

INSTRUCTION FOR USE OF PERSONAL PROTECTIVE EQUIPMENT**santex® powdered**

RD11010001-05

RD11086001-05

The instruction below should be used in conjunction with detailed information on the packaging.

Short description of the product

Examination and protective gloves, latex, powdered, for single use, non-sterile

Full description of the product

Reference number	: RD11010001-05 / RD11086001-05
External surface	: smooth / textured
Raw material	: natural rubber latex
Cuff	: beaded
Colour	: creamy
Shape	: ambidextrous, fitting to the right and left hand
Size range	: XS (5-6), S (6-7), M (7-8), L (8-9), XL (9-10)
AQL	: 1.0
Quantity in packaging	: 100 pcs. by weight
Shelf life	: 5 years (from the date of manufacturing)

Storage instructions

It is recommended to store the gloves in dry place, in the temperature of 5-35°C and to protect them against direct sunlight.

Keep the gloves in a distance of not less than 1m from heating devices, sources of fire and ozone.

Do not keep in direct vicinity of solvents, oils, fuels and lubricants.

Food contact

Gloves are marked with food contact symbol  and comply with the requirements of Regulation (EU) No 10/2011, European Regulation (EC) No 1935/2004 and with Regulation (EC) No 2023/2006 on Good Manufacturing Practice. Gloves are suitable for handling the food, except for acidic and fat foods, and have been tested for Overall Migration Test acc. EN 1186:

Extraction conditions (tested for 30 min in 40°C)	Analysis results [mg/dm ²]	Test Result (limit < 10 mg/dm ²)
10% Ethanol	5.0	Pass

MD classification & compliance

Gloves are classified as class I according to Annex VIII of the Regulation (EU) 2017/745 and comply to standards:

EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021, EN 1041:2008+A1:2013.

PPE classification & compliance

Gloves are category III Personal Protective Equipment as per Annex I of the Regulation 2016/425 and comply to standards:

EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN 374-4:2013, EN ISO 374-5:2016.

Notified Body responsible for EU Type Examination (Module B) and on-going conformity (Module C2):

Satra Technology Europe Ltd

Bracetown Business Park,
Clonee, Dublin 15,
Dublin, Ireland



Declaration of Conformity and this instruction for use can be found under below web address:

<https://mercatormedical.eu>**Intended use**

These are non-sterile examination and protective gloves for single use, intended for use in medical field to: protect patient and user from cross-contamination, conducting medical examinations, diagnostic and therapeutic procedures and for handling medical contaminated material. Gloves are classified as Medical Devices Class I and as a Personal Protective Equipment Category III, type C. Gloves designed to protect against substances and mixtures which are hazardous to health and against harmful biological agents. Gloves designed to protect against chemical risk according with EN ISO 374-1:2016+A1:2018 and microorganism (viruses, bacteria and fungi) risks according with EN ISO 374-5:2016. Their design and labelling corresponds to the requirements of the European Regulation 2017/745 on Medical Device and the European Regulation 2016/425 on Personal Protective Equipment. Gloves should be used solely according to their intended application.

Precautions and indications for use

Dry hands before taking the gloves out from the packaging. Before usage, inspect the gloves for any defect or imperfections. Use at least 1 pair of gloves for one patient and one procedure, these are disposable gloves. Do not let chemical substances get under the gloves through the cuff. If a chemical substance reaches the skin, wash it away immediately with plenty of water. If the gloves get punctured, torn or broken during their use, take them off and put on the new ones. Avoid using gloves dirty in the inside as they may cause irritation leading to skin inflammation or more serious damages.

It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on the temperature, abrasion and degradation. The gloves should not be used in contact with open fire and to protect against any sharp tools. The gloves are not intended for welding, electric shock protection, ionizing radiation or from the effect of hot or cold objects.

The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in case where glove is equal to or over 400 mm – where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture. This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.

When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.

Gloves are suitable for special purposes as they are examination gloves where risk of wrist injury caused by chemicals is considered to be minimal. Length suitable for tasks that require hand protection. Gloves shorter than minimum lengths required by EN 420 standard. Glove minimum length in accordance to EN 455-2 standard.

