.6	
					5.8	6.5	6.2	6.2	5.8	6.1	
					6.6	7.4	7.1	7.3	6.7	7.0	
					6.1	7.0	7.1	7.1	6.4	6.7	
					6.2	6.5	7.0	6.6	6.2	6.5	
				T.C.	6.4	7.3	7.1	7.3	6.7	7.0	
					6.2	6.9	7.0	6.8	6.2	6.6	
					6.1	7.0	7.3	7.0	6.5	6.8	
					5.7	6.4	6.5	6.6	6.1	6.3	
6.2	6.6	6.7	6.8		6.2	6.5					

Note 1:

at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than 25 % for FFP1 11 % for FFP2 5 % for FFP3
in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 22 % for FFP1 8 % for FFP2 2 % for FFP3.

Table A-1- Test subjects—Facial dimension

Test Subject No.	Length of face (mm)	Width of face (mm)	Depth of face (mm)	Width of mouth (mm)
1	120	130	109	59
2	122	140	115	65
3	119	160	139	55
4	112	122	119	63
5	110	130	118	60
6	115	119	110	59
7	112	123	113	55
8	103	130	100	50
9	118	139	130	63
10	120	135	125	50

Testbericht zur Baumusterprüfung

Report No.: [2020] WSZ FHL NO.5329

Table C- Clogging Test—Breathing resistance

S.No. (CLNo.)	Test item ^(1,2)		Unit	Technical requirements ^(1,2) (mbar)	Test result						Single item decision
					Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	
18 (7.17)	Clogging test—	Inhalation 95 L/min	mbar	—	A.R.						N/A
					T.C.						
	Breathing resistance	Exhalation 95 L/min	mbar	—	A.R.						N/A
					T.C.						

Note 1: Valved particle filtering half masks

After clogging the inhalation resistances shall not exceed FFP1: 4 mbar FFP2: 5 mbar FFP3: 7 mbar at 95 L/min continuous flow;
The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow.

Note 2: Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed FFP1: 3 mbar, FFP2: 4 mbar FFP3: 5 mbar at 95 L/min continuous flow.

Table D- Clogging Test—Penetration of filter material

S.No. (CLNo.)	Test item	Unit	Technical requirements	Test result		Single item decision
19 (7.17)	Clogging test- Penetration of filter material	Paraffin oil	—	A.R.		N/A
				T.C.		
				T.C.		

Note: Maximum penetration of test aerosol test 95 L/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%

Abbreviations :

A.R. As received

M.S. Mechanical strength

S.W. Simulated wearing treatment

T.C. Temperature conditioned

F.C. Flow conditioned

C.D. Cleaning and Disinfecting

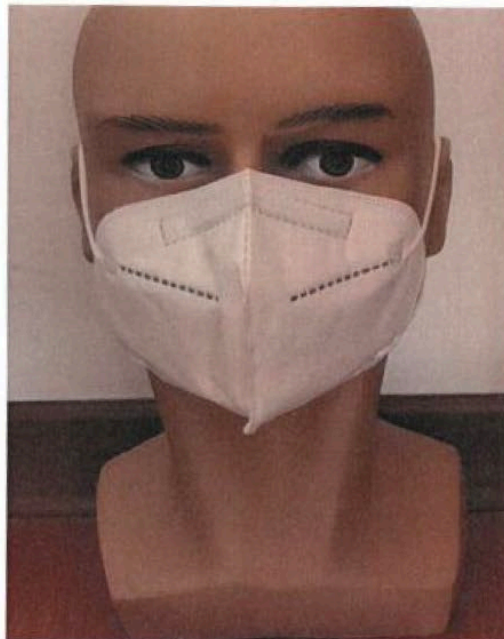
Testbericht zur Baumusterprüfung

Report No.: [2020] WSZ FHL NO.5329

Annex A- Estimates of the uncertainty of measurement

Test item	Uncertainty
Total inward leakage	2.98%
Penetration of filter material	1.00%
Flammability	1.00%
Carbon dioxide content of the inhalation air	0.93%
Breathing resistance	1.90%

Annex B- Sample Photo



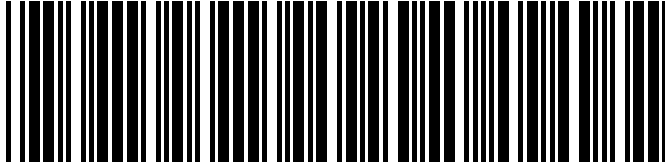
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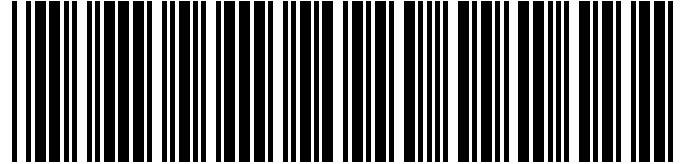
Pharmazentralnummer des Artikels

PZN 1 Stück Verkaufsverpackung



PZN - 17195396

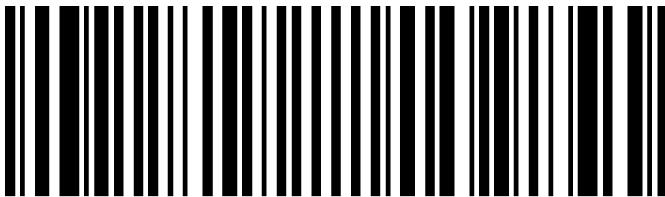
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PZN - 17195404

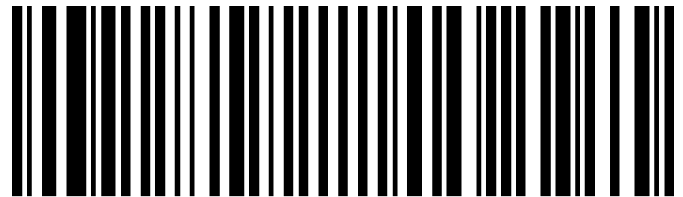
Global Trade Item Number (GTIN)

GTIN 1 Stück Verkaufsverpackung



(01)04270002175624

GTIN 50 Stück Verkaufsverpackung



(01)04270002175631

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