

PRODUCT INFORMATION SHEET

sempermed® syntegra IR



| | | |
|-----------------------------|-------------------|---|
| GENERAL PRODUCT INFORMATION | Material | Polyisoprene |
| | Colour | Creme |
| | Surface | Micro-roughened |
| | Former | Fully anatomical |
| | Inside | Powder free / polyurethane derivatives and butadien based copolymer cross linked by polyacrylates |