Components / hazardous components

Product contains natural rubber latex which may cause allergic reactions including anaphylactic responses. Components used in making gloves may cause allergic reactions in some people. Some gloves may contain components known to be a possible cause of allergy for person allergic to them, who may develop contact irritation and/or allergic reaction. In case of an allergic reaction consult a doctor.

Disposal

Used gloves should be treated as a contaminated material, therefore local regulations regarding the disposal of such materials should be applied.

Manufacturer**MERCATOR MEDICAL S.A.**

ul. H. Modrzejewskiej 30
31-327 Cracow, Poland

www.mercatormedical.eu

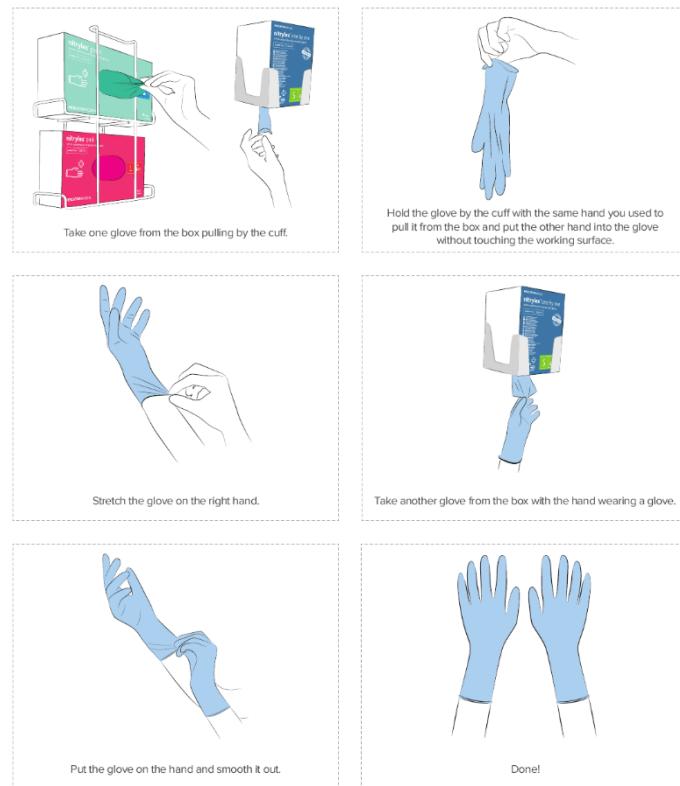
Permeation performance levels as per EN ISO 374-1:2016+A1:2018		
• Level 1 > 10 min • Level 2 > 30 min • Level 3 > 60 min • Level 4 > 120 min • Level 5 > 240 min • Level 6 > 480 min		
Test results acc. to EN 16523-1:2015+A1:2018		EN 374-4:2013 Degradation [%]
Chemical	Level	
40% Sodium Hydroxide	1	-15.2

EN 374-4: 2013 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

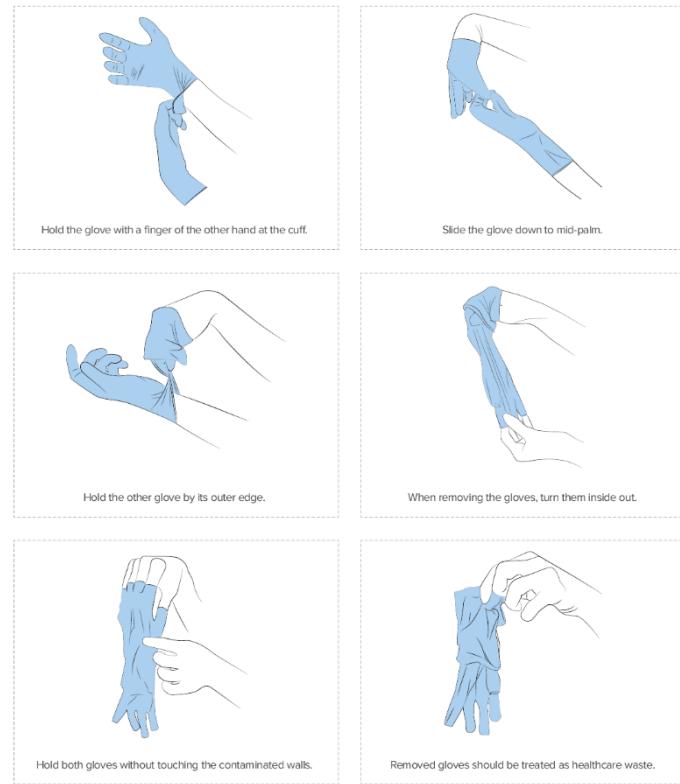
Test acc. to EN ISO 374-2:2019 – Level 2 (ISO 2859)	Test acc. to EN ISO 374-5:2016	
Performance level AQL	Protection against bacteria & fungi Pass	
Level 3 < 0.65	Protection against viruses Pass	
Level 2 < 1.5	EN ISO 374-5:2016 The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.	
Level 1 < 4.0		

