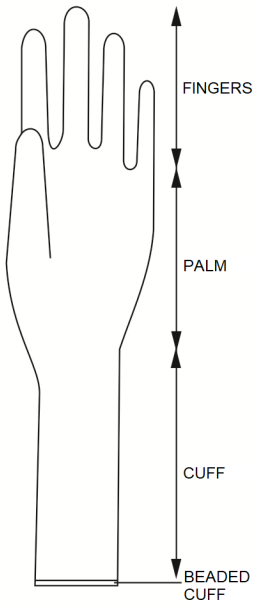
INFORMATION ON THE MEDICAL DEVICE						
name of device	safeCARE Latex surgical gloves, powdered, sterile					
device identification (models, sizes, catalogue numbers)	REF	model				size
	RCHLP-55-50-03	safeCARE Latex surgical gloves, powdered, sterile				5.5
	RCHLP-60-50-03	safeCARE Latex surgical gloves, powdered, sterile				6.0
	RCHLP-65-50-03	safeCARE Latex surgical gloves, powdered, sterile				6.5
	RCHLP-70-50-03	safeCARE Latex surgical gloves, powdered, sterile				7.0
	RCHLP-75-50-03	safeCARE Latex surgical gloves, powdered, sterile				7.5
	RCHLP-80-50-03	safeCARE Latex surgical gloves, powdered, sterile				8.0
	RCHLP-85-50-03	safeCARE Latex surgical gloves, powdered, sterile				8.5
	RCHLP-90-50-03	safeCARE Latex surgical gloves, powdered, 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
classification of medical device		class	IIa	rule	7	
classification of Personal Protective Equipment		category	III	type in accordance with EN ISO 374-1	B	
EC Certificate Number (if applicable)	2777/11101-03/E02-01	Notified Body involved in conformity assessment (if applicable)		SATRA Technology Europe Limited Bracetown Business Park, Clonee, Co. Meath, D15 YN2P, Ireland		
Notified Body number	2777					
microbiological status	sterile	type of sterilisation		radiation	standard	EN ISO 11137
Basic UDI-DI	59079968T01010101-RYM	EMDN code		T010101	GMDN code	47179
reference to the standards and specifications (factory standards) applicable to the device	EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-23:2021, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-1:2020/A1:2023, EN ISO 11607-2:2020/A11:2022, EN ISO 11607-2:2020/A1:2023, EN ISO 11737-1:2018+ EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, EN ISO 11137-1:2015, EN ISO 11137-2:2015+A1:2023, EN ISO 11137-3:2017, EN 556-1:2024, EN ISO 14971:2019+EN ISO 14971:2019/A11:2021, EN ISO 15223-1:2021, EN ISO 20417:2021, EN 62366-1:2015+EN 62366-1:2015/A1:2020, ISO 10282:2023, ISO 2859-1:1999/Amd 1:2011, ASTM D5712, ASTM D5151, ASTM D6124, ASTM D7161, ASTM D3577, ASTM D6978, ASTM F1671, EN ISO 21171:2006, EN ISO 13485:2016, EN ISO 13485:2016/A11:2021, EN ISO 9001:2015, EN ISO 9001:2015/A1:2024, EN ISO 14001:2015, EN ISO 14001:2015/A1:2024, EN ISO 21420:2020/A1:2024, EN ISO 374-1:2016, EN ISO 374-1:2016/A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016					

