

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC Signatory of EA, IAF and ILAC





EU Type Examination Certificate

Date: 2021/05/28 n. 617212101/TE Validity: 2026/05/27

> This Certificate cancels the previous one n° 617194301/TE dated 2019/10/21 and is a translation in English of the original Certificate issued in Italian.

The hereunder described items of Personal Protective Equipment have overcome positively the "EU type examination" (Module B), proving their conf<mark>or</mark>mity to the safety and h<mark>ealth requirem</mark>ents of the Regulation <mark>(E</mark>U) 2016/425 (Annex II)

Manufacturer: (Responsible of the PPE)	KORA srl Via G. Carducci 32 - 20123 MILANO (MI)- Italia		
Type of PPE:	protective gloves against mechanical risks and cold		
Category of PPE:	III : "severe" risks. the certificate shall be reconfirmed by the annual surveillance (module C2)		

Model "CRYOKIT 400"

Description:

model: five fingers;

Art. CRYOKIT 400



palm side and fourchettes: petroleum blue fabric coupled with white membrane coupled with black knitting "TESSUTO COMPOSITO/NYLON/LYCRA/PU" (003075E5);

back side and cuff: black perforated knitting coupled with white membrane coupled with black fleeced pile-liked knitting "TESSUTO COMPOSITO POLIESTERE/PU" (VG0000684/N):

lining of palm side, cuff and back of the thumb: mid-layer made of white polymeric membrane "Porelle" (P355), internal layer made of orange fleeced pile-liked knitting "PILE POLIESTER" (8297/M/8297/M150);

lining of back side and fourchettes: mid-layer made of white polymeric membrane "Porelle" (P355), internal layer made of grey fleeced pile-liked knitting "PILE POLIESTERE" (750);

cuff: about 12 cm long;

edging: with different coloured webbing depending from the size (*).

Model available also in the following variants:

"CRYOKIT 300" which differs from the base model:

<u>cuff</u>: 7 cm long, edged with different coloured webbing depending from the size (*).

"CRYOKIT 550" which differs from the base model:

cuff: about 28 cm long, edged with different coloured webbing depending from the size

(*) 7 = red, 8 = yellow, 9 = white, 10 = green, 11 = blue.

Technical Standard:	EN ISO 21420:2020 EN 388:2016 + A1:2018 EN 511:2006	Protective gloves – General requirements and test methods. Protective gloves against mechanical risks. Protective gloves against cold.
Intended use:		of liquid cryogenic gas by hospital staff: it protects from its and from splashes of liquid gas (liquid nitrogen).
Size range:	7 - 8 - 9 - 10 - 11.	
Technical File:	DC-12656/E	
Test report:	RCT n°3913902	



PRD N° 0230 B

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC Signatory of EA, IAF and ILAC Mutual Recognition Agreements





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Functions and performance levels: EN ISO 21420:2020

Protective gloves - General requirements and test methods: the gloves satisfy the general requirements of design and manufacturing, innocuousness, comfort and efficiency. <u>Dexterity</u>: **3** (min. 1 - max. 5).

EN 388:2016 + A1:2018

Protective gloves against mechanical risks:

PROTECTION TYPE		LEVEL
Abrasion resistance	(max. 4)	2
Cut resistance	(max. 5)	2
Tear resistance	(max. 4)	3
Penetration resistance	(max. 4)	1
Resistance to cutting by sharp objects (EN ISO 13997:1999)	(min. A- max. F)	x

EN 511:2006

Protective gloves against cold

Convective cold	(min. 1 – max. 4)	2
Contact cold	(min. 1 – max. 4)	2
Water penetration	(min. 0 – max. 1)	1

Resistance to liquid nitrogen (test performed according to a RCT internal method with simulation of splashes of liquid nitrogen). X (performance not tested or not applicable).

<u>GENERAL NOTES CONCERNING THE PERFORMANCE LEVELS</u>: the performance level, if not otherwise indicated, refers to the palm side (fingers included).

Marking:

printed on a label stitched to the glove and displaying the following information:

- **CE Marking** and number of the Notified Body in charge of the annual control of the
- registered Trademark of the Manufacturer; designation of the item and size;
- nr. and year of the Standards of reference with pictograms and performance levels achieved;
- pictogram "i in the booklet" inviting to read the User Manual;
- additional info: intended use indication, production date.









USO CRIOGENICO CRYOGENIC USE WATERPROOF



DICHIARAZIONE DI CONFORMITA' (UE) DISPONIBILE SUL SITO DECLARATION OF CONFORMITY (UE) AVAILABLE ON CRYOKIT.NET







NOTE: the Technical File contains a more detailed description of the PPE (material, method of assembly, photographs or drawings), performance data, safety functions and level of protection, elements of conformity to the basic and supplementary requirements.

The Technical File is integral part of the present Certification, which has to be kept available by the applicant to be forwarded - upon request - to the entitled person (supervising body, Controlling Officer).