Due to the wide range of potential applications for examination gloves, Sempermed recommends the following Sempercare® products in the defined segments in

ı	LATEX GLC	(EXA OVES	М			٨	ITRILI GLO	E EXA	M				NYL EX		_	RILE E	XAM S
Sempercare	Sempercare® edition IC		Sempercare®	Sempercare®	Sempercare® chi	Sempercare® sot.	Sempercare® silL	Sempercare® alc.	Sempercare® ₅ /:: 3	Sempercare® velv.	Sempercare	Sempercare®	Sempercare® vinyl pf	Sempercare® proc.	Sempercare® _{p.t}	١ الرياق	diex pp sterile
х			х	х							х			х	х		
x	х	х			х	x	x	x	х	x				x		х	

	orda ir us	nce with the demands on e.	Sempercare® r	Sempercare®	Sempercare® e	Sempercare® I	Sempercare® _r	Sempercare® e	Sempercare® c	Sempercare® c	Sempercare® 2	Sempercare® 3	Sempercare® e	Sempercare® _v	Sempercare®	Sempercare® v	Sempercare® v	Sempercare®	Sempercare® n	Sempercare® la
		Higher wall thickness	х	x			х	х							х			x	x	
		Tactile sensitivity	x	x	x	х			x	x	х	х	x	x				x		x
RES		Higher grip and dexterity		х	х	х	х												x	х
FEATU		Innercoating	х	х							х	х			х	х		x		
PRODUCT FEATURES		High wearing comfort	х	х	х	x				х	х	x	х	x				x		x
PRC		Extended cuff protection						х	х											
		Suiteable for Type-I allergy sufferers					х	х	х	х	х	х	х	x	х	х	х		х	
		Suiteable for Type-IV allergy sufferers													x	х	х			
	risk	Patient mobilisation	х	х	х	x			х	х			х	х	x	х	х	x		x
	minimal risk	Medication dispensing	x	x	x	х			x	x			x	x	x	x	х	x		x
	Ε	Food preparation	x	x	x	х			х	x			х	x				x		x
		Non-invasive physical examinations	х	х	x	х	х		х	х			х	х	х	x	х	x	x	x
		Operation theater cleaning	х	х	х		x	х	х	х			х	х		х		x	х	
SNO		Instrument handling	x	x	x	х	х	x	x	x	x	х	x	x	x			x	x	x
APPLICATIONS		Dental procedures	x	x	x				x	x	x	х	x	x				x		
APP		IV injection / insersion	х	х	x		х		х	х			х	х	х	х		x	x	
		Staple removal	х	х	х		х		х	х			х	х				х	x	
		Patient wound dressing	х	х	х		х		х	х			х	х	х			х	х	
	isk	Desinfection of instruments					х	х			х	х							х	
	complex risk	Handling cytotoxics*					х	х											х	
	9	Catheterization																х	х	х
NTS	(Hospital	\$	S	S		S	\$	\$	\$	\$	S	\$	S	S	S		S	S	S
DMMENDED SEGMENTS	X	Dental		\$	S				\$	\$	\$	\$	\$	S						
NDED 8		Primary care	\$	S	S	S				S			\$	S	S	S	S	S	S	S
OMME		Longterm care	S		S					S			S	S		S	S			



EXAMINATION GLOVES FROM SEMPERMED – WE PROTECT YOUR HANDS

As one of the world's leading manufacturers of medical gloves, with more than 95 years of experience in research, development and production, it is important for us to give our clients and users recommendations for the optimal use of our extended range of Sempercare® products.

2-Times Certified Protection

Sempercare® Product Portfolio

MD Directive

The Optimal Glove Choice

2-Times Certified Protection

certified according to the

(medical device directive

certified according to the

Hepatitis B, Hepatitis C, or HIV – as required.

(personal protective equipmen

The demands vary greatly. In addition to protecting against

chemicals and cleaning products* our gloves are used to avert the

Impermeable to liquids and chemicals, yet elastic, adapting optimally to the hand form and skin, as well as unprecedented dexterity - there is hardly a glove that meets all of these requirements. Therefore is the selection of the most appropriate glove for each application area, of great importance. The protective function in

this case is dependent on the glove material to defend against

Because selecting the right glove can have an impact on the health of the user as well as the patient, the high requirements of the European standards and guidelines are controlled: All Sempercare® products are certified as medical devices in accordance with the Medical Devices Regulation guideline 93/42 EWG, and fulfill all parts of standard EN455. Moreover, they are also certified as Personal Protective Equipment in accordance with Directive 89/686 EEC. This advanced purpose enables the use of Sempercare® gloves in many applications.



Material: Latex, Nitrile or Vinyl. Sempermed generally recommends the use of Nitrile gloves, as it fulfills the following criteria: nitrile products provide optimum protection against vi-

ral infections, various chemicals* and score with high tensile strength. Thanks to the innovative material mix of Sempermed the wearing of the glove is extremely comfortable. Produced without latex proteins and powder, they also have excellent skin-friendliness, without the danger of Type-I Allergies.



Grip: Some application areas require a textured glove, others with a smooth surface structure. Depending on what type of glove is needed, our glove portfolio offers the optimal solution.



Innercoating: If you are on the search for a glove that looks after your skin too, there are gloves with a functional inner coating, the inner lining enables easy glove donning and removal.



