Spec code: PFM-116SC-S-6AX
Product name: Sempermed® Syntegra IR
Date of issue: January 2019

Synthetical gloves from **Polyisoprene,** creme 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.
Personal Protective Equipment according to Regulation (EU) 2016/425, CE Category III

Gloves: In accordance with EN 455 -1/2/3/4, EN ISO 374-1:2016, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013, ISO 374-5:2016, EN 420:2003+A1:2009, EN 421:2010, ASTM F 1671.
Produced with Dithiocarbamat. No Thiuram and Mercapto-accelerators.
Compound description available on request.
Marking: Size stamped on cuff with mark „NRL-free" (Natural Rubber Latex free) on cuff-end 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).
Powderfree (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 0,65 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 Eurofins Germany, Endotoxins controlled by specialised laboratory, Cooperation with institutes specialised in chemical analysis following EN 455/3. Audited by TÜV according ISO 9001, ISO 13 485 and EU-directive EEC 93/42 as amended by 2007/47/EC, inspected by FDA.

Storage of Medical Gloves and Natural Latex Rubber-products applied on gloves from synthetic material:

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 Syntegra IR, 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 270 x 150 mm, optimized for Radiation-Sterilization: 1 pair with folded cuffs in folded 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: (for size 7,5 = 9,8 kg) 480 x 283 x 450 mm, 6 x 50 = **300 pairs**

Pallets: (for size 7,5 = 328 kg) 80 x 120 cm, 32 x 300 = **9.600 pairs**

Information:
This product does not contain natural rubber latex and cannot cause Type I allergic reactions.

Vigilance and Reporting system of MDD:

Meeting the requirements of the MDD 93/42/ECC, FDA and various national regulations, Sempermed as the (legal) manufacturer has to ensure that all information which is indicating possible harm to users and/or patients related to Sempermed products is evaluated immediately (without undue delay) in order to take actions preventing any risk.
Therefore we would like you to confirm that you will immediately (without undue delay) forward any product safety related information (e.g. complaints, incidents, wrong or misleading product- and / or user- information, recurring quality deviations etc.) and corresponding samples to the Sempermed complaints handling department (+43 2630 310 Phone 0 - Fax 479 or sempermed.complaints@semperitgroup.com). Based on the information provided, Sempermed has to decide about any risk related to the product and whether a notification to the local medical device authorities might be necessary.
In case Sempermed decides in close cooperation with our distribution partners that we have to take action (e.g. through FSCA, Field Safety Corrective Actions or FSN, Field Safety Notices such as additional user information, manuals, recall activities etc.) we ask you to provide full support in order to get access to samples and other mandatory information or to carry these indispensable FSCAs out properly and in full compliance with the applicable national regulations and laws.

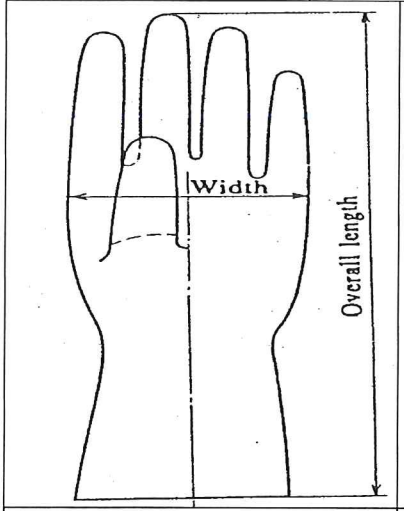
All quoted standard references refer to the latest version.

Handschuhmaße / Dimensions / Glove measurements

Produktgruppe / Product group - Medizinische Handschuhe / Medical gloves

Syntegra IR – 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 ISO 10282 ASTM D 3577		72 ± 4 72 ± 4 70 ± 6	250 250 245
6 Sempermed	**63 ±2**	**79 ± 3**	**270**
EN 455-2 ISO 10282 ASTM 3577		77 ± 5 77 ± 5 76 ± 6	260 260 265
6 ½ Sempermed	**66 ± 2**	**85 ± 3**	**270**
EN 455-2 ISO 10282 ASTM 3577		83 ± 5 83 ± 5 83 ± 6	260 260 265
7 Sempermed	**69 ± 2**	**91 ± 3**	**280**
EN 455-2 ISO 10282 ASTM 3577		89 ± 5 89 ± 5 89 ± 6	270 270 265
7 ½ Sempermed	**71 ±3**	**97 ± 3**	**280**
EN 455-2 ISO 10282 ASTM 3577		95 ± 5 95 ± 5 95 ± 6	270 270 265
8 Sempermed	**76 ± 3**	**105 ± 3**	**280**
EN 455-2 ISO 10282 ASTM 3577		102 ± 6 102 ± 6 102 ± 6	270 270 265
8 ½ Sempermed	**83 ± 3**	**111 ± 3**	**285**
EN 455-2 ISO 10282 ASTM 3577		108 ± 6 108 ± 6 108 ± 6	280 280 265
9 Sempermed	**86 ± 3**	**114 ± 3**	**285**
EN 455-2 ISO 10282 ASTM 3577		114 ± 6 114 ± 6 114 ± 6	280 280 265



Doppelte Wanddicke - Double Wall-thickness

Finger:	max. 0,54 mm
Hand/Palm:	0,43 +/-0,05 mm
Schaft / Cuff:	min. 0,34 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:
Die Wandstärke ist nicht in der EN 455-2 spezifiziert
Wall-thickness is not specified in EN 455-2
Methods / Messmethoden:
EN 455-2, ISO 23529
Für Handumfang die Breite doppelt nehmen
For round distance multiply single distance by two

Established (PM):	Reviewed (HoP):	Approved (RA- Manager):
R. Fleck	E. Brandstätter	J. Glantschnig