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TECHNICAL DATA SHEET



medaSEPT NITRILE PREFER BLUE

MEDICAL AND PROTECTIVE NITRILE POWDER-FREE GLOVES



SPECIFICATION					
RAW MATERIAL	NITRYL				
COLOR	BLUE				
POWDERING AGENT	NONE, POWDER-FREE GLOVES				
SHAPE	UNIVERSAL				
CUFF	ROLLED				
INTERIOR SURFACE	CHLORINATED				
EXTERNAL SURFACE	TEXTURE ON THE TIPS OF THE FINGERS				
AQL	1.0 final product control level: G-1 according to ISO 2859-1				

CLASSIFICATION & NORMATIVE STANDARDS						
CLASSIFICATION	MEDICAL DEVICE	PERSONAL PROTECTIVE EQUIPMENT				
	CLASS I	CATEGORY III, TYPE B				
	in accordance with Regulation (EU) 2017/745	in accordance with Regulation (EU) 2016/425				
STANDARDS	EN 455 1-4	EN ISO 374-1, EN ISO 374-2,				
	EN ISO 15223-1, EN 1041	EN 16523, EN ISO 374-4,				
		EN ISO 374-5, EN ISO 21420				
CODE BASIC UDI-DI		590173887RDNPFLG				

PRODUCT PROPERTIES				
RESISTANCE TO BACTERIA AND FUNGI	in accordance with EN ISO 374-2			
RESISTANCE TO VIRUSES	in accordance with EN ISO 374-5 (ISO 16604) & ASTM F 1671			
CHEMICAL RESISTANCE	in accordance with EN 16523-1 & EN ISO 374-1			
RESISTANCE TO CYTOSTATICS	in accordance with ASTM D 6978			





TECHNICAL PARAMETERS &	MASTER DATA						
size		XS (5-6)	S (6-7)	M (7-8)	L (8-9)	XL (9-10)	
reference number		MSNPRE100XS	MSNPRE100S	MSNPRE100M	MSNPRE100L	MSNPRE100XL	
hand width	[mm]	≤80	80±10	95±10	110±10	≥110	
length	[mm]	min. 240					
thickness (single glove wall)	[mm]	finger: 0.09±0.03 palm: 0.08±0.03 cuff: 0.07±0.03					
breaking force	[N]	before aging: 6.0 N after aging 6.0 N					
powder content	[mg/gloves]	< 2 mg/gloves, powder-free gloves					
latex protein content	[µg/g]	none, latex-free gloves					
quantity in a box		100 pieces according to weights					
quantity in a carton		10 boxes					
EAN box		5901738874657	5901738874664	5901738874671	5901738874688	5901738874695	
EAN carton		5901738874701	5901738874718	5901738874725	5901738874732	5901738874749	
box size	[mm]	225 (L) X 115 (W) X 60 (H)					
carton size	[mm]	310 (L) X 240 (W) X 235 (H)					
expiration date		5 years from the production date					

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INTENDED USE

A single-use device intended to be used to protect the patient and user in order to minimize the risk of cross-infection. Gloves suitable for medical examinations and other diagnostic procedures.

STORAGE INSTRUCTIONS

Protect from sunlight, fluorescent light and ozone and store in a dry place. The recommended relative humidity of the room where the gloves are stored is 60±20%. Keep gloves away from heating devices and sources of fire.

UTILIZATION

Dispose of in accordance with applicable regulations.

CONTACT WITH FOOD

Suitable for contact with food in accordance with: Regulation (EC) 10/2011, Regulation (EC) 1935/2004.



PRODUCER

medaSEPT S.A. street Forteczna 19 61-362 Poznań Poland www.medasept.com