Extra Length: Additional protection for the wrist and forearm as well as an increased splashguard, our gloves provide the portfolio with extra length (265mm/300mm) – your margin of safety.

risk of infections, especially blood-transmitted infections, such as

The Sempercare® product portfolio, of fers the right solution for the most diverse demands. For more information see: substances as well as the mechanical stresses faced by the glove.

IMPORTANT NOTE: The latest information is available at www.sempermed.com, Failure to observe this information, in particular with regard to (chemical) resistance, frequency of use and tolerability of the gloves, can result in personal injury and/or material damage. Semperit does not accept any liability for incorrect use of the gloves. In case of doubt, obtain expert advice before use. The information and classification correspond to the latest status prior to printing. Technical details are average values from production and may vary in individual

The wearing time of the glove also plays an important role.

CONTACT US!

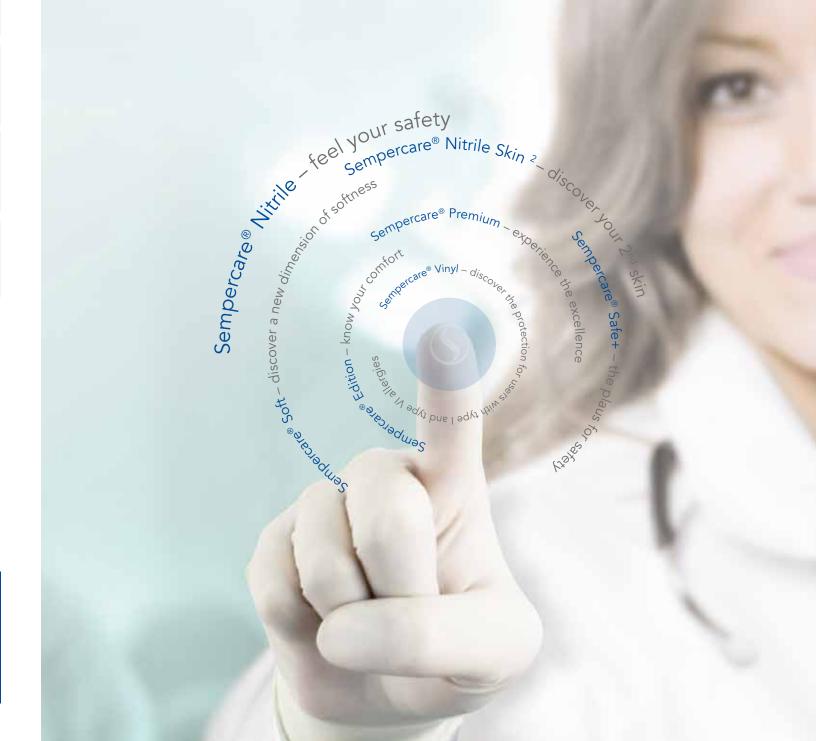
Semperit Investments Asia Pte Ltd Singapore 609434 · 8 Jurong Town Hall Road #29-03 to 06 The JTC Summit E-Mail: sempermed@semperitgroup.com

Semperit Technische Produkte Gesellschaft m.b.H. Segment Sempermed Austria . 1030 Vienna . Modecenterstr. 22 Tel.: +43 1 79 777-0 E-Mail: sempermed@semperitgroup.com www.sempermed.com

