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<b>Trademark:</b>	SAFE®	
<b>REF:</b>	878	
<b>Manufacturer:</b>	DACH Schutzbekleidung GmbH & Co. KG	

<b>Classification:</b>	CAT III of Regulation (EU) 2016/425 for personal protective equipment (PPE). Class I of Regulation (EU) 2017/745 for medical devices; UMDNS code: 11-882.												
<b>Materials:</b>	Carboxylated nitrile butadiene rubber												
<b>Product description:</b>	<p>The nitrile glove is powder-free, latex-free and impervious to liquids.</p> <p>It offers excellent dexterity with high comfort and maximum dexterity (level 5/5). High elasticity with low effort. No hand fatigue.</p> <p>Ambidextrous wear, 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, especially cytostatics and solvents, acids and bases, oxidizing agents, viruses, bacteria and fungi. Suitable for contact with foodstuff.</p>												
<b>Pictograms and standards:</b>	<table border="0"> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>												
													
													

<b>Product performance:</b>	Testing against chemicals
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<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	-3.9
30% Hydrogen Peroxide (P)	1	8.1
40% Acrylamide	6	NT
1% Ethidium Bromide	6	NT
NT = not tested		
<b>Testing against infective agents accordingly EN ISO 374-5:2016 and ISO 16604:2004</b>		
Protection against bacteria and fungi	Pass	
Protection against viruses	Pass	
<b>Determination of resistance to penetration accordingly EN 374-2:2014</b>		
Air leak test	Pass	
Water leak test	Pass	
<i>Testing against the permeation of cytostatic drugs</i>		
<b>ASTM D6978-05(2019)</b>		
Chemical	Minimum breakthrough detection time (Specimen 1/2/3) (Minutes)	Average steady state permeation rate (Specimen 1/2/3) (µg/cm <sup>2</sup> /Minute)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	14.9 (16.9, 14.9, 14.3)	0.5 (0.6, 0.5, 0.5)
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
Paclitaxel 6.0 mg/ml (6,000 ppm)	>240	N/A
ThioTepa 10.0 mg/ml (10,000 ppm)	17.1 (17.2, 17.1, 18.5)	0.9 (0.9, 0.9, 0.8)
<i>Dexterity and innocuousness of material testing</i>		
<b>EN ISO 21420:2020</b>		
Dexterity		Level 5
pH Level		Pass
Polycyclic Aromatic Hydrocarbons Content		Not detected - Pass
<i>Food safety testing</i>		
<b>Resolution ResAP (2004) 4 and Regulation (EG)1935/2004</b>		
Overall migration		Pass
Specific migration of primary aromatic amine		Pass
Specific migration of nitrosamine and nitrosatable substances		Pass
<i>Medical examination gloves testing</i>		
Standard	Test	Result
EN 455-1:2000	Freedom from holes	Pass
EN 455-2:2015	Physical properties:	Pass
Partial tests	Length: $\geq 240$ mm	246 mm
	Width S: $80 \pm 10$ mm	84 mm
	Width M: $95 \pm 10$ mm	94 mm
	Width L: $110 \pm 10$ mm	104 mm
	Width XL: $\geq 110$ mm	113 mm

	Force at break: $\geq 6.0$ N	9,25 N	
	Force at break after challenge testing: $\geq 6.0$ N	9,1 N	
	EN 455-3:2015	Labelling	Pass
	Partial tests	Gloves shall not be dressed with talcum powder (magnesium silicate)	Pass
		Powder residues < 2mg	0,23 mg
EN 455-4	Shelf life	Pass	
<b>Thickness:</b>	Cuff: 0.05 mm; Palm: 0.06 mm; Finger: 0.11 mm ( $\pm 0.02$ mm)		
<b>Weight:</b>	S: 3,2g, M: 3,5g, L: 3,8g, XL: 4,2g ( $\pm 0,2$ g)		
<b>Physical properties:</b>	Tensile strength before ageing: $\geq 14$ MPa Tensile strength after ageing: $\geq 14$ MPa Elongation before ageing: $\geq 500\%$ Elongation after ageing: $\geq 400\%$		
<b>Other features:</b>	 No intolerance reactions: This product does not contain natural latex.   Non sterile.		
<b>Color:</b>	Blue, White, Black		

Packaging and variants:	Quantity	Packaging
	200 pcs.	Dispenser box
	2000 pcs.	Shipping carton
<b>GTIN:</b>	<b>878/B/S</b>	4049825006725
	<b>878/B/M</b>	4049825006732
	<b>878/B/L</b>	4049825006749

	<b>878/B/XL</b>	4049825006756
	<b>878/BK/S</b>	4049825006763
	<b>878/BK/M</b>	4049825006770
	<b>878/BK/L</b>	4049825006787
	<b>878/BK/XL</b>	4049825006794
	<b>878/W/S</b>	4049825006800
	<b>878/W/M</b>	4049825006817
	<b>878/W/L</b>	4049825006824
	<b>878/W/XL</b>	4049825006831
<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>	