

x-ray protection gloves latex free

XP GLOVES



x-ray protection gloves
made of dry natural rubber
micro rough surface

PPE of III category
MD of class IIa

anallergic

latex free

powder free

three different
thickness
for every need

XP/1 *

thickness mm 0.18 - 0.20

XP/2 * *

thickness mm 0.32 - 0.34

XP/3 * * *

thickness mm 0.42 - 0.46

Completely manufactured in Italy

 **agssa** gomma
tradition, experience, quality, innovation

New

XP gloves

PRODUCTS

Protective gloves for ionising radiations, made of natural dry rubber (no latex) added with lead oxides

Gloves **XP/1***
Gloves **XP/2****
Gloves **XP/3*****

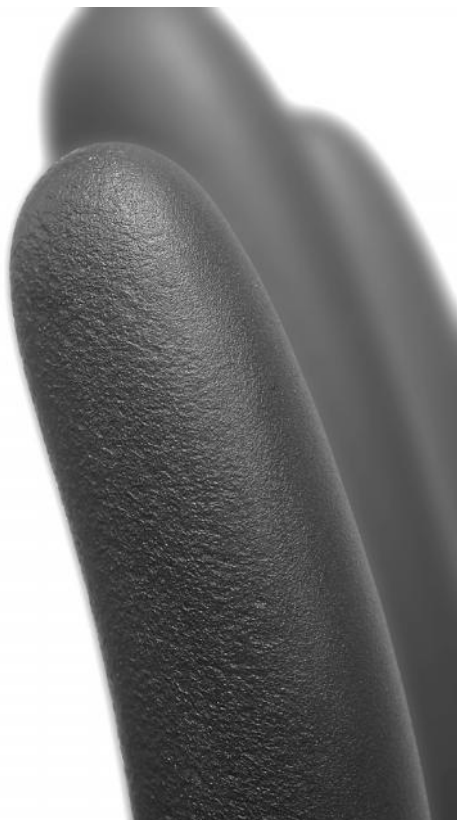
Sterile - light type
Sterile - medium type
Sterile - heavy type

item AG01
item AG02
item AG03

FEATURES

XP gloves are made of natural dry rubber mixed with lead oxide. The mix of these two raw materials grants high elasticity and softness combined with the best x-ray protective curve without negative peaks typical of other protective materials.

We decided to use this raw material because, even though a latex by-products, thanks to their particular extractable process, dry rubber is completely free from allergic soluble latex proteins. The gloves are so suitable for use in **"Latex-Free"** places and for patients and users allergic to latex. Using natural dry rubber we have the possibility to manufacture gloves in a geographic area different from the extraction latex areas, so we can produce our gloves in Italy, in perfect accordance with European Standards and with a continuous and direct control of each manufacturing phase and products quality.



Each single gloves, besides, is controlled and tested by specialized operators that verify the full conformity to the Standards requisites and to the strictly requirements defined by our Quality Management System. New XP glove gives perfect grip in any work condition, also with wet surface, thanks to the **micro-rough palm and fingers** that allows to work with maximum precision and safety. Besides the glove's shape was revised for better fit to the hand's anatomy and to permit a long use without stress and with maximum comfort. The palm dimension, the curved fingers, the cylindrical wrist and the anti-rolling edge were perfected thanks to our long experience and our manufacturing line renovation.

NEWS

Line XP, natural dry rubber gloves (no latex) added with lead oxide, powder free, manufactured in three difference thickness for every need. Now all the gloves of Line XP have a **DOUBLE CE CERTIFICATE** to offer a **complete protection** both for users as for patients and hospital environmental. All the gloves are **CE** certificate like Medical Device (MD) in accordance with the European Directive 93/42/CEE and in the same time are **CE** certificate like Personal Protective Equipment (PPE) in accordance with the European Directive 89/686/CEE.

The CE for MD is to grant a complete protection against the crossed microbiological contamination between patients and users, so you can use these gloves directly in sterile room and in contact with the patient without any risks of contamination. This CE grant also the specific manufacturer treatment of these products that grant clean a not contaminated products to safe also the hospital environmental.

The CE for PPE is to grant the protect of the user against the ionizing radiation.

XP line is composed with three gloves in different thickness to offer an adequate choice for requested x-ray shielding: till use where tactile sensitivity is essential to use where high protection level is basic.

XP/1* gloves born for use where sensitivity and dexterity are essential requirements; their thin thickness allows to the hand natural performance without considerable tactile reduction while maintaining an adequate protection. The suggested application fields are: angiography, cardiology, urography, haemodynamics and fine surgery.

In **XP/2**** model, in medium thickness, operative comfort and ideal protection arrive to a perfect balance. The offered protection allows to work for long period and in a surgical intervention where gloves are particularly stressed, preserving adequate sensitivity and reduced fatigue. This glove is thought for use in: urology, oncological centre, orthopaedic surgery, pace-maker positioning and general surgery.