sempercare (

DESIGNED AROUND YOUR HANDS

EXAMINATION GLOVES



pf = powderfree pp = powdered

S S S

			SEMPERC	ARE® NITRILE PORTFOLIC	O / unsterile		
BRAND NAME	Sempercare® safe+	Sempercare® nitrile	Sempercare® nitrile shine+	Sempercare® silk	Sempercare® soft	Sempercare® nitrile skin²	Sempercare® Velvet
	60	0			70	0	
KEY GLOVE FEATURES	1) 300mm long – for additional protection 2) secure grip – thanks to finger texturing 3) chemical resistance*	1) good chemical resistance (acc. to chemical list)* 2) 9N force at break (typical prod. value) 3) suitable for specific cytostatics (acc. to cytostatics list)*	l) longer cuff: 265mm l) higher wallthickness innovative opening foil glove box size colour code	1) liquide silk inside 2) high wearing comfort 3) easy to don – with special silk innercoating	1) extremely comfortable to wear – particularly soft material 2) light pink – pleasant color 3) optimum protection	1) lavender blue colored 2) high wearing comfort due to soft material 3) great tactile sense	1) feather light formulation combin with a force at break of ≥6 N ² 2) extra soft material, wears like a second skin 3) excellent sense of touch and superior wearing comfort 4) glove box size colou code
BASIC INFORMATION							
Material	nitrile-butadien-rubber	nitrile-butadien-rubber	nitrile-butadien-rubber	nitrile-butadien-rubber	nitrile-butadien-rubber	nitrile-butadien-rubber	nitrile-butadien-rubbe
Length	median 300 mm	median 240 mm	median 265 mm	median 240 mm	median 240 mm	median 240 mm	median 240 mm
Inside Treatment	powder free / chlorinated	powder free / chlorinated	powder free / chlorinated	powder free / silk coated	powder free / chlorinated	powder free / chlorinated	powder free / online chlorinated
Surface	finger textured	finger textured	finger textured	finger textured	finger textured	finger textured	finger textured
Typical production values thickness at palm (double)	0.20 mm	0.20 mm	0.15 mm	0.14 mm	0.14 mm	0.14 mm	0.11 mm
FORCE AT BREAK typical production value according to EN 455-2	median 8 N	median 9 N	median 6 N	median 6 N	median 7 N	median 7 N	median 6 N
Shelf Life	3 years	3 years	3 years	3 years	3 years	3 years	3 years
Color	blue	blue	white	white	light pink	lavender blue	lavender blue
Latex-proteins	no	no	no	no	no	no	no
Accelerating chemicals	✓	✓	✓	✓	✓	✓	✓
LABELLING							
MD Directive (medical device directive)	CE Class I	CE Class I	CE Class I	CE Class I	CE Class I	CE Class I	CE Class I
PPE Directive (personal protective equipment directive)	CE Category III complex risk	CE Category III complex risk	CE Category III complex risk	CE Category III complex risk	CE Category III complex risk	CE Category III complex risk	CE Category III complex risk
ASTM D6319	✓	~	✓	✓	✓	✓	✓
EN 455 1-4	✓	~	✓	✓	✓	✓	✓
EN 420	✓	~	✓	✓	✓	✓	✓
EN 374-1, -2	✓	✓	✓	✓	✓	✓	✓
EN 374-3 / EN 16523-1	✓	✓	✓	✓	✓	✓	✓
AQL for pinholes (inspection level G1)	1.5	1.5	1.5	1.5	1.5	1.0 & 1.5	1.5
Food contact Reg. 1935/2004	✓	✓	✓	✓	✓	✓	✓
PACKAGING / LOGISTIC							
Reference Number	100 pcs. 8267 5803x ("x" = 1 for XS, 3 for S, 5 for M, 7 for L, 9 for XL)	100 pcs. 8267 8163x 200 pcs. 8267 9143x ("x" = 1 for XS, 3 for S, 5 for M, 7 for L, 9 for XL)	8267 7843x ("x" = 1 for XS, 3 for S, 5 for M, 7 for L, 9 for XL)	8267 6083x ("x" = 1 for XS, 3 for S, 5 for M, 7 for L, 9 for XL)	8267 6853x ("x" = 1 for XS, 3 for S, 5 for M, 7 for L, 9 for XL)	100 pcs.: 8267 9804x 200 pcs.: 8267 9384x AQL 1.0: 8267 9914x ("x" = 1 for Xs, 3 for S, 5 for M, 7 for L, 9 for XL)	300 000x (100 pcs: "x" = 6795 for XS, 6796 for S 6797 for M, 6798 for I 6799 for XL 200 pcs: "x" = 6800 for XS, 6801 for S 6802 for M, 6803 for I 6804 for XL)
Available sizes	XS/S/M/L/XL	XS/S/M/L/XL	XS/S/M/L/XL	XS/S/M/L/XL	XS/S/M/L/XL	XS/S/M/L/XL	XS/S/M/L/XL
Pcs / dispenser	XS/S/M/L: 100 pcs. XL: 90 pcs.	XS/S/M/L: 100 or 200 pcs. XL: 90 or 180 pcs.	XS/S/M/L: 150 pcs. XL: 135 pcs.	XS/S/M/L: 150 pcs. XL: 135 pcs.	XS/S/M/L: 200 pcs. XL: 180 pcs.	XS/S/M/L: 100 or 200 pcs. XL: 90 or 180 pcs.	XS/S/M/L: 100 or 200 p XL: 90 or 180 pcs.
Pcs / transport carton	XS/S/M/L: 1.000 pcs. XL: 900 pcs.	XS/S/M/L: 1.000 or 2.000 pcs XL: 900 or 1.800 pcs.	XS/S/M/L: 1.500 pcs. XL: 1.350 pcs.	XS/S/M/L: 1.500 pcs. XL: 1.350 pcs.	XS/S/M/L: 2.000 pcs. XL: 1.800 pcs.	XS/S/M/L: 1.000 or 2.000 pcs. XL: 900 or 1.800 pcs.	XS/S/M/L: 1.000 or 2.0 pcs. XL: 900 or 1.800 pcs

