sempermed

REF: 8227 51..1

Surgical gloves sempermed Supreme, powderfree – sterile – foil

Customer:

Natural rubber- latex – gloves, natural colour, micro-rough, rolled rim, 8 sizes.
Intended use: Glove is suitable for all medical sterile applications.
EXP - Storage: 3 years (storage conditions see page 2). Single use.

Production:

Following EU-directive EEC 93/42 as amended by 2007/47/EC, EN ISO 13 485 and EN 556 for sterile products,
In compliance with GMP rules (Good Manufacturing Practice). CE 0123 Class IIa.

Gloves: In accordance with EN 455 -1/2/3/4
Produced with Dithiocarbamat-types, without Thiuram and without Mercapto-accelerators.
Compound description available on request.
Marking : Size stamped in black on cuff.
Measurements: according to ASTM D 3577, ISO 10282 and EN 455/2.
Fit: Fully anatomical shaped with curved fingers and rolled rim.

Physical and Chemical Properties : EN 455/2 and EN 455/3 and EN 455/4
During shelf life and after challenge testing according to EN 455/2
Before and after ageing according to ASTM D 3577 and ISO 10282
Length according to glove size, see attachment: min 270 mm
Wall thickness double: see attachment for dimensions / glove measurements

Surface/Donning Support:
Micro rough surface. Following EN 455/3 free of TALCUM (Magnesium silicate).
Free of cornstarch (according ASTM 6124 and EN 455/3).
Synthetic inner layer to ensure donning and change of gloves without powder.

Radiation-Sterilization: Acc. to ISO 11 137 with min. 25 kGy (2,5 Mrad SAL 10^{-6})
Indicator-dot on dispenser box and transport carton: Change of colour from yellow to violet-brown.
Placed on pallet: colour-change of indicator dot from yellow to red after sterilisation.

Sampling Inspection:
Acc. to DIN ISO 2859/1: Pinholes AQL 1,0 G-I / Major defects AQL 2,5 S-2 / Minor defects AQL 4 S-2. Minimum requirement following EN 455/1 and ASTM D 3577**:** AQL 1,5
Major defects are non-conformities which prevent correct or intended use of the product.
Minor defects are non-conformities of low degree of concern, which do not prevent correct or intended use of gloves

Supervision of Product and Design:
In house: internal control in chemical, physical and microbiological laboratories.
Bio-compatibility following ISO 10 993 and EN 455/3. Risk analysis done following ISO 14 971.
External: Validation by Bioservice Germany, Endotoxins controlled by LS-AG Germany, Cooperation with institutes specialised in chemical analysis following EN 455/3. Inspected by FDA and TÜV according ISO 9001, ISO 13 485 and EU-directive EEC 93/42 as amended by 2007/47/EC.

Storage of Medical Gloves and Natural Latex Rubber-products

Transportcartons and Dispenser must be stored under conditions described in the following standards - covering the identical subject.

Peel pouches have to be stored in dispenser boxes until using.

ISO 2230 „Vulcanised rubber - guide to storage“
DIN 7716 "Rubber Products - Requirement for storage, Cleaning and Maintenance"

Store latex gloves in a cool, dry environment and free of dust. Avoid extreme air circulation. Low temperature is not deleterious, but gloves may become stiffer. Moist conditions (condensation) for packages should be avoided. Higher temperatures may lead to accelerated aging, stickiness and discoloration.

Sources of heat in storage rooms should be so arranged that overheating is precluded (Temperature not higher than **30°C**). Protection from direct sunlight and strong artificial light with a high ultraviolet content has to be assured. Packages should be protected from circulating air (extreme change of temperature) by wrapping or other suitable means.

Unless the articles are packed, it is advisable to cover any window of storage rooms with a red or orange (no blue!) coating or screen. As ozone is particularly deleterious, storage rooms should not contain any equipment that is capable of generating ozone, such as fluorescent or mercury vapour lamps, photocopier, or high voltage equipment which may give rise to electric sparks or discharges.
Do not clean gloves with oxidizing (bleaching) cleaning additives! Avoid contact of gloves made of Natural- and Synthetic Latex with Copper containing base metals. It may lead to discolouration and aging.

Protect gloves from heat, light and ozone !

Packaging of sempermed Supreme, 50 pairs - sterile in foil:

Marking and users instructions according to EN 455/3, EN 1041 and ISO 15223-1.
All packaging material is free of PVC, material is suitable for recycling.

Peel pack with lashes for easy handling min 270 x 150 mm, is optimized for Radiation-Sterilization:
1 pair with folded cuffs in paper bag protected against microbiological contamination.
Tightness: Statistically checked according to ISO 11607-1.

