

	TECHNICAL DATA		TD-49-I.1.1-4.1.2-A
	annex to the technical data sheet		revision 2
	device: safeCARE pf Latex surgical gloves, powder-free		date: 2024-02-08
	general group name: sterile surgical gloves		amendment of: 2025-03-31

INFORMATION ON THE MEDICAL DEVICE

name of device	safeCARE Latex surgical gloves, powder-free, sterile		
device identification (models, sizes, catalogue numbers)	REF	model	size
	RCHLB-55-50-03	safeCARE pf Latex surgical gloves, powder-free, sterile	5.5
	RCHLB-60-50-03	safeCARE pf Latex surgical gloves, powder-free, sterile	6.0
	RCHLB-65-50-03	safeCARE pf Latex surgical gloves, powder-free, sterile	6.5
	RCHLB-70-50-03	safeCARE pf Latex surgical gloves, powder-free, sterile	7.0
	RCHLB-75-50-03	safeCARE pf Latex surgical gloves, powder-free, sterile	7.5
	RCHLB-80-50-03	safeCARE pf Latex surgical gloves, powder-free, sterile	8.0
	RCHLB-85-50-03	safeCARE pf Latex surgical gloves, powder-free, sterile	8.5
	RCHLB-90-50-03	safeCARE pf Latex surgical gloves, powder-free, sterile	9.0
manufacturer	ZARYS International Group sp. z o.o. sp.k.		
manufacturer's address	ul. Pod Borem 18, 41-808 Zabrze, Poland	SRN	PL-MF-000000410
website	www.zarys.com		
standard	EN 455-2 Medical gloves for single use. Part 2: Requirements and testing for physical properties point 5.2, 5.3*		
parameter	result		
weight [g]	9,2 ± 0,2		
outer surface	smooth with micro-texture over the entire grip area		
internal surface	polymer for easy donning		
thickness [mm]*	part of glove	single wall	
	finger (13mm from the tip)	0,18 ± 0,02	
	palm (in the middle part)	0,16 ± 0,02	
	cuff	0,14 ± 0,02	
force at break [N]*	before aging	after aging	
	min. 18	min. 16	
elongation at break [%]	min. 750	min. 600	
tensile strength [MPa]	min. 25	min. 20	