AMPri Handelsgesellschaft mbH
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Technical Data Sheet

Article-No.: **01194**

Description: **MED-COMFORT Blue Ultra 300**
Nitrile examination glove
blue, non sterile, powder free

THICKNESS*		
cuff	**palm**	**fingertips**
0,09 mm	0,13 mm	0,15 mm

PRODUCT DESCRIPTION							
material	☐ Latex	☑ Nitrile	☐ Vinyl	☐ Vinyl-Nitrile-mixture	☐ Polyethy-lene (PE)	☐ TPE	☐ cotton
colour	☐ white	☑ blue	☐ black	☐ mint	☐ purple	☐ mix	☐ bordeaux
characteristics	☐ prepowdered	☑ powderfree	☐ sterile	☑ non sterile	☑ ambidex-trous	☐ fits hand-specific	☐ Aloe Vera inner coating
surface	☑ textured	☐ not textured	☐ embossed				

SIZES							
	XS (5-6)	**S (6-7)**	**M (7-8)**	**L (8-9)**	**XL (9-10)**	**XXL (10-11)**	**XXXL (11-12)**
width	-	80 ± 10 mm	95 ± 10 mm	110 ± 10 mm	115 ± 10 mm	125 ± 10 mm	-
length	-	≥ 300 mm	≥ 300 mm	≥ 300 mm	≥ 300 mm	≥ 300 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						

	chemical	**code letter**	
EN 374-1 Chemical Risks	Sodium hydroxide 40%	K	ISO 374-1/Type B
	Hydrogen Peroxide 30%	P	
EN 374-4 Degradation	Formaldehyde 37%	T	
			KPT

EN 374-5 microorganism tightness	The glove is tight against microorganisms (viral, bacteria and fungi). Test according to ISO 16604 - method B.
EN ISO 21420 protective gloves	The glove meets the requirements according to EN ISO 21420
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. Force at break ≥ 6 N.
EN 455-1 freedom from holes	The glove has an AQL < 1.5 in regards to the water retention test (sampling inspection in acc. to ISO 2859-1, general Inspection Level I)
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	4044941009964
GTIN subpacking size M	4044941009971
GTIN subpacking size L	4044941009988
GTIN subpacking size XL	4044941040519
GTIN subpacking size XXL	4044941010526
GTIN subpacking size XXXL	-
PZN subpacking size XS	-
PZN subpacking size S	15570341
PZN subpacking size M	15570335
PZN subpacking size L	15570329
PZN subpacking size XL	15570385
PZN subpacking size XXL	15570364
PZN subpacking size XXXL	-
measures & size	
length	280 mm
width	135 mm
heigth	70 mm
weights	
size	**gross weight***
XS	-
S	710 g
M	760 g
L	800 g
XL	840 g
XXL	880 g
XXXL	-

LOGISTIC DATA OUTER PACKING	
generell information	
material	carton
subpackings per outer packing	10
GTIN outer packing size XS	-
GTIN outer packing size S	4044941010533
GTIN outer packing size M	4044941010540
GTIN outer packing size L	4044941010557
GTIN outer packing size XL	4044941010564
GTIN outer packing size XXL	4044941010571
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	390 mm
width	285 mm
heigth	295 mm
weights	
size	**gross weight***
XS	-
S	7.600 g
M	8.100 g
L	8.500 g
XL	8.900 g
XXL	9.300 g
XXXL	-

LOGISTIC DATA PALETTE	
general information	
kind of palett	euro-palette
measures & size	
cartons per layer	8
layers per palette	6
heigth of the palette	192 cm
weights	
size	**gross weight***
XS	-
S	390 kg
M	414 kg
L	433 kg
XL	452 kg
XXL	471 kg
XXXL	-

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WARNINGS AND SAFETY INFORMATION

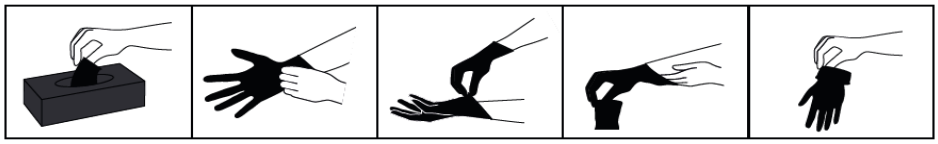
storage / expiry date	Store gloves in original packaging in a cool and dry place without additional weight, protect from direct sunlight. Do not store near ozone sources (laser printers, copiers). The actual expiry time in use cannot be specified in general terms, as it depends on the general conditions 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, which may cause allergic reactions

donning and doffing instructions	

*slight deviations possible due to standard tolerances

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changes and errors excepted