

Product:	GentleSafe® Nitrile	
Trademark:	SAFE®	
REF:	883/B 883/BK	
Manufacturer:	DACH Schutzbekleidung GmbH & Co. KG	

Classification:	CAT III according to Regulation (EU) 2016/425 for personal protective equipment (PPE). Class I according to Regulation (EU) 2017/745 for medical devices; UMDNS code: 11-882.		
Materials:	Carboxylated nitrile butadiene rubber		
Product description:	The nitrile glove is liquid impermeable, powder-free and free of natural latex. It offers excellent dexterity with high comfort (dexterity level 5/5). High elasticity with low effort. No hand fatigue. Ambidextrous wearable, with rolled edge, non-sterile, excellent tactile sensation. Textured surface on the fingertips. Excellent grip, even when handling wet or moist objects. Excellent performance against chemicals and tested against cytostatics, viruses, bacteria and fungi. Also suitable for food contact.		
Pictograms and standards:			
Product performance:	<i>Testing against chemicals</i>		
	EN ISO 374-1:2016+A1:2018 and EN 16523-1:2015+A1:2018		
	Chemical	Level	EN ISO 374-4:2019 Degradation %
	40% Sodium Hydroxide (K)	6	-8.3
	30% Hydrogen Peroxide (P)	2	34.1
	37% Formaldehyde (T)	4	34.3
	Testing against infective agents accordingly EN ISO 374-5:2016 and ISO 16604:2004		

	Protection against bacteria and fungi	Pass	
	Protection against viruses	Pass	
	Determination of resistance to penetration accordingly EN 374-2:2014		
	Air leak test	Pass	
	Water leak test	Pass	
	Testing against the permeation of cytostatic drugs		
	ASTM D6978-05(2019)		
	Chemical	Minimum breakthrough detection time (Specimen 1/2/3) (Minutes)	Average steady state permeation rate (Specimen 1/2/3) (µg/cm²/Minute)
	Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	14.7 (15.1, 14.7, 16.8)	0.6 (0.5, 0.5, 0.7)
	Cisplatin, 1 mg/ml (1,000 ppm)	>240	N/A
	Cylophosphamid (Cytoxan) 20.0 mg/ml (20,000 ppm)	>240	N/A
	Dacarbazine 10.0 mg/ml (10,000 ppm)	>240	N/A
	Doxorubicin HCl 2 mg/ml (2,000 ppm)	>240	N/A
	Etoposide 20.0 mg/ml (20,000 ppm)	>240	N/A
	Fluorouracil 50.0 mg/ml (50,000 ppm)	>240	N/A
	Ifosfamide 50.0 mg/ml (50,000 ppm)	>240	N/A
	Methotrexate 25 mg/ml (25,000 ppm)	>240	N/A
	Mitomycin C 0.5 mg/ml (500 ppm)	>240	N/A
	Mitoxantrone 2.0 mg/ml (2,000 ppm)	>240	N/A

	Paclitaxel 6.0 mg/ml (6,000 ppm)	>240	N/A
	ThioTepa 10.0 mg/ml (10,000 ppm)	58.8 (110.0, 58.8, 67.0)	0.5 (0.3, 0.5, 0.6)
	Vincristine Sulfate 1.0 mg/ml (1,000 ppm)	>240	N/A
	Dexterity and innocousness of material testing		
	EN ISO 21240:2020		
	Dexterity	Level 5	
	pH Level	Pass	
	Polycyclic Aromatic Hydrocarbons Content	Not detected - Pass	
	Food safety testing		
	Resolution ResAP (2004) 4 and Regulation (EG)1935/2004		
	Overall migration	Pass	
	Specific migration of primary aromatic amine	Pass	
	Specific migration of nitrosamine and nitrosatable substances	Pass	
	Medical examination gloves testing		
	Standard	Test	Result
	EN 455-1:2000	Freedom from holes	Pass
	EN 455-2:2015	Physical properties:	Pass
	Partial tests	Length: ≥ 240 mm	246 mm
		Width S: 80±10 mm	83 mm
		Width M: 95±10 mm	93 mm
		Width L: 110±10 mm	104 mm
		Width XL: ≥ 110 mm	114 mm
		Force at break: ≥ 6.0 N	≥ 6.0 N

		Force at break after challenge testing: ≥ 6.0 N	≥ 6.0 N
	EN 455-3:2015	Labelling	Pass
	Partial tests	Gloves shall not be dressed with talcum powder (magnesium silicate)	Pass
		Powder residues < 2mg	0,8 mg
	EN 455-4	Shelf life	Pass
Thickness:	Cuff: 0,06 mm; Palm: 0,07 mm; Finger: 0,10 mm (± 0,02 mm)		
Weight:	S: 3,0g, M: 3,5g, L: 3,9g, XL: 4,3g (± 0,3g)		
Physical properties	Tensile strength before ageing: ≥ 14 MPa Tensile strength after ageing: ≥ 14 MPa Elongation before ageing: ≥ 500% Elongation after ageing: ≥ 400%		
Other features:	 No intolerance reactions: This product does not contain natural latex.  Non sterile.		
Color:	Blue, Black (For White color variant, please refer to the separate data sheet)		

Packaging and variants:	Packaging	Quantity
	Dispenser box	100 pcs.
	Shipping Carton	1000 pcs.
	Pallet	108.000 pcs.
GTIN:	883/B/S	4049825007616
	883/B/M	4049825007623
	883/B/L	4049825007630

	883/B/XL	4049825007647
	883/BK/S	4049825007692
	883/BK/M	4049825007708
	883/BK/L	4049825007715
	883/BK/XL	4049825007722
Limitation:	The gloves are designed for single use. The duration of protection in working use may differ from the breakthrough time determined according to EN 374, as it depends on the working conditions.	
Storage:	Store in a dry place without direct sunlight in the original packaging (see packaging). If the storage conditions are observed, the product has a storage life of 5 years (see labeling on the product).	
Environmental sustainability and disposal:	In the case of contaminated products, the type and extent of contamination determines the disposal, and the applicable laws and regulations of the relevant country must be followed. A non-contaminated product can be thermally recycled or disposed of in landfills without releasing toxic substances. The recyclable packaging (dispenser box and shipping carton) is made of cardboard.	