## **Technical Data Sheet**



## nitrylex® beFree

PRODUCT DESCRIPTION		PHYSICAL PROPERTIES						
Type of the glove	Non-sterile, powder free, examination and	Dimensions	Size	XS	S	M	L	XL
	protective glove for single use			(5-6)	(6-7)	(7-8)	(8-9)	(9-10)
Material	Nitrile	Length [mm]		240	240	240	240	240
Donning powder	-	Minimum		240	240	240	240	240
Colour	Berryblue	Width [mm]		≤80	80	95	110	≥110
Shape	Ambidextrous, gloves fitting either hand				±10	±10	±10	
Cuff	Beaded	Thickness						
External surface	Microtextured + fingertip textured,	(single wall)	Middle finger			0,07		
	polymerized	[mm]	Palm			0,05		
Internal surface	Polymerized + chlorinated	Minimum	Cuff			0,04		
Packaging	10 x 100 pcs							
PRODUCT REFERENCES		Elongation at	Before ageing			500		
SIZE / REFERENCE	XS RD30083001	break [%]	After ageing			400		
NUMBER	S RD30083002	Minimum						
	M RD30083003	Force at	Before ageing			6,0		
	L RD30083004	break[N]	After ageing			6,0		
	XL RD30083005	Minimum						

## **MANUFACTURING AND SAFETY STANDARDS**

AQL Manufacturing final release: G-I inspection level AQL 1.0 in accordance with ISO 2859-1

Powder content < 2 mg/glove

Protein content N/A

CE classification Class I – Medical Device (Council Directive 93/42/EEC) Category III – Personal Protective Equipment (Regulation (EU)

2016/425)

**Compliances** EN 455-1, EN 455-2, EN 455-3, EN 455-4 EN ISO 374-1 (Type C), EN 374-2, EN 374-4, EN ISO 374-5

EN ISO 15233-1, EN 1041 EN 16523-1 EN ISO 13485 EN 420

Viral test Test in accordance with ASTM F1671 & ISO 16604

Cytostatics Test in accordance with ASTM D6978

permeation

Chemical substances Test in accordance with EN 16523-1

permeation

Food contact Declaration of conformity for food contact in accordance with Regulation (EC) No 1935/2004 and with Commission Regulation (EU)

No 10/2011 and Overall Migration Test in accordance with Commission Regulation (EU) No 10/2011

Shelf life 3 years

**STORAGE** 

**Storage instruction** Keep out of direct sunlight. Store in a cool, dry place in temperature 5-35° C. Keep away from sources of ozone and ignition.