XP/3*** thanks to his higher thickness, offers the maximum protection of our line, though maintaining a good dexterity. This glove is destined for use where protection is basic, without having to tolerate a reduced operating comfort typical of stiff gloves. We suggested to use this glove in traumatology, in some applications of nuclear medicine and for assistance of operating theatre.

Patented manufacturing process; subsequent dipping in lead dry rubber solution are made with computer controlled equipment and exclusive thickness regulation system to grant a very good tactile sensitivity. The gloves are successively and repeatedly washed for long time, after they are submitted to a special silicon lubrication process; so the gloves may be worn without vegetal or mineral powder (**powder free**).

Specialized operators inspect gloves one by one with adequate tools and accurate visual control to verify the perfect conformity to fixed requirements.

ABSORPTION AND SCREENING PERCENTAGES

Total filtering 2.5 mm Al		Ray's power		
		60 kV	80 kV	100 Kv
XP/1*	- light type	40% ($\pm 5\%$)	35% ($\pm 5\%$)	30% ($\pm 5\%$)
XP/2**	- medium type	68% ($\pm 5\%$)	61% ($\pm 5\%$)	54% ($\pm 5\%$)
XP/3***	- heavy type	75% ($\pm 5\%$)	69% ($\pm 5\%$)	63% ($\pm 5\%$)

The reported data are determined and periodically verified by Radio Protection Institute of ENEA (Italian National Agency for New Technologies, Energy and Sustainable Economic Development).

THICKNESS	XP/1*	XP/2**	XP/3***
Finger thickness (mm.)	0.18	0.33	0.46
Palm thickness (mm.)	0.20	0.34	0.45
Wrist thickness (mm.)	0.20	0.32	0.42
Total length (mm.)	290	290	290

DESCRIPTION AND USE

MANUFACTURING PROCESS

PROTECTION

TECHNICAL SPECIFICATIONS

PHYSICAL PROPERTIES

	XP/1*	XP/2**	XP/3***
Tensile strength	> 17 N	> 17 N	> 30 N
Ultimate elongation	> 440 %	> 510 %	> 600 %
Tensile strength after aging	> 10 N	> 17 N	> 28 N
Ultimate elongation after aging	> 450 %	> 515 %	> 550 %
Acceptable Quality Level - AQL	0.065	0.065	0.065
Powder free	yes	yes	yes

SIZES: 6 - 6^{1/2} - 7 - 7^{1/2} - 8 - 8^{1/2} - 9

Sizes correspond to surgical gloves. Half-sizes or one size more than that use in surgery is advisable, especially for models XP/2** and XP/3***, in relation to the lower polymer elasticity due to the load of lead oxides.

Product code for size

	6	6.5	7	7.5	8	8.5	9
XP/1*	AG01-60	AG01-65	AG01-70	AG01-75	AG01-80	AG01-85	AG01-90
XP/2**	AG02-60	AG02-65	AG02-70	AG02-75	AG02-80	AG02-85	AG02-90
XP/3***		AG03-65	AG03-70	AG03-75	AG03-80	AG03-85	AG03-90

PACKAGING STERILIZATION

Packaging: exterior envelope in medical polyethylene (PET/PE) to grant sterility, inside one pair of half-turned gloves in inner-wallet for aseptic wearing procedure, with size and right and left indications. Every envelope, sterile or not sterile, is printed with the protective information about the gloves and with all the dictate indications required from the European Directive. Each master box contains use and storage instructions.

	XP/1*	XP/2**	XP/3***
Minimal packaging	5 pairs	5 pairs	5 pairs
Multiple packaging	20 pairs	15 pairs	10 pairs

Sterilization by gamma ray (25 kGy) with specific validated protocol in accordance with European Standards, carried out in specialized Italian centre.

CERTIFICATION

Patented Product

Medical Device of Class IIa - Personal Protective Equipment of III category.

Reference Standards: DIR 93/42 CEE, DIR 2007/47/CE, D.Lgs. 46/97, D.Lgs 37/10, DIR 89/686/CEE, 93/68/CEE, 93/95/CEE, 96/58/CEE, D.L. 475/92, D. Lgs. n.10/97, UNI EN ISO 13485, UNI EN ISO 9001, UNI EN 455-(1-2-3-4), UNI EN 556 (1-2), UNI EN ISO 11137, UNI EN 421, EN 11737 (1-2), ISO 10993 (5-7-10-11), UNI CEI EN ISO 15223-1, UNI EN 14971, UNI EN ISO 14155, UNI EN 420, UNI EN 374 (1-2-3), D.Lgs 81/08, BS 2606, U.E. Directive 84/466 Euratom (D.L. 230, 19/03/95)

CE 0476 issued by Notified Body Kiwa-Cermet - Cadriano (BO) Italy

CE 0497 issued by Notified Body CSI Spa - Senago (MI) Italy

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