AMPri Handelsgesellschaft mbH
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Technical Data Sheet

Article-No.: **01144**

Description: **MED-COMFORT**
Latex surgical gloves
white, powder free, ETO sterile

THICKNESS		
cuff	**palm**	**fingertips**
0,14 mm	0,17 mm	0,19 mm

PRODUCT DESCRIPTION							
material	☑ Latex	☐ Nitrile	☐ Vinyl	☐ Vinyl-Nitrile-mixture	☐ Polyethy-lene (PE)	☐ TPE	☐ cotton
colour	☑ white	☐ blue	☐ black	☐ mint	☐ purple	☐ mix	☐ cobalt-blue
characteristics	☐ prepowdered	☑ powderfree	☑ sterile	☐ non sterile	☐ ambidex-trous	☑ fits hand-specific	☐ biodgra-dable
surface	☑ full textured	☐ finger textured	☐ not textured	☐ embossed	☑ polymer coated inside		

SIZES							
	6.0	**6.5**	**7.0**	**7.5**	**8.0**	**8.5**	**9.0**
width	-	83 ± 5 mm	89 ± 5 mm	95 ± 5 mm	102 ± 5 mm	108 ± 6 mm	-
length	-	≥ 280 mm	≥ 280 mm	≥ 285 mm	≥ 285 mm	≥ 285 mm	-

REGULATORY AFFAIRS							
PPE-Regulation (EU) 2016/425	☐ Category I	☐ Category II	☑ Category III	☐ no PPE-article			CE
MD-Regulation (EU) 2017/745	☑ Class I	☐ Class II a	☐ Class III	☐ sterile	☐ measuring function	☐ no medical device	
Food Contact (EG) 1935/2004	☐ acidic foods	☐ aqueous foods	☐ fatty foods	☐ alcoholic foods	☐ dry foods	☑ not approved for food-contact	

STANDARDISATION							
EN 388 Mechanical Risks	**abrasion resistance**	**blade cut resistance Coupe-Test**	**tear resistance**	**puncture resistance**	**blade cut resistance TDM-Test**	**impact test**	
Level	not applicable						

EN 374-1 Chemical Risks	**chemical**	**code letter**	**level**	**permeation time**	**degradation**	ISO 374-1/Type C
	Sodium hydroxide 40%	K	5	> 240 min	22,9 %	
	Hydrogen Peroxide 30%	P	6	> 480 min	20,5 %	
EN 374-4 Degradation	Formaldehyde 37%	T	1	> 10 min	10,6 %	
EN 374-5 microorganism tightness	The glove is tight against microorganisms (viral, bacteria and fungi). Test according to ISO 16604 - method B.					EN ISO 374-5:2016 VIRUS
EN 420 protective gloves	The glove meets the requirements according to EN 420					
EN 455 medical gloves for single use	The glove meets the requirements according to EN 455-1, EN 455-2, EN 455-3, EN 455-4					EN 455
EN 455-1 freedom from holes	The glove has an AQL < 0.65 in regards to the water retention test (sampling inspection in acc. to ISO 2859-1, general Inspection Level I)					AQL 0.65
EN 16350 electrostatic properties	not applicable					

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LOGISTIC DATA SUBPACKING	
generell information	
material	carton
pieces per subpacking	100
GTIN subpacking size XS	-
GTIN subpacking size S	4044941017365
GTIN subpacking size M	4044941017370
GTIN subpacking size L	4044941017389
GTIN subpacking size XL	4044941017396
GTIN subpacking size XXL	4044941017402
GTIN subpacking size XXXL	-
PZN subpacking size XS	-
PZN subpacking size S	-
PZN subpacking size M	-
PZN subpacking size L	-
PZN subpacking size XL	-
PZN subpacking size XXL	-
PZN subpacking size XXXL	-
measures & size	
length	260 mm
width	130 mm
heigth	200 mm

weights		
size	**net weight**	**gross weight**
6.0	-	-
6.5	1.000 g	1.060 g
7.0	1.050 g	1.110 g
7.5	1.100 g	1.160 g
8.0	1.200 g	1.260 g
8.5	1.300 g	1.360 g
9.0	-	-

