








<b>Manufacturer:</b>	DACH Schutzbekleidung GmbH & Co. KG	
<b>Trademark:</b>	EcoComfort®	
<b>Product:</b>	GentleSafe® Nitrile Extra	
<b>REF:</b>	873	

<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.			
<b>Materials:</b>	100% nitrile, textured surface on the fingertips - improved grip safety.			
<b>Product description:</b>	<p>The nitrile glove is powder-free, impermeable to liquids and offers excellent dexterity with high wearing comfort.</p> <p>Ambidextrous, rolled edge, non-sterile, excellent tactile sensitivity.</p> <p>EXTRA longer glove for even more safety against chemicals and EXTRA wearing comfort.</p> <p>Suitable for contact with foodstuff.</p>			
<b>Pictograms and standards:</b>	<p>EN ISO 374-5:2016</p> 	<p>EN ISO 374-1:2016 TYPE C</p> 	<p>CAT 3</p>	<p>AQL 1,5</p>

<b>Product performance:</b>	<i>Testing against chemicals</i>			
	<b>EN ISO 374-1:2016/Type C and EN 16523-1:2015</b>			
	Chemical	Permeation breakthrough time (minutes)	Level	<b>EN ISO 374-4:2019</b> Degradation %
	25% Ammonium hydroxide (O)	>10	1	60,8
	40% Sodium hydroxide (K)	>480	6	-10,1

37% Formaldehyde (T)	>480	6	45,4
<b>Testing against infective agents accordingly EN ISO 374-5:2016 and ISO 16604:2004</b>			
Protection against bacteria and fungi			Passed
Protection against viruses (ISO 16604)			Passed
<b>Determination of resistance to penetration accordingly EN 374-2:2014</b>			
Air leak test			Passed
Water leak test			Not applicable
<i>Testing against the permeation of cytostatic drugs</i>			
<b>ASTM D 6978-05</b>			
Chemical	Minimum breakthrough detection time (Specimen 1/2/3) (Minutes)	Steady state permeation rate (Specimen 1/2/3) (µg/cm²/Minute)	
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	18.2 (18.2, 24.6, 18.6)	0.3 (0.3, 0.3, 0.4)	
Cisplatin 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	
Cyclophosphamide (Cytoxan) 20 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	
Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	
Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	
Etoposide (Toposar) 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	
Fluorouracil 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	
Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	
Thiotepa 10.0 mg/ml (10,000 ppm)	57.3 (80.7, 57.3, 69.4)	0.5 (0.4, 0.5, 0.5)	

<i>Dexterity and innocuousness of material testing</i>		
<b>EN 420:2003+A1:2009</b>		
Dexterity		Level 5
pH Level		Pass
Polycyclic Aromatic Hydrocarbons Content		Not detected - pass
<i>Food safety testing</i>		
<b>Resolution ResAP (2004) and EN 1186</b>		
Overall migration		Pass
<i>Medical examination gloves testing</i>		
Standard	Test	Result
EN 455-1:2000	Freedom from holes	Pass
EN 455-2	Physical properties:	Pass
Partial tests	Length: $\geq 240$ mm	300 mm
	Width S: $80 \pm 10$ mm	85 mm
	Width M: $95 \pm 10$ mm	95 mm
	Width L: $110 \pm 10$ mm	105 mm
	Width XL: $\geq 110$ mm	115 mm
	Force at break: $\geq 6.0$ N	8,5 N
	Force at break after challenge testing: $\geq 6.0$ N	7,8 N
EN 455-3:2015	Labelling	Pass
Partial tests	Gloves shall not be dressed with talcum powder (magnesium silicate)	Pass
	Powder residues < 2mg	0,54 mg
EN 455-4	Shelf life	Pass

<b>Thickness:</b>	Cuff: 0.07 mm; Palm: 0.10 mm; Finger: 0.15 mm ( $\pm$ 0.02 mm)	
<b>Weight:</b>	S: 6,0g, M: 6,5g, L: 7,0g, XL: 7,5g ( $\pm$ 0,2g)	
<b>Other features:</b>	<div>  <p>No intolerance reactions: This product does not contain natural latex.</p> <div>    </div> <p>Non sterile.</p> </div>	
<b>Color:</b>	Blue	
<b>Packaging and variants:</b>	<b>Packaging</b>	<b>Quantity</b>
	Dispenser box	100 pcs.
	Shipping carton	1000 pcs.
<b>GTIN:</b>	<b>873/S</b>	4049825002079
	<b>873/M</b>	4049825002086
	<b>873/L</b>	4049825002093
	<b>873/XL</b>	4049825002109
<b>Restriction:</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 dry in original packaging without direct sunlight. (see packaging)</p> <p>If the storage conditions are observed, the product has a storage life of 3 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>	