SPECIFICATION OF THE MEDICAL DEVICE	
intended purpose	device intended for use by medical staff in the operating theatre environment to provide a barrier to the transmission of micro-organisms between the operator and the patient, minimising the risk of cross-contamination
nature of body contact (invasiveness of the device)	the device is a invasive, surgical medical device
site of contact (organs/tissues/body fluids with which the device comes into contact)	the device comes into direct contact with the patient's skin, blood, mucous membranes, external tissues, internal tissues and/or body fluids
maximum service life	up to 30 days
frequency of use	single-use device, use at least 1 pair of gloves for one patient and one procedure
shelf-life	5 years - from the date of manufacture
purpose of use	a device used in the operating theatre environment to provide a barrier to the transmission of microorganisms between the operator and the patient, minimizing the risk of cross-infection
patient population	patients regardless of gender and age
target group of users	operator / user during medical examinations, surgical procedures, diagnostic and therapeutic activities, and preparation of medicines under aseptic conditions
patient selection criteria	patients requiring surgery, invasive procedures, dental procedures, procedures requiring sterile conditions, diagnostic and therapeutic activities requiring strict asepsis
indications for use	the necessity to ensure a barrier for the transmission of microorganisms between the operator and the patient
contraindications for use	The gloves contain natural latex and other ingredients used at the manufacturing process that may cause allergic reactions, including anaphylactic shock. If these reactions occur, discontinue use of the gloves and contact a medical specialist. Do not use on persons allergic to latex.

warnings	▪ gloves made of natural rubber latex - may cause allergic reactions including anaphylactic shock ▪ gloves are intended for single use only and should be replaced after use ▪ change the gloves immediately in case of mechanical damage ▪ the device should be used for surgical procedures or therapeutic activities during patient care that may involve exposure to infectious material (contact with blood and body fluids, mucous membranes, broken skin), during care of patients colonised or infected by contact-transmitted pathogens ▪ the glove is a single-use product, it is not subject to cleaning, maintenance or disinfection procedures; do not re-use ▪ do not use if the packaging is damaged ▪ use immediately after removal from the packaging ▪ do not use the device after the expiry date specified on the packaging
principle of operation and use	▪ Take one glove without touching the packaging. ▪ Holding the upper part of the cuff with the dominant hand, put the glove on the non-dominant hand (each glove is anatomically shaped). ▪ Then with the gloved hand (or with the help of operating theatre staff) take the second glove (avoid touching the packaging) and holding the upper part of the cuff, put the glove on the dominant hand. ▪ After the procedure, grab one glove by the upper part of the cuff and take it off the hand while turning the glove inside out. ▪ Holding the first glove pulled off, slide the fingers of the gloveless hand between the glove and the wrist and, holding the glove from the inside, pull the glove off by turning it inside out until it slides completely off the hand, or remove it together with the surgical gown. ▪ Holding the glove by the uncontaminated part, dispose of it in the medical waste container.
novel features	N/A no new properties
accessory	N/A device has no equipment
products/ accessories intended to be used in combination with the device	N/A device is not designed to be combined with other accessory/device
characteristics of compatibility with other products/ accessories	N/A the device is not designed to be combined with any other accessory/product
possible configurations/ device variants	device available in 8 sizes: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0
features	• powder: slightly powdered with maize flour, the content of powder ≤ 10mg/dm^2 • AQL: 0.65 • protein content ≤ 50µg/g anatomical shape, with opposing thumb for the left and right hand in each pair biodegradable due to use of natural raw material • free of substances of very high concern (SVHCs) in the REACH (EC) regulation published by the European Chemicals Agency (ECHA) • intermediate packaging: 50 pairs • sterile – radiation
diagram / photograph / drawing	

description of key functional elements	**description of the device component**	**features**	**material/ raw material**	**colour**
	finger	anatomical shape	100% natural rubber latex	natural latex, white and cream
	palm	fitting to the right and left hand, with opposing thumb		
	cuff	straight		
	cuff edge	rolled		

detailed dimensions / specifications	**REF**	**size**	**hand width (mm)**	**glove lenght (mm)**
	RCHLP-55-50-03	5.5	75±5	min. 280mm
	RCHLP-60-50-03	6.0	77±5	min. 280mm
	RCHLP-65-50-03	6.5	82±5	min. 280mm
	RCHLP-70-50-03	7.0	88±5	min. 280mm
	RCHLP-75-50-03	7.5	96±5	min. 280mm
	RCHLP-80-50-03	8.0	102±5	min. 280mm
	RCHLP-85-50-03	8.5	108±5	min. 280mm
	RCHLP-90-50-03	9.0	112±5	min. 280mm