		SEMPERCARE® LATEX P	OWDER-FREE AND POWDER	RED PORTFOLIO / unsterile	
BRAND NAME	Sempercare® premium	Sempercare® edition IC	Sempercare® edition	Sempercare® latex powdered	Sempermed® latex powdered (ASTM)
	ZOJ				
KEY GLOVE FEATURES	1) special synthetic inner-coating for skin friendliness & easier donning 2) 9 N force at break (typical prod. value) 3) extra smooth surface & extra large pass formers	special synthetic inner-coating for skin friendliness & easier donning fully textured – overall grip high wearing comfort	finger textured for good handling of instruments high wearing comfort thanks to softness of material and elasticity excellent sense of touch	powdered for easy donning finger textured for good handling of instruments high wearing comfort	1) powdered for easy donning 2) finger textured for good handling of instruments 3) high wearing comfort
BASIC INFORMATION					
Material	natural latex	natural latex	natural latex	natural latex	natural latex
Length	median 240 mm	median 240 mm	median 240 mm	median 240 mm	min. 230 mm
Inside Treatment	powder-free /	powder-free /	powder-free / inner coated or chlorinated	powdered (cornstarch)	powdered (cornstarch)
Surface	inner coated & chlorinated extra smooth, finger textured	inner coated grippy, fully textured	grippy, finger textured	micro rough	micro rough
Typical production values	0.27 mm	0.24 mm	0.21 mm	0.21 mm	0.19 mm
thickness at palm (double) FORCE AT BREAK typical production value according to EN 455-2	median 9 N	median 8 N	median 6 N	median 6 N	not specified
Shelf Life	3 years	3 years	3 years	5 years	5 years
Color	natural white	natural white	natural white	natural white	natural white
Latex-proteins	√	√	✓	✓	✓
Accelerating chemicals	√	√	√	✓	✓
LABELLING					
MD Directive (medical device directive)	CE Class I	CE Class I	CE Class I	CE Class I	no
PPE Directive (personal protective equipment directive)	CE Category III complex risk	CE Category III complex risk	CE Category III complex risk	CE Category III complex risk	no
ASTM D3578	✓	✓	✓	✓	✓
EN 455 1-4	~	~	~	✓	no
EN 420	✓	✓	✓	✓	no
EN 374-1, -2	~	~	~	✓	no
EN 374-3 / EN 16523-1	✓	✓	✓	✓	no
AQL for pinholes (inspection level G1)	1.5	1.5	1.5	1.5	2.5
Food contact Reg. 1935/2004	√	✓	√	✓	no
PACKAGING / LOGISTIC					
INFORMATION Reference Number	8237 8104x ("x" = 1 for XS, 3 for S, 5 for M, 7 for L, 9 for XL)	8237 8174x ("x" = 1 for XS, 3 for S, 5 for M, 7 for L, 9 for XL)	8237 8173x ("x" = 1 for XS, 3 for S, 5 for M, 7 for L, 9 for XL)	8239 8102x ("x" = 1 for XS, 3 for S, 5 for M, 7 for L, 9 for XL)	8239 8022x ("x" = 1 for XS, 3 for S, 5 for M, 7 for L, 9 for XL)
Available sizes	XS/S/M/L/XL	XS/S/M/L/XL	XS/S/M/L/XL	XS/S/M/L/XL	XS/S/M/L/XL
Pcs / dispenser	XS/S/M/L: 100 pcs. XL: 90 pcs.	XS/S/M/L: 100 pcs. XL: 90 pcs.	XS/S/M/L: 100 pcs. XL: 90 pcs.	XS/S/M/L: 100 pcs. XL: 90 pcs.	XS/S/M/L: 100 pcs. XL: 90 pcs.
Pcs / transport carton	XS/S/M/L: 1.000 pcs. XL: 900 pcs.	XS/S/M/L: 1.000 pcs. XL: 900 pcs.	XS/S/M/L: 1.000 pcs. XL: 900 pcs.	XS/S/M/L: 1.000 pcs. XL: 900 pcs.	XS/S/M/L: 1.000 pcs. XL: 900 pcs.

	SEMPERCARE® LATEX P	OWDER-FREE AND POWDER	ED PORTFOLIO / unsterile	
Sempercare® premium	Sempercare® edition IC	Sempercare® edition	Sempercare® latex powdered	Sempermed® latex powdered (ASTM)
Z.0.3				A S
ecial synthetic er-coating for skin endliness & sier donning I force at break sical prod. value) tra smooth surface & tra large pass formers	special synthetic inner-coating for skin friendliness & easier donning fully textured – overall grip high wearing comfort	finger textured for good handling of instruments high wearing comfort thanks to softness of material and elasticity excellent sense of touch	powdered for easy donning finger textured for good handling of instruments high wearing comfort	powdered for easy donning finger textured for good handling of instruments high wearing comfort
natural latex	natural latex	natural latex	natural latex	natural latex
median 240 mm	median 240 mm	median 240 mm	median 240 mm	min. 230 mm
powder-free / er coated & chlorinated	powder-free / inner coated	powder-free / inner coated or chlorinated	powdered (cornstarch)	powdered (cornstarch)
smooth, finger textured	grippy, fully textured	grippy, finger textured	micro rough	micro rough
0.27 mm	0.24 mm	0.21 mm	0.21 mm	0.19 mm
median 9 N	median 8 N	median 6 N	median 6 N	not specified
3 years	3 years	3 years	5 years	5 years
natural white	natural white	natural white	natural white	natural white
✓	✓	✓	✓	✓
✓	✓	✓	✓	✓
CE Class I	CE Class I	CE Class I	CE Class I	no
CE Category III complex risk	CE Category III complex risk	CE Category III complex risk	CE Category III complex risk	no
✓	✓	✓	✓	✓
✓	✓	✓	✓	no
✓	✓	✓	✓	no
✓	✓	✓	✓	no
✓	✓	✓	✓	no
1.5	1.5	1.5	1.5	2.5
✓	✓	✓	✓	no
8237 8104x <" = 1 for XS, 3 for S, or M, 7 for L, 9 for XL)	8237 8174x ("x" = 1 for XS, 3 for S, 5 for M, 7 for L, 9 for XL)	8237 8173x ("x" = 1 for XS, 3 for S, 5 for M, 7 for L, 9 for XL)	8239 8102x ("x" = 1 for XS, 3 for S, 5 for M, 7 for L, 9 for XL)	8239 8022x ("x" = 1 for XS, 3 for S, 5 for M, 7 for L, 9 for XL)
XS/S/M/L/XL	XS/S/M/L/XL	XS/S/M/L/XL	XS/S/M/L/XL	XS/S/M/L/XL
XS/S/M/L: 100 pcs. XL: 90 pcs.	XS/S/M/L: 100 pcs. XL: 90 pcs.	XS/S/M/L: 100 pcs. XL: 90 pcs.	XS/S/M/L: 100 pcs. XL: 90 pcs.	XS/S/M/L: 100 pcs. XL: 90 pcs.
S/S/M/I · 1 000 pcs	XS/S/M/I · 1 000 pcs	XS/S/M/I · 1 000 pcs	YS/S/M/I · 1 000 pcs	XS/S/M/I · 1 000 pcs

