

# PRODUCT INFORMATION PROTECTIVE GLOVE Manu N

Nitrile protective gloves for handling chemicals, cytotoxic drugs and microbiological agents

## Application range

**Maximum protection and comfortable to wear:** Type-tested and certified as complex PPE<sup>1)</sup> of the highest category III; good grip; good tactile sensitivity; ambidextrous.

**Application range:** Chemical protective gloves for handling chemicals, CMR<sup>2)</sup> drugs (e.g. cytostatics) and microorganisms.

**Protective properties:** Protective gloves for handling tested substances (in accordance with permeation results - test sheet) and biological agents<sup>3)</sup>. Protection against all CMR drugs and chemicals cannot be guaranteed!

**Glove replacement interval:** Recommendation for Germany, in accordance with M620, BGW and DGOP: Change every 30 minutes. In other countries in accordance with the test results and national /local regulations. Immediately in case of visible contamination. Single use!

Protective glove material: Nitrile.

**Before use:** Check for damage! Do not use damaged gloves!

**Disposal:** Assignment of waste to European waste codes (EWC) for human or animal health care and / or related research, based on directive 2000/532/EC.

## Waste code in accordance to European waste catalogue

Substance	Hazardous potential - Human		Hazardous potential - Animal	
	Low	High	Low	High
CMR-drugs	180101	180108*	180203	180207*
Microorganisms	180104	180103*	180203	180202*

\* Dangerous or waste needing special supervision. <sup>1)</sup> Personal protective equipment – (EU) 2016/425.

<sup>2)</sup> Carcinogenic mutagenic reproductive toxic. <sup>3)</sup> Microorganism and infectious agents as in EN 374-1: e.g. bacteria and fungi.

## Versions

Size	XS or 6	S or 7	M or 8	L or 9	XL or 10
Item No. (non-sterile – 100 pieces)	3010	3015	3020	3025	3030
Item No. (sterile - 100 pairs)	100248	100249	100250	100251	100252
Length of gloves (EN 420)	290 ± 10 mm				

## Flexibility

Dexterity tested in accordance with EN 21420:2020

Performance level	Level 5 (highest level)
Smallest diameter <sup>1)</sup>	5 mm

<sup>1)</sup> Smallest diameter of the pin, to meet the test conditions.

**AQL (Acceptable Quality Level)** AQL<sup>1)</sup>= 1.5

<sup>1)</sup> Penetration test according to EN 374-2:2014; specification according to standard: ≤ 1.5

## The following allergens are not present:

Substance		Measured value [ $\mu\text{g/g}$ ] <sup>1)</sup>
<b>Thiurame:</b>	Tetramethylthiuram disulfide (TMTD)	n.d.
	Mercaptobenzothiazole (MBT)	n.d.
	Zinc mercaptobenzothiazole (ZMBT)	n.d.
	Zinc mercaptobenzimidazole (ZMBI)	n.d.
<b>Dithiocarbamate</b>	Zinc dibutyl dithiocarbamate (ZDBC)	n.d.
	Zinc dibutyl dithiocarbamate (ZDEC)	n.d.
	Zinc pentamethylene dithiocarbamate	n.d.
<b>p-Phenylendiamine</b>	Diphenylthiourea (DPT)	n.d.
	Diphenylguanidine (DPG)	n.d.
<b>Other:</b>	Butylated hydroxytoluene (BHT)	n.d.
	Butylated hydroxyanisole (BHA)	n.d.

<sup>1)</sup> n.d.: Not detectable, i.e. the allergen was not detected or the measured value was below the determined threshold value.

## Material

Special nitrile mixture

Colour Light blue

## Material thickness

Measuring points	Material thickness d
Finger, 15 mm from the end of the tip	$\geq 0,14$ mm
Middle of the palm	$\geq 0,09$ mm

## Protection from chemical hazards

Permeation<sup>1)</sup> according to EN ISO 374-1:2016; test method EN 16523-1:2015. Degradation according to EN 374-4:2013. Breakthrough times<sup>2)</sup> [min] / performance classes<sup>3)</sup> (1-6) were determined for the following chemicals:

Chemical	Breakthrough time (min)	Performance class	Degradation
37% Formaldehyde (T)	>241	5	8.0%
30% Hydrogen peroxide (P)	> 121	4	-0.8%
40% Sodium hydroxide (K)	> 480	6	-34.0%
<b>Tests according to EN 374-3:2003</b>			
Benzene	45	2	-
Bortezomib (1.000 ppm)	> 480	6	-
Carmustine (BCNU) (3300 ppm)	> 480	6	-

Chlorhexadin (CHX), 4%	> 480	6	-
Cisplatin (1.000 ppm)	> 480	6	-
Cyclophosphamide (20.000 ppm)	> 480	6	-
Daunorubicin Hydrochloride (5.000 ppm)	> 480	6	-
Doxorubicin Hydrochloride (2.000 ppm)	> 480	6	-
Epirubicin (2.000 ppm)	> 480	6	-
Ethanol, 35%	> 480	6	-
Ethanol, 70%	26	1	-
Ethidiumbromide, 1%	> 480	6	-
Etoposide (20.000 ppm)	> 480	6	-
Fluorouracil (50.000 ppm)	> 480	6	-
Gemcitabine (38.000 ppm)	> 480	6	-
Glutaraldehyde, 1%	> 480	6	-
Hydrogen peroxide	> 480	6	-
Isopropanol	48	2	-
Methanol	3	0	-
n-Heptane	55	2	-
n-Hexane	40	2	-
Perchloric acid, 70%	> 480	6	-
Sulphuric acid, 96%	14	1	-

<sup>1)</sup> Movement of a chemical through a material on a molecular level. <sup>2)</sup> At a permeation rate of 1µg/min·cm<sup>2</sup>.

<sup>3)</sup> The performance rate does not reflect the actual duration of protection at the work place!

## Penetration

Requirements met in compliance with EN 374-2:2019 - test conditions fulfilled.

## Resistance against viruses, bacteria & fungi

Requirements met in compliance with EN ISO 374-5:2016. Test results: Pass.

## Sterilisation

### Procedure

### Radiation dose D per sterilisation process

Gamma irradiation

≥ 25 kGy

## Storage and transport conditions

Dark (protect from direct UV light and sunlight)

Cool (+ 5 to + 40°C)

Dry (relative humidity 30 % - 60 %)

Keep away from equipment or installations that can produce ozone (e.g. through mercury vapour lamps, high voltage equipment, etc.)

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Avoid contact with oil-based antiseptic phenols and their derivatives, fats, petrolatum, petroleum, paraffin or other similar compounds

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No contact with pointed and/or sharp objects

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## Shelf life

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Non-sterile: 5 years from date of manufacture

Sterile: 3 years from the date of manufacture

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## CE marking and notified body

CE marking according to the EU PPE regulation (EU) 2016/425 for complex PPE of category III.

Type examination performed based on EN ISO 374-1:2016+A1:2018 Type B; EN 16523-1:2015+A1:2018, EN 374-2:2019, EN 374-4:2019; EN 374-5:2016; EN 21420:2020; EC Type Examination Certificate No. 2777/10922-04/E02-01.

Notified body: SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, D15YN29P, Republic of Ireland.

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## Manufacturer / distributor

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