technical specifications	included in annex A of the technical sheet - technical data	
materials, substances, gases coming into contact with the device during use	among others, cytostatic drugs, chemicals, inorganic bases, aldehydes, peroxides	
compatibility with medicinal products administered by the device	N/A the device is not intended to administer substances to the patient	
flow rate of substances administered to the patient	N/A the device is not intended to administer substances to the patient	
content of carcinogens	type of substance	N/A
	substance content in percentage by weight	the device does not contain carcinogenic substances
content of mutagenic substances	type of substance	N/A
	substance content in percentage by weight	the device does not contain mutagenic substances
content of substances toxic for reproduction	type of substance	N/A
	substance content in percentage by weight	the device does not contain substances toxic to reproduction
applied safeguards against unintentional intrusion of substances into the device	N/A applied safeguards against unintentional intrusion of substances into the device	
applied safeguards against unintentional cutting and pricking of the device	N/A the device does not imply cuts or pricks	
applied safeguards to prevent use errors or interpretation of results	▪ data labels in accordance with EN ISO 15223-1 and EN ISO 20417 ▪ Instructions for use in accordance with the requirements of Regulation (EU) 2016/425 of the European Parliament and of the Council	
measuring function	ensuring measurement precision and stability	N/A the device has no measuring function
	measurement accuracy limits	N/A the device has no measuring function
	units of measurement used	N/A the device has no measuring function
methods of effective disposal of the device after use	▪ in accordance with the applicable procedures of the medical facility in question ▪ recommended disposal by thermal method (incineration in specialized incinerators) ▪ improper disposal of the product poses a threat of microbiological contamination of bystanders and the environment	

description of packaging	**type of packaging**	**REF**	**packaging dimensions [mm]**	**packaging material**	**number of devices [pcs]**	**number of labels**	**print colour**
	intermediate packaging	RCHLP-55-50-03	13,1cm x 14cm x 24,5cm	flat cardboard – a cardboard box with a perforation to open	50 pairs	printing on each wall	PANTONE BlackC PANTONE 429 C
		RCHLP-60-50-03					PANTONE BlackC PANTONE 429 C
		RCHLP-65-50-03					PANTONE BlackC PANTONE 429 C
		RCHLP-70-50-03					PANTONE BlackC PANTONE 429 C
		RCHLP-75-50-03					PANTONE BlackC PANTONE 429 C

		RCHLP-80-50-03					PANTONE BlackC PANTONE 429 C
		RCHLP-85-50-03					PANTONE BlackC PANTONE 429 C
		RCHLP-90-50-03					PANTONE BlackC PANTONE 429 C
	transport packaging	RCHLP-55-50-03	54,5cm x 29,3cm x 26cm	carton – corrugated cardboard with printing	8 x 50 pairs	direct printing on 4 walls	PANTONE BlackC PANTONE 429 C
		RCHLP-60-50-03					PANTONE BlackC PANTONE 429 C
		RCHLP-65-50-03					PANTONE BlackC PANTONE 429 C
		RCHLP-70-50-03					PANTONE BlackC PANTONE 429 C
		RCHLP-75-50-03					PANTONE BlackC PANTONE 429 C
		RCHLP-80-50-03					PANTONE BlackC PANTONE 429 C
		RCHLP-85-50-03					PANTONE BlackC PANTONE 429 C
		RCHLP-90-50-03					PANTONE BlackC PANTONE 429 C
marking used	list of the used markings is included in point I.2.a of the technical documentation – device label						
storage and transport conditions	**temperature [°C]**	5°C - 30°C		**humidity [%]**	protect from humidity		
	other	store in a cool, dry, well-ventilated and clean place away from direct sunlight; keep away from ozone and fire sources; store gloves in original packaging					