LOGISTIC DATA OUTER PACKING	
generell information	
material	carton
subpackings per outer packing	8
GTIN outer packing size XS	4044941017440
GTIN outer packing size S	4044941017457
GTIN outer packing size M	4044941017464
GTIN outer packing size L	4044941017471
GTIN outer packing size XL	4044941017488
GTIN outer packing size XXL	-
GTIN outer packing size XXXL	-
PZN outer packing size XS	-
PZN outer packing size S	-
PZN outer packing size M	-
PZN outer packing size L	-
PZN outer packing size XL	-
PZN outer packing size XXL	-
PZN outer packing size XXXL	-
measures & size	
length	530 mm
width	270 mm
heigth	410 mm

weights		
size	**net weight**	**gross weight**
6.0	-	-
6.5	8.480 g	8.980 g
7.0	8.880 g	9.380 g
7.5	9.280 g	9.780 g
8.0	10.080 g	10.580 g
8.5	10.880 g	11.380 g
9.0	-	-

LOGISTIC DATA PALETTE	
general information	
kind of palett	euro-palette
measures & size	
cartons per layer	6
layers per palette	4
heigth of the palette	179 cm

weights		
size	**net weight**	**gross weight**
6.0	-	-
6.5	216 kg	241 kg
7.0	225 kg	250 kg
7.5	235 kg	260 kg
8.0	254 kg	279 kg
8.5	273 kg	298 kg
9.0	-	-

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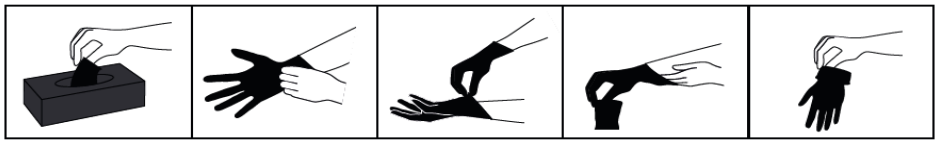
WARNINGS AND SAFETY INFORMATION

storage / expiry date	Store gloves in original packaging in a cool and dry place without additional weight, protect from direct sunlight. Do not store near ozone sources (laser printers, copiers). The actual expiry time in use cannot be specified in general terms, as it depends on the general conditions of use. An individual risk assessment must be carried out in each case. The expiry date - valid for proper storage - is stated on the packaging.
use and control	Always use protective gloves only for the intended use and in the correct size. A check/risk assessment must be carried out to ensure that the gloves are suitable for the intended use, as the conditions at the workplace may deviate from those of the type test depending on temperature, abrasion and degradation. Breakthrough times and permeation levels are based on laboratory measurements and are determined using samples taken from the palm of the hand. The actual duration of protection of a glove with a specific substance can vary significantly due to the conditions of use (temperature, abrasion, stretching). In the case of aggressive chemicals, degradation (change in mechanical properties) can be an important factor to consider when selecting chemical-resistant gloves. This information does not reflect the actual duration of protection in the workplace and the distinction between mixtures and pure chemicals. The chemical resistance was determined under laboratory conditions only on the basis of samples from the palm and refers only to the chemicals tested. The situation may be different if the chemical is used in a mixture. The penetration resistance was evaluated under laboratory conditions and refers only to the tested specimen. The degradation results according to EN ISO 374-4 show the change in puncture resistance of the gloves after exposure to the tested chemical. Before use, the gloves must be checked for holes or damage.
disposal	Used gloves must be disposed of in accordance with the disposal regulations of the local waste disposal company. Unused gloves can be disposed of with household waste.
disinfection	Disinfection is not intended for these gloves and is the responsibility of the user.
warnings/ allergy information	Protective gloves are intended for single use only. This product contains dithiocarbamates and natural latex, which can trigger allergic reactions, including anaphylactic reactions
donning and doffing instructions	

rev-no.: 5
date 10.03.2025

changes and errors excepted