Symbols used on the packaging					
MD	Medical Device		Keep dry		Latex gloves
PPE	Personal Protective Equipment		Keep away from sunlight		Powdered gloves
	Manufacturer		Temperature limitation 5-35°C		For single use only
LOT	Lot / batch number		Keep away from ozone		Non-sterile
REF	Catalogue number		Product quality is not ensured if the package is damaged		Designed to protect against to chemical risks acc. with EN ISO 374-1 (type C)
	Expiry date		Recyclable packaging		Designed to protect against microorganisms risks acc. with EN ISO 374-5
	Date of manufacture		Package can be treated as municipal waste		
	Indicates compliance with the requirements of Ukrainian market		Suitable for food contact (for details check the instruction for use)		Consult instructions for use

■ HOW TO PUT THE GLOVES ON?



■ HOW TO TAKE THE GLOVES OFF?



ISTRUZIONI PER L'USO DEI DISPOSITIVI DI PROTEZIONE INDIVIDUALE**santex® powdered****RD11010001-05****RD11086001-05**

Le istruzioni riportate di seguito devono essere utilizzate congiuntamente alle informazioni dettagliate riportate sulla confezione.

Breve descrizione del prodotto

Guanti per esame e protezione, in lattice, con polvere, monouso, non sterili

Descrizione completa del prodotto

Numero di riferimento	: RD11010001-05 / RD11086001-05
Superficie esterna	: liscia / texture
Materia prima	: lattice di gomma naturale
Polso	: con bordino
Colore	: crema
Forma	: ambidestro, si adatta alla mano destra e sinistra
Taglie	: XS (5-6), S (6-7), M (7-8), L (8-9), XL (9-10)
AQL	: 1,0
Quantità nella confezione	: 100 pz. a peso
Shelf life	: 5 anni (dalla data di fabbricazione)

Istruzioni per la conservazione

Si raccomanda di conservare i guanti in un luogo asciutto, a una temperatura di 5-35°C e di proteggerli dalla luce solare diretta.

Tenere i guanti a una distanza non inferiore a 1 m da dispositivi di riscaldamento, fonti di incendio e ozono.

Non conservare nelle immediate vicinanze di solventi, oli, carburanti e lubrificanti.

Contatto con alimenti

I guanti sono contrassegnati con il simbolo del contatto con alimenti  e sono conformi ai requisiti del Regolamento (UE) n. 10/2011, del Regolamento europeo (CE) n. 1935/2004 e del Regolamento (CE) n. 2023/2006 sulle buone pratiche di fabbricazione. I guanti sono adatti per la manipolazione degli alimenti, ad eccezione degli alimenti acidi e grassi, e sono stati testati per le prove di migrazione globale secondo EN 1186:

Condizioni di estrazione (testati per 30 min a 40°C)	Risultati dell'analisi [mg/dm ²]	Risultato della prova (limite <10 mg/dm ²)
10% Etanolo	5,0	Superato

Classificazione e conformità MD

I guanti sono classificati in classe I secondo l'allegato VIII del Regolamento (UE) 2017/745 e sono conformi alle norme:

EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021, EN 1041:2008+A1:2013.

Classificazione e conformità PPE

I guanti sono Dispositivi di Protezione Individuale di categoria III di cui all'Allegato I del Regolamento 2016/425 e sono conformi alle norme:

EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN 374-4:2013, EN ISO 374-5:2016.