Dispenser box with pull-out opening 270 x 150 x 220 mm: **50 pairs**

Transport carton: (Size 7,5 = approx. 11,4 kg) 480 x 283 x 450 mm: 6 x 50 = **300 pairs**

Pallet: (size 7,5 = approx. 378 kg) 100 x 120 cm, 32 x 300 = **9.600 pairs**

Warning following EN 455/3:

Caution: Product contains natural rubber latex which can cause allergic reactions including anaphylactic responses.

Vigilance and Reporting system of MDD:

Information referring to sterile surgical gloves and similar sterile products, and all products made from natural latex which can lead to problems and reactions according to the official reporting criteria of MDD (Medical Device Directive) must be reported by phone or fax within one day to the Semperit security officer. (+43 2630 310 Phone 510 - Fax 549)

All quoted standards are latest version.

The Technical Product Information will be obligatory for Semperit Technische Produkte Gesellschaft m.b.H. after the signed legal certificate of acceptance has been received at the addresser.

Trade under the name of Semperit:

SEMPERIT
Semperit Technische Produkte
Gesellschaft m.b.H.
Modecenterstraße 22
A-1031 Wien
Telefon +43/1/79777-0

Acceptance of customer

Ing.Mag.Fleck/DI Dr.Stempfer/Mag.Schnetzlinger

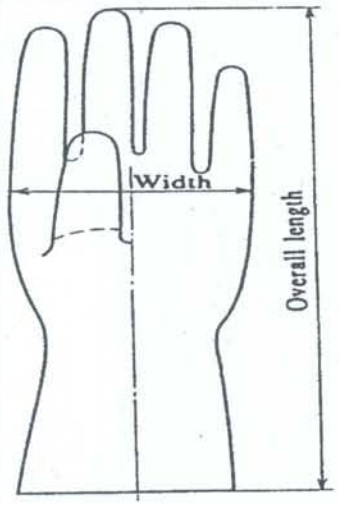
Datum/Stampiglie/Unterschrift

Handschuhmaße / Dimensions / Glove measurements

Produktgruppe / Product group - Medizinische Handschuhe / Medical gloves

Supreme – anatomisch puderfrei beschichtet Rollrand / powderfree coated rolled rim

Größe - Size Norm - Standard	Zeige-Index-finger Länge - Length in mm	Handbreite Palm-Width in mm	Gesamtlänge - Total length Minimum in mm
5 ½ Sempermed	**59 ±2**	**73 ± 3**	**270**
EN 455-2		72 ± 4	250
ISO 10282		72 ± 4	250
ASTM D 3577		70 ± 6	245
6 Sempermed	**60 ±2**	**79 ± 3**	**270**
EN 455-2		77 ± 5	260
ISO 10282		77 ± 5	260
ASTM 3577		76 ± 6	265
6 ½ Sempermed	**63 ± 2**	**85 ± 3**	**270**
EN 455-2		83 ± 5	260
ISO 10282		83 ± 5	260
ASTM 3577		83 ± 6	265
7 Sempermed	**66 ± 2**	**91 ± 3**	**280**
EN 455-2		89 ± 5	270
ISO 10282		89 ± 5	270
ASTM 3577		89 ± 6	265
7 ½ Sempermed	**71 ±3**	**97 ± 3**	**280**
EN 455-2		95 ± 5	270
ISO 10282		95 ± 5	270
ASTM 3577		95 ± 6	265
8 Sempermed	**74 ± 3**	**105 ± 3**	**280**
EN 455-2		102 ± 6	270
ISO 10282		102 ± 6	270
ASTM 3577		102 ± 6	265
8 ½ Sempermed	**77 ± 3**	**111 ± 3**	**285**
EN 455-2		108 ± 6	280
ISO 10282		108 ± 6	280
ASTM 3577		108 ± 6	265
9 Sempermed	**80 ± 3**	**112 ± 3**	**285**
EN 455-2		114 ± 6	280
ISO 10282		114 ± 6	280
ASTM 3577		114 ± 6	265



Doppelte Wanddicke - Double Wall-thickness

Hand/Palm: 0,42 +/-0,03 mm
Schaft / Cuff: min 0,32 mm

ASTM D 3577 and ISO 10282
Anforderung für Wanddicke min 0,1 mm
Requirement for single wall-thickness min 0,1 mm
EN 455-2:
Keine Angabe für Wanddicke
Wall-thickness is not specified in EN 455-2
Methods / Messmethoden:
EN 455-2, ISO 4648
Für Handumfang die Breite doppelt nehmen
For round distance multiply single distance by two
Wanddickenwerte Median aus 13
Wall thickness values Median out of 13

Issued-erstellt:	Controlled-geprüft:	Released/freigegeben	Beilage/Attachment to
PM/Ing.Mag.Fleck	QM/DI (FH) Sebauer	Prod/Dr.Zörnpfenning	Spec **14+15+32 all** Versions Edition May 2011 Replaces older attachments