		SEMPERCARE® / sterile		S	EMPERCARE® VINYL / unsteri	ile
BRAND NAME	Sempercare® premium	Sempercare® nitrile	Sempercare® latex powdered	Sempercare® syn-stretch	Sempercare® vinyl powder-free	Sempercare® vinyl powdered
		-	-			











www.sempermed.com

KEY GLOVE FEATURES

special synthetic inner-coating for skin friendlin & easier donning) 9 N force at break (typical prod. value) i extra-smooth surface & extra large pass formers

1) good chemical resistance (acc. to chemical list)*
2) 9 N force at break (typical prod. value)
3) suitable for specific cytostatics (acc. to cytostatics list)*

1) powdered for easy donning
2) finger textured for goo handling of instrument 3) high wearing comfort 4) available in pairs and peel pouch e 1) powdered for easy doning:
2) finger textured for good handling of instruments
3) high wearing comfort
4) available in pairs and pcs. peel pouch

1) more elastic than usual Vinyl gloves
2) free of natural rubber latex (suitable for people with type I allergy)
3) free from accelerant chemicals (suitable for people with type IV allergy)
4) DOP free

1) more elastic than usual
Vinyl gloves
2) free of natural
2) free from natural rubber latex
(suitable for people with type I allergy)
2) free from accelerant chemicals
(suitable for people with type IV allergy)
3) DOP free

BASIC INFORMATION

Material	natural latex	nitrile-butadien-rubber	natural latex	synthetic polymer / vinyl	vinyl	vinyl
Length	median 240 mm	median 240 mm	median 240 mm	median 240 mm	median 240 mm	median 240 mm
Inside Treatment	powder-free, sterile / inner coated & chlorinated	powder-free, sterile / chlorinated	powdered, sterile / powdered (cornstarch)	powder-free / inner coated	powder-free / inner coated	powdered (cornstarch)
Surface	extra smooth, finger textured	finger textured	micro rough	smooth	smooth	smooth
Typical production values thickness at palm (double)	0.27 mm	0.20 mm	0.21 mm	0.16 mm	0.13 mm	0.13 mm
FORCE AT BREAK typical production value according to EN 455-2	median 9 N	median 9 N	median 6 N	median 3.6 N	median 3.6 N	median 3.6 N
Shelf Life	3 years	3 years	5 years	3 years	5 years	5 years
Color	natural white	blue	white	yellowish	transparent	transparent
Latex-proteins	✓	no	✓	no	no	no
Accelerating chemicals	✓	✓	✓	no	no	no
LABELLING						

LABELLING						
MD Directive (medical device directive)	CE Class Is	CE Class Is	CE Class Is	CE Class I	CE Class I	CE Class I
PPE Directive (personal protective equipment directive)	CE Category III complex risk	CE Category I minimal risk	CE Category I minimal risk			
ASTM	ASTM D3578	ASTM D6319	ASTM D3578	ASTM D5250	ASTM D5250	ASTM D5250
EN 455 1-4	✓	✓	✓	✓	✓	✓
EN 420	✓	✓	✓	✓	✓	✓
EN 374-1, -2	✓	✓	✓	✓	✓	✓
EN 374-3 / EN 16523-1	✓	✓	✓	✓	no	no
AQL for pinholes (inspection level G1)	1.5	1.5	1.5	1.5	1.5	1.5
Food contact Reg. 1935/2004	✓	✓	✓	no	no	no

PACKAGING / LOGISTIC INFORMATION

Reference Number	pair 8267 59x27 ("x" = 6 for S, 7 for M, 8 for L)	pair 8267 53x27 ("x" = 6 for S, 7 for M, 8 for L)	pcs. 8261 52x27 pair 8262 52x27 ("x" = 6 for S, 7 for M, 8 for L)	8257 9323x ("x" = 1 for XS, 3 for S, 5 for M, 7 for L, 9 for XL)	100 pcs.: 8257 8103x 200 pcs.: 8257 9193x ("x" = 1 for XS, 3 for S, 5 for M, 7 for L, 9 for XL)	100 pcs.: 8259 8102x 200 pcs.: 8259 9182x ("x" = 1 for XS, 3 for S, 5 for M, 7 for L, 9 for XL)
Available sizes	S/M/L	S/M/L	S/M/L	XS/S/M/L/XL	XS/S/M/L/XL	XS/S/M/L/XL
Pcs / dispenser	S/M/L: 40 pairs	S/M/L: 50 paris	pairs: S/M/L: 50 pairs pcs: S/M/L: 50 pcs.	XS/S/M/L: 100 pcs. XL: 90 pcs.	XS/S/M/L 100 or 200 pcs. XL: 90 or 180 pcs.	XS/S/M/L 100 or 200 pcs. XL: 90 or 180 pcs.
ocs / transport carton	S/M/L: 240 pairs	S/M/L: 300 pairs	pairs: S/M/L: 300 pairs pcs: S/M/L 300 pcs.	XS/S/M/L: 1.000 pcs. XL: 900 pcs.	XS/S/M/L 1.000 or 2.000 pcs. XL: 900 or 1.800 pcs.	XS/S/M/L 1.000 or 2.000 pcs. XL: 900 or 1.800 pcs.

