

## PRODUCT INFORMATION\* TT® Clear

Doc 4 Revision:02 Effective: 01/08/2015

Page 1/1

Product Information:				
Trade Name	TT <sup>®</sup> Clear			
Туре	Medical Examination Glove, Polyvinyl Chloride (PVC), Non-sterile, Single Glove, Powdered, Ambidextrous			
Intended Use	To conduct medical examination, diagnostic and therapeutic procedures to protect patient and user from			
	cross contamination or infection.			
Product Conformance	In compliance with European Medical Device Directive 93/42/EEC. In accordance to: EN 420, EN 455			
Material	Polyvinyl Chloride (PVC)			
Accelerators	None associated with NRL			
Donning Lubricant	Corn Starch (according to U.S.P. Absorbable Dusting Powder			
Cuff Finishing	Beaded			
Color	Nature white			
Design	Ambidextrous			
Storing conditions	Keep dry, Keep away from sunlight			
Temperature limitation	Between 5°C and 25°C			
Residual Powder	Maximum 10,0 mg			
Dimensions of the innerboxes	245 x 130 x 67 mm			
Dimensions of the outer carton	358 x 273 x 260 mm			
Product Specification:	556 X 275 X 266 Hilli			
Conform EN 420, EN455				
Reference codes	Size	Order code	Packing unit	Innerboxes
Reference codes	Small	02000	1000	10 x 100
	Medium	02001	1000	10 x 100
	Large	02001	1000	10 × 100
		02002	900	10 x 100
Dimensions	Extra Large Size	Palm Width (mm)	Length (mm)	10 X 100
Dimensions Thickness	Small	80 ± 10	min. 240	
	Medium	95 ± 10	min. 240	
		95 ± 10 110 ± 10	min. 240	
	Large		-	
	Extra Large ≥ 110 min. 240			
	Single wall thickness (mm) / Location		0.00	
	Palm 		0.08	
	Finger		0.08	
	Cuff		0.08	
Physical Properties	Before Aging	Properties		
	Force at Break (N)	Minimum 3,6 Newton		
	Elongation (%)	Minimum 350%		
Physical Properties	After Aging	Properties		
	Force at Break (N)	Minimum 3,6 Newton		
	Elongation (%)	Minimum 350%		
Shelf life	3 Years upon manufacti	uring date		
5.6	lon :	1	101	
Performance requirements	Criteria	Inspection Level	AQL	
	1000 ml Water Leak	G-1	1.5	
	Physical properties	S-2	4.0	
	Dimension	S-2	4.0	
	Visual Inspection	S-2	4.0	

Manufactured under FDA Quality System Regulation (QSR) and ISO9001 Quality Systems

Medica Europe BV	
Quality assurance	Medica Europe operates with a quality management system which complies with the requirements of ISO13485: 2003

 $<sup>\</sup>overline{\text{TT}^{\$}}$  Clear and Medica Europe are registered trademarks of Medica Europe B.V.

<sup>©</sup> Medica Europe. Not to be reproduced or distributed without prior written permission of Medica Europe B.V.

<sup>\*</sup> The product information provided is a guideline of typical performance characteristics of the product and is not to be used as actual product specification.