




<b>Product:</b>	GentleSafe® EXTRA	
<b>REF:</b>	865/B 865/W 865/BK	
<b>Manufacturer:</b>	DACH Schutzbekleidung GmbH & Co. KG	

<b>Classification:</b>	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.		
<b>Materials:</b>	Carboxylated nitrile butadiene rubber		
<b>Product description:</b>	<p>Extra-long nitrile examination and protective glove for increased safety when handling chemicals.</p> <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, 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 accordingly (EG) Nr.1935/2004.</p>		
<b>Pictograms and standards:</b>			
<b>Product performance:</b>	<i>Testing against chemicals</i>		
	<b>EN ISO 374-1:2016+A1:2018 and EN 16523-1:2015+A1:2018</b>		
	Chemical	Level	EN ISO 374-4:2019 Degradation %
	40% Sodium Hydroxide (K)	6	-11.5

	30% Hydrogen Peroxide (P)	2	-9.5
	37% Formaldehyde (T)	3	7.4
	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 3.3 mg/ml (3,300 ppm)	12.1 (18.9, 19.7, 12.1)	0.6 (0.4, 0.5, 0.4)
	Cisplatin 1 mg/ml (1,000 ppm)	>240	N/A
	Cylophosphamide 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
	Fentanyl Citrate Injection 100mcg/2mL	>240	N/A
	Fluorouracil 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
	Paclitaxel 6.0 mg/ml (6,000 ppm)	>240	N/A
	ThioTepa 10.0 mg/ml (10,000 ppm)	10.1 (12.0, 12.4, 10.1)	0.7 (0.7, 0.5, 0.8)
	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: ≥ 300 mm	308 mm
		Width S: 80±10 mm	84 mm

		Width M: 95±10 mm	95 mm
		Width L: 110±10 mm	104 mm
		Width XL: ≥ 110 mm	113 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	1,0 mg
	EN 455-4	Shelf life	Pass
<b>Thickness:</b>	Cuff: 0,05 mm; Palm: 0,06 mm; Finger: 0,10 mm (± 0,02 mm)		
<b>Weight:</b>	S: 3,0g, M: 3,5g, L: 3,9g, XL: 4,3g (± 0,3g)		
<b>Physical properties</b>	Tensile strength before ageing: ≥ 14 MPa Tensile strength after ageing: ≥ 14 MPa Elongation before ageing: ≥ 500% Elongation after ageing: ≥ 400%		
<b>Other features:</b>	 No intolerance reactions: This product does not contain natural latex.   Non sterile.		
<b>Color:</b>	Blue, Black, White		

Packaging and variants:	Packaging	Quantity
	Dispenser box	100 pcs.

	Shipping Carton	1000 pcs.	
	Pallet	63.000 pcs.	
GTIN:	REF	Primary packaging (dispenser box)	Secondary packaging (shipping carton)
	Blue colour variant:		
	865/B/XS	4049825008460	4049825508458
	865/B/S	4049825008477	4049825508465
	865/B/M	4049825008484	4049825508472
	865/B/L	4049825008491	4049825508489
	865/B/XL	4049825008507	4049825508496
	865/B/XXL	4049825008729	4049825508717
	White colour variant:		
	865/W/XS	4049825008514	4049825508502
	865/W/S	4049825008521	4049825508519
	865/W/M	4049825008538	4049825508526
	865/W/L	4049825008545	4049825508533
	865/W/XL	4049825008552	4049825508540
	865/W/XXL	4049825008569	4049825508557
	Black colour variant:		
	865/BK/XS	4049825008576	4049825508564
	865/BK/S	4049825008583	4049825508571
	865/BK/M	4049825008590	4049825508588
	865/BK/L	4049825008606	4049825508595
	865/BK/XL	4049825008613	4049825508601

	865/BK/XXL	4049825008620	4049825508618
<b>Limitation:</b>	<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>		
<b>Storage:</b>	<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>		
<b>Environmental sustainability and disposal:</b>	<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>		