www.sempermed.com * see chemical resistance list at www.sempermed.com/en/sempermed-informs/chemical-resistance **as per EN 455-2:2015

Sempermed®

CONFIDENTIAL INFORMATION

Formulation of Final Product

In accordance with Regulations (EU) 2017/745 & (EU) 2016/425 and the following standards: EN 455-3 & EN 420.

We, Semperit Technische Produkte Ges.m.b.H. Modecenterstrasse 22 1030 Vienna Austria authorised EC representative of the manufacturer Semperit Investments Asia Ltd, 8 Jurong Town Hall Road #29-03 to 06 JTC Summit Singapore 609434,

disclose the formulation of the final product identified as

sempercare nitrile skin²

DESCRIPTION	RAW MATERIAL	CAS- NUMBER	COMPOSITION [%]
BASE MATERIAL	Nitrile latex	9010-81-5	90 - 95%
PH ADJUSTER	Potassium hydroxide	1310-58-3	1.0 - 2.0%
CROSSLINKING SYSTEM	Zinc oxide	1314-13-2	1.0 - 4.0%
CROSSLINKING SYSTEM	Sulphur Zinc diethyldithiocarbamate Zinc dibutyldithiocarbamate Zinc 2-mercaptobenzothiazole	7704-34-9 14324-55-1 136-23-2 155-04-4	1.0 - 3.0%
PIGMENT	Titanium dioxide C.I. Pigment Blue 15 C.I. Pigment Violet 23	13463-67-7 147-14-8 6358-30-1	1.0 - 4.0%
OUTSIDE	Calcium stearate	1592-23-0	< 0.1%

All data are provided only for the purpose of your orders hereafter. No part of them may be made available to others without prior consent.

Issued: 09 June 2020

Dr. Alexander Weinert Head of Technical Product Management

Christoph Hafenscher Technical Product Manager

Semperit Investment Asia Pte Ltd, 8 Jurong Town Hall Road, #29-03 to 06 JTC Summit, 609434 Singapore | Semperit Technische Produkte Gesellschaft m.b.H., Modecenterstraße 22, 1030 Vienna, Austria sempermed@semperitgroup.com; www.sempermed.com

This declaration has a validity of 2 years, subject to unexpected legal modifications. It replaces all previous versions.



Recommendation on Chemical Resistance - Cytostatics

Sempermed gloves for single use have been tested in accordance with ASTM D6978 "Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs" by independent accredited test institutes.

Classification:

Not suitable

Suitable if changed before permeation breakthrough

Suitable for longer surgeries*

Caution: Damaged or swelling gloves shall be changed immediately!
*For reason of precaution it is recommended to change gloves after 2 hours!

Permeation Rate:	
The tests were performed according to ASTM D6978	

TEST RESULTS by:

· ARDL Akron Rubber Development Laboratory, Ohio, USA

Breakthrough Detection Time (BDT) = Minutes (min)*

Chemotherapy Drug	mg/ml	Sempercare® Green NCF-035GR Nitrile – NBR	Sempercare® Shine / Silk NCF-035WH Nitrile – NBR	Sempercare® Cobalt Blue NOF-030CO Nitrile – NBR	Sempercare® Velvet NOF-030VB Nitrile – NBR	Sempercare® Skin²/ Aloe NOF-035 Nitrile – NBR	Sempercare® Shine+ NOF-039WH Nitrile – NBR	Sempercare® Nitrile NOF-047 Nitrile – NBR	Sempercare ® Nitrile sterile NOF-047 Nitrile – NBR	Sempercare® Safe+ NOF-065RB Nitrile – NBR
5-Fluorouracil	50,0	BDT > 240	BDT > 240	BDT > 240	BDT > 240	BDT > 240	BDT > 240	BDT > 240	BDT > 240	BDT > 240
Carmustine (BiCNU)	3,3	22	14	25	13	23	14	46	46	14
Cisplatin	1,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Cyclophosphamide (Cytoxan)	20,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Cytarabine	100,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Dacarbazine (DTIC)	10,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Daunorubicin HCl	5,0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Doxorubicin HCI	2,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Epirubicin	2,0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Etoposide	20,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Ifosfamid	50,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Methotrexate (Amethopterine Hydrate)	25,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Mitomycin C	0,5	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Mitoxantrone HCI	2,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	n/a
Oxaliplatin	5,0	n/a	n/a	n/a	n/a	> 240	n/a	> 240	> 240	> 240
Paclitaxel (Taxol)	6,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Thio-Tepa	10,0	27	13	37	14	47	13	38	38	58
Vincristine sulfate	1,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240

*Concentration: according instruction leaflet

n/a not available

IMPORTANT NOTE: The latest chemical resistance list can be found at www.sempermed.com. Please note that the product characteristics are directly dependent on the conditions of use and on the purity of the chemical substances concerned. The chemical resistance has been assessed under laboratory conditions and cannot reflect all actual conditions. When working with materials that are harmful to the skin, please always inspect the glove for any holes or tears prior to use. In principle, tests and certificates may only be regarded as general indications and do not exempt the user from the responsibility of making sure that the glove affords the protection requirements for the intended purpose prior to use. The chemical resistance recommendations do not form part of the specifications.