Organismo notificato responsabile dell'esame UE del tipo (modulo B) e della conformità (modulo C2):

Satra Technology Europe LtdBracetown Business Park,
Clonee, Dublin 15,
Dublino, Irlanda

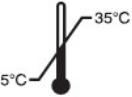
La dichiarazione di Conformità e le presenti istruzioni per l'uso sono reperibili al seguente indirizzo web:

<https://mercatormedical.eu>

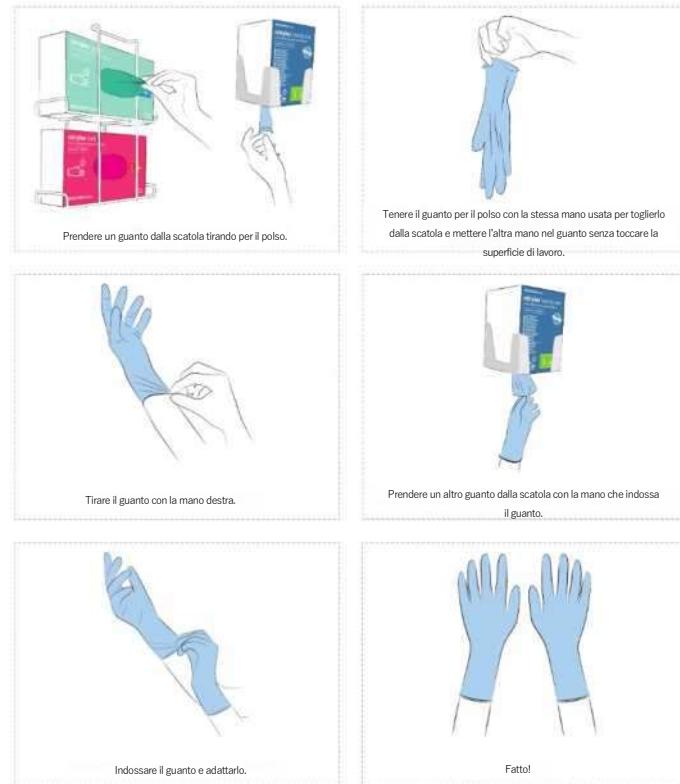
Livelli prestazionali di permeazione secondo EN ISO 374-1:2016+A1:2018		
• Livello 1 > 10 min • Livello 2 > 30 min • Livello 3 > 60 min • Livello 4 > 120 min • Livello 5 > 240 min • Livello 6 > 480 min		
Risultati delle prove secondo EN 16523-1:2015+A1:2018		
Sostanze chimiche	Livello	EN 374-4:2013 Degradazione [%]
40% Idrossido di sodio	1	-15,2

EN 374-4: 2013 I livelli di degradazione indicano la variazione della resistenza alle forature dei guanti dopo l'esposizione alla sostanza chimica in esame.

Test secondo EN ISO 374-2:2019 – Livello 2 (ISO 2859)		Test secondo EN ISO 374-5:2016	
Livello di prestazioni	AQL	Protezione contro batteri e funghi	Superato
Livello 3	<0,65	Protezione contro i virus	Superato
Livello 2	<1,5	EN ISO 374-5:2016 La resistenza alla penetrazione è stata valutata in condizioni di laboratorio e si riferisce solo al campione testato.	
Livello 1	<4,0		

Simboli utilizzati sulla confezione							
MD	Dispositivo medico		Conservare in luogo asciutto		Guanti in lattice		
PPE	Dispositivi di protezione individuale		Tenere al riparo dalla luce solare		Guanti con polvere		
	Fabbricante		Limitazione di temperatura 5-35°C		Esclusivamente monouso		
LOT	Numero di lotto / partita		Tenere lontano dall'ozono		Non sterile		
REF	Numero di catalogo		La qualità del prodotto non è garantita in caso di confezione danneggiata	 ISO 374-1/Type C	Progettati per proteggere contro i rischi chimici secondo EN ISO 374-1 (tipo C)		
	Data di scadenza		Confezione riciclabile	 ISO 374-5:2016	Progettati per proteggere contro i rischi da microrganismi secondo EN ISO 374-5		
	Data di fabbricazione		Le confezioni possono essere trattate come rifiuti urbani	 VIRUS			
	Indica la conformità ai requisiti del mercato ucraino		Adatto al contatto con alimenti (per i dettagli controllare le istruzioni per l'uso)		Consultare le istruzioni per l'uso		

COME INDOSSARE I GUANTI?



COME TOGLIERE I GUANTI?

