

Technical Data Sheet

Article-No.: **118-038**

Description: **pura comfort black**
Nitrile examination glove
black, non sterile, powder free



THICKNESS*		
cuff	palm	fingertips
0,04 mm	0,05 mm	0,06 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 mm	80 ± 10 mm	95 ± 10 mm	110 ± 10 mm	115 ± 10 mm	-	-
length	≥ 240 mm	≥ 240 mm	≥ 240 mm	≥ 240 mm	≥ 240 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	code letter	ISO 374-1/Type B  KPT
Chemical Risks	Sodium hydroxide 40%	K	
	Hydrogen Peroxide 30%	P	
EN 374-4	Formaldehyde 37%	T	
Degradation			
EN 374-5 microorganism tightness	The glove is tight against microorganisms (viral, bacteria and fungi). Test according to ISO 16604 - method B.		EN ISO 16604-2:2016  VIRUS

EN ISO 21420 protective gloves	The glove meets the requirements according to EN ISO 21420	
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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
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)	AQL 1.5

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	4044941018300
GTIN subpacking size S	4044941018317
GTIN subpacking size M	4044941018324
GTIN subpacking size L	4044941018331
GTIN subpacking size XL	4044941018348
GTIN subpacking size XXL	-
GTIN subpacking size XXXL	-
PZN subpacking size XS	15433006
PZN subpacking size S	15432975
PZN subpacking size M	15432969
PZN subpacking size L	15432952
PZN subpacking size XL	15432981
PZN subpacking size XXL	-
PZN subpacking size XXXL	-
measures & size	
length	200 mm
width	110 mm
height	50 mm
weights	
size	gross weight*
XS	300 g
S	330 g
M	360 g
L	390 g
XL	420 g
XXL	-
XXXL	-

LOGISTIC DATA PALETTE	
general information	
kind of palett	euro-palette
measures & size	
cartons per layer	14
layers per palette	9
height of the palette	204 cm
weights	
size	gross weight*
XS	466 kg
S	504 kg
M	542 kg
L	579 kg
XL	617 kg
XXL	-
XXXL	-

LOGISTIC DATA OUTER PACKING	
generell information	
material	carton
subpackings per outer packing	10
GTIN outer packing size XS	4044941018362
GTIN outer packing size S	4044941018379
GTIN outer packing size M	4044941018386
GTIN outer packing size L	4044941018393
GTIN outer packing size XL	4044941018409
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	260 mm
width	230 mm
height	210 mm
weights	
size	gross weight*
XS	3.500 g
S	3.800 g
M	4.100 g
L	4.400 g
XL	4.700 g
XXL	-
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 after contact with chemicals in accordance with the disposal regulations for the chemical and the 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