CAUTION: Failure to observe this information, in particular with regard to (chemical) resistance, frequency of use and tolerability of the gloves, can result in personal injury and/or material damage. Semperit does not accept any liability for incorrect use of the gloves. In case of doubt, obtain expert advice before use.

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Date of Issue: 07.02.2022





Recommendation on Chemical Resistance

Below protective gloves have been tested in accordance with EN 374-3:2003 "Determination of resistance to permeation by chemicals" and EN 16523-1:2015 "Determination of material resistance to permeation by chemicals" and achieve following test results.

Caution: Damaged or swelling gloves shall be changed immediately!
For reason of precaution it is recommended to change gloves after 2 hours!

Chemicals (synonyms)	Brand Name	Sempercare® Green	Sempercare® Velvet	Sempercare® Skin²/ Aloe	Sempercare® Shine / Silk	Sempercare® Soft	Sempercare® Shine+	Sempercare® Nitrile	Sempercare® Safe+
Chemicals (synonyms)	Cas-No. / Spec Code	NCF-035GR	NOF-030VB	NOF-035VB	NOF-035WH	NOF-037PK	NOF-039WH	NOF-047OB	NOF-065RB
Acetic acid (10%)	64-19-7	Level 3	Level 3	Level 3	Level 3	Level 6	Level 3	Level 5	Level 5
Acetone (2-propanone, methyl ketone)	67-64-1	Х	Х	Х	Х	Х	Х	Х	Х
Acetonitrile (cyanomethane, ethyl nitrile)	75-05-8	Х	Х	Х	Х	Х	Х	Х	Х
Acryl amide (40%)	79-06-1	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Ammonium hydroxide (25 %)	1336-21-6	n/a	А	Level 1	Level 1	Level 1	Level 1	Level 1	Level 1
Benzalconiumchloride liquid (Quats)	63449-41-2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Chlorhexidindigluconat (0,5 %)	18472-51-0	n/a	n/a	Level 6	Level 6	Level 6	Level 6	n/a	n/a
Chloroform (trichlormethan)	67-66-3	Х	Х	Х	Х	Х	Х	Х	Х
Dichlormethan (Methylendichlorid, Freon 30)	75-09-2	Х	Х	Х	Х	Х	Х	Х	Х
Diethyl amine (DEA)	109-89-7	Х	Х	Х	Х	Х	Х	Х	Х
Diethyl ether (diethyloxid, ethoxyethane)	60-29-7	Х	Х	Х	Х	Х	Х	Х	Х
Dimethylsulfoxid DMSO (deltan, demasorb)	67-68-5	Х	Х	Х	Х	Х	Х	Х	Х
Ethanol (10%) (ethyl alcohol)	64-17-5	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Ethanol (20%) (ethyl alcohol)	64-17-5	Level 1	Level 1	Level 1	Level 1	Level 6	Level 1	Level 6	Level 6
Ethanol (70%) (ethyl alcohol)	64-17-5	n/a	n/a	Х	Х	А	А	А	А
Ethidium bromide (1%) (homidium bromide)	1239-45-8	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Ethyl acetate (Aceto acid ether)	141-78-6	n/a	n/a	Х	Х	Х	Х	Х	Х
Fentanyl Citrate Inj. (100µg/2ml)		n/a	n/a	Level 5	Level 5	Level 5	Level 5	n/a	n/a
Formaldehyd (37%) with Methanol (10%)	50-00-0	Level 6	Level 4	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Gasoline (Petrol, heavy, 150 - 190°C)	8032-32-4	Х	Х	Х	Х	Х	Х	Х	Х
Glutaraldehyde (5%) (Pentan-1,5- dial, Glutaral)	111-30-8	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Heptane - n	142-82-5	n/a	n/a	Х	Х	Х	Х	Х	Х
Hexane - n	110-54-3	n/a	n/a	Х	Х	Х	Х	А	А
Hydrochloric acid (10%) (muriatic acid, chlorhydric acid)	7647-01-0	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	n/a	n/a
Hydrochloric acid (36%) (muriatic acid, chlorhydric acid)	7647-01-0	n/a	n/a	Level 2	Level 2	Level 2	Level 2	n/a	n/a
Hydrofluoric acid (40%)	7664-39-3	n/a	n/a	n/a	n/a	n/a	n/a	А	A
Hydrogen peroxide (30 %)	7722-84-1	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Isopropyl alcohol (70%) (2-propanol, IPA)	67-63-0	Level 1	n/a	Level 2	Level 2	Level 2	Level 2	Level 3	Level 3
Methanol (5%) (methyl alcohol)	67-56-1	n/a	n/a	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Methanol p.a. (methyl alcohol)	67-56-1	n/a	n/a	Х	Х	Х	Х	Х	Х
Methylmethacrylate (MMA)	80-62-6	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Ninhydrin (0,2%)	485-47-2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Nitric acid (10%)	7697-37-2	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Nitric acid (36%)	7697-37-2	n/a	n/a	n/a	n/a	Level 2	n/a	Level 3	Level 3
Octenidin (0,1%)	71251-02-0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

