







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:	<p>The nitrile glove is liquid impermeable, powder-free and free of natural latex.</p> <p>It offers excellent dexterity with high comfort (dexterity level 5/5). High elasticity with low effort. No hand fatigue.</p> <p>Ambidextrous wearable, with rolled edge, non-sterile, excellent tactile sensation.</p> <p>Textured surface on the fingertips. Excellent grip, even when handling wet or moist objects.</p> <p>Excellent performance against chemicals and tested against cytostatics, viruses, bacteria and fungi.</p> <p>Also suitable for food contact.</p>		
Pictograms and standards:	<div><div><div>EN ISO 374-1:2016 TYPE B</div><div></div><div>KPT</div></div><div><div>EN ISO 374-5:2016</div><div></div><div>VIRUS</div></div><div><div>CAT 3</div><div>EN 21420</div></div><div><div>AQL 1,5</div><div>EN 455</div></div><div><div>ASTM 1671</div><div>ASTM D7160</div></div><div></div></div>		
Product performance:	Testing against chemicals		
	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 (Cytosan) 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:	<div>  <p>No intolerance reactions: This product does not contain natural latex.</p> </div> <div>  <p>Virus-tight according to ASTM 1671: Determination of the resistance of materials to the penetration of viral pathogens.</p> </div> <div>  <p>Non sterile.</p> </div>		
Color:	Blue, Black (For White color variant, please refer to the separate data sheet)		

Packaging and variants:	Packaging	Quantity
	Dispenser box	100 Stk.
	Shipping Carton	1000 Stk.
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:	<p>The gloves are designed for single use.</p> <p>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.</p>	
Storage:	<p>Store in a dry place without direct sunlight in the original packaging (see packaging).</p> <p>If the storage conditions are observed, the product has a storage life of 5 years (see labeling on the product).</p>	
Environmental sustainability and disposal:	<p>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.</p> <p>A non-contaminated product can be thermally recycled or disposed of in landfills without releasing toxic substances.</p> <p>The recyclable packaging (dispenser box and shipping carton) is made of cardboard.</p>	