PROTEXTRA™

Sensitive Nitril medical examination gloves

Optimal skin-friendliness and versatility

Product description

In addition to our Standard and Standard+ nitrile examination gloves, these special Sensitive Nitril gloves offer extra skin-friendliness. This is achieved by the MGEN-2 production technology, which results in the glove being free of chemical accelerators and other potentially allergy-causing substances. These substances are present in regular nitrile gloves, and can cause allergic reactions and deterioration of the skin condition. The Sensitive Nitrile glove is therefore not only suitable for use by people with latex allergies, but also for users with other Type I and Type IV allergies and/or sensitive hand skin.

The excellent performance of this glove makes it a widely applicable protective product, with which all common, non-sterile and low-chemical activities can be performed in healthcare. In addition, the glove has been proven to be suitable for use with cytostatics in accordance with ASTM D6978-05, making it extremely versatile within the hospital.

Product specifications	
Certification	• Manufactured as per ISO 9001:2015, ISO 13485:2016 and ISO 14001:2015 • EU Declaration of Conformity (MDR EU 2017/745) • PPE category III certified (EU 2016/425) • FDA 510(k) and REACH compliant

Notified Body (CE)	SATRA Technology Europe Limited Bracetown Business Park, Clonee, D15YN2P, Ireland CE code: 2777
Classification	• Medical Device class I (MDR EU2017/745 Annex VIII) • PPE category III (EU 2016/425)
Thickness (+/- 0.02)	Palm: 0.07 mm, fingers: 0.09 mm, cuff: 0.06 mm
Size range	XS – S – M – L - XL
AQL	1.5
Dimensions	As per EN455-2. Average length >240mm for all sizes.
Material composition	Butadiene-Acrylonitrile Latex, Zinc Oxide, Titanium Dioxide (TiO2), Nitrile Accelerator Free Crosslinker, Diluent – DEG, Wax Emulsion, Pigment (Copper Phthalaocyanine Blue & Dioxazine Violet).
Color	Light blue
Norms	• ASTM D6319, ASTM D7160, ASTM D7161 & ASTM D6978-05 • EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 (ISO 21171:2006) & EN 455-4:2009 • EN ISO 21420:2020 • EN ISO 374-1:2016+A1:2018 • EN 374-2:2014 • EN 16523-1:2015+A1:2018 (Type C) • EN 374-4:2013 • EN ISO 374-5:2016 (ISO 16604:2004, resistance to penetration by bacteria, fungi and viruses confirmed) • EN 1041:2008+A1:2013 • ISO 10993-10:2010
Force at break	**1. As per EN455-2 (Europe):** > 6N, both before and after aging **2. As per ASTM D6319 (USA):** >18 Mpa before aging, >16 Mpa after aging
Chemical resistance	Type C as per EN 16523-1:2015+A1 :2018. Normally, Type C glove are tested with only one test chemical. The Sensitive Nitril glove is classified as Type C, but has been tested with two test chemicals for a more comprehensive view:

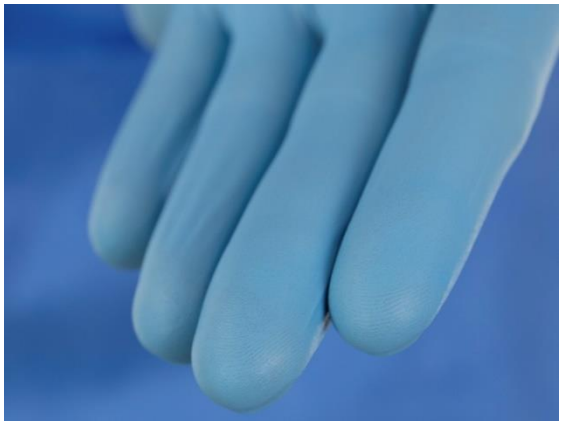
Code	Chemical description	CAS	Level	Degradation (EN 374-4:2013)(%)
K	Sodium hydroxide 40%	1310-73-2	6	-48.8
T	Formaldehyde 37%	50-00-0	4	13.4

Cytostatic suitability	This product meets the ASTM D6978-05 norm[1], with the below test results:	
		Minimal breakthrough detection time:
	Carmustine, 3.3mg/ml (3,300 ppm)	24.7 minutes
	Cisplatin, 1.0mg/ml (1,000 ppm)	>240 minutes
	Cyclophosphamide, 20.0mg/ml (20,000 ppm)	>240 minutes
	Dacarbazine, 10.0mg/ml (10,000 ppm)	>240 minutes
	Doxorubicin HCl, 2.0mg/ml (2,000 ppm)	>240 minutes
	Etoposide, 20.00mg/ml (20,000 ppm)	>240 minutes
	Fluorouracil 50.0mg/ml (50,000 ppm)	>240 minutes
	Methotrexate, 25.0mg/ml (25,000 ppm)	>240 minutes
	Mitomycin C, 0.5mg/ml (500 ppm)	>240 minutes
	Paclitaxel (Taxol), 6.0mg/ml (6,000 ppm)	>240 minutes
	Thiotepa, 10.0mg/ml (10,000 ppm)	47.8 minutes
	Vincristine Sulfate, 1.0mg/ml (1,000 ppm)	>240 minutes
Applications	These gloves are primarily intended and suitable for medical (non-surgical, non-sterile) examination use by HCP with and without latex allergies or other (more specific) allergies.	
Other specifications	• Non-sterile • Single use only • Ambidextrous • Textured fingertips	
Packing information	Packed in dispensers of 100, 150, of 200 gloves, and subsequently per 10 dispensers in an outer carton. See product table on next page for applicable REF codes.	

[1] Since there are no European standards yet for cytostatic testing of gloves, the ASTM D6978-05 standard (primarily drawn up for the American market) is used. This standard is also much more stringent than the European EN 374 standard in various other performance areas, such as the breakthrough test limit and the test temperature used, which is in line with the actual body temperature of a user (35 C° +/- - 2), while the EN 374 standard works with a temperature of 23 C° +/- 1).

Product table

REF	Size	Packing unit	Ordering unit
138563-XS	XS	BOX/100	10 x BOX/100
138563-S	S	BOX/100	10 x BOX/100
138563-M	M	BOX/100	10 x BOX/100
138563-L	L	BOX/100	10 x BOX/100
138563-XL	XL	BOX/100	10 x BOX/100
138563-XS-150	XS	BOX/150	10 x BOX/150
138563-S-150	S	BOX/150	10 x BOX/150
138563-M-150	M	BOX/150	10 x BOX/150
138563-L-150	L	BOX/150	10 x BOX/150
138563-XL-150	XL	BOX/150	10 x BOX/150
138563-XS-200	XS	BOX/200	10 x BOX/200
138563-S-200	S	BOX/200	10 x BOX/200
138563-M-200	M	BOX/200	10 x BOX/200
138563-L-200	L	BOX/200	10 x BOX/200
138563-XL-180	XL	BOX/180	10 x BOX/200



Version no: 2022.P-138563-XX-PB2.1.1