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Phenol (10%)	108-95-2	n/a	Х	Level 1	Level 1	Level 1	Level 1	Х	X
Phosphoric acid (85%) (orthophosphoric acid)	7664-38-2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Potassium hydroxide (50%) (caustic potash, lye	1310-58-3	n/a	n/a	Level 6	Level 6	Level 6	Level 6	n/a	n/a
Povidone iodine (10%)	25655-41-8	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Sodium hydroxide (40%) (caustic soda, lye, white caustic)	1310-73-2	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Sodium hypochlorite (10%)	7681-52-9	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Sulfuric acid (30%) (vitriol)	7664-93-9	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Sulfuric acid (96%) (vitriol)	7664-93-9	А	A	А	А	А	А	А	Level 1
Toluene (methylbenzol, phenylmethan, toluol)	108-88-3	Х	Х	Х	Х	Х	Х	Х	Х
Trichlorethane (methyltrichloromethane)	71-55-6	Х	Х	Х	Х	Х	Х	Х	Х
Xylene (xylol, dimethylbenzene)	95-47-6	Х	Х	Х	Х	Х	Х	Х	Х

х	Not Recommended	Level 3	> 60min
А	Splash Protection - change glove immediately after contact!	Level 4	> 120min
Level 1	> 10min	Level 5	> 240min
Level 2	> 30min	Level 6	> 480min

n/a not available

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Date:

25.10.2018 / Q4 2018

Sempermed Always keeping you up to date.

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Technical product specification

Product name	sempercare nitrile skin²	Version / Index no:
Spec code	NOF/NCF-035VB-N-3CZ	sempercare nitrile skin²_Version
Date of issue	28/02/2019	D_February 2019_EN

General information

Type single use examination and disposable protective glove, non sterile

Labelling information printed on dispenser box

Shape ambidextrous - straight fingers

Material Nitrile Butadiene Rubber (NBR) [not made with natural rubber latex]

Colourviolet blueInsidepowder freeOutsideno treatment

Cuff / surface rolled cuff / finger textured

Shelf life 3 years

Available sizes XS (5-6) S (6-7) M (7-8) L (8-9) XL (9-10)

Dimensions, physical properties and biocompatibility

Glove length median ≥ 240 mm (according to EN 455-2)

Minimum wall
thicknessat finger0.14 mm (double measured) / 0.07 mm (single measured)0.12 mm (double measured) / 0.06 mm (single measured)

at cuff 0.08 mm (double measured) / 0.04 mm (single measured)

Glove width according to EN 455-2: median XS ≤ 80 mm, S 80 ± 10 mm, M 95 ± 10 mm, L 110 ± 10 mm, XL

≥ 110 mm

Force at Break median ≥ 6 N (during shelf life according to EN 455-2)

Tensile Strength min. 14 MPa after aging (according to ASTM D6319)

Elongation at

min. 400% after aging (according to ASTM D6319)

Break

Residual powder / ≤ 2 mg (according to EN 455-3)

Powder content

Performance requirements and inspection levels

Freedom from holes (Barrier) AQL ≤ 1.5

(as per EN 455-1, sampling in accordance with ISO 2859-1, G-1)

Dimensions and physical properties AQL 4.0

(as per ASTM D6319, sampling in accordance with ISO 2859-1, S-2)

Standards, guidelines & quality certificates

Quality certification ISO 9001, ISO 13485, ISO 14001

Conformity to directives and regulations - Medical Device Directive 93/42/EEC: Class I - PPE Regulation (EU) 2016/425: Category III

- Food Contact Materials Regulation (EC) 1935/2004

Conformity to standards EN 420, EN ISO 374-1, EN 374-2, EN 16523-1, EN 374-4, EN ISO 374-5,

EN 455 1-4, ASTM D6319, ASTM F1671



Technical product specification

Product name	sempercare nitrile skin²	Version / Index no:
Spec code	NOF/NCF-035VB-N-3CZ	sempercare nitrile skin²_Version
Date of issue	28/02/2019	D_February 2019_EN

Instructions and additional statements

Storage instruction

Store in original packaging in a dry and dark place at 10 °C to 30 °C. Refer to guidelines of storage of rubber products as described in ISO 2230:2002. Ensure that storage area is kept cool, dry and dust free, avoid ventilation and storage close to photocopy equipment. Copper-ions discolour the glove. Protect gloves against ultraviolet light sources, as sunlight and oxidizing agents. Storage above 30 °C will lead to accelerated aging and should be avoided.

Cautionary statement and ingredient information

This product contains accelerators (Dithiocarbamate type, Zinc-mercaptobenzothiazol) not to be used in a hypersensitivity of these substances.

For further information, a list of substances contained in the glove is available upon request.

Reporting system

Medical device vigilance and reporting system

According to the official reporting criteria of the Medical Device directive, incidents caused by examination gloves must be reported immediately to our Medical Device reporting officer. E-Mail:

sempermed.complaints@semperitgroup.com or Tel.: +43 2630 310 0

A. Wöss / Director J. Glantschnig

Regulatory Affairs Manager

Sempermed

L. Rieger

Head of Product Management

Remark

Replaces all previous versions.

All standards references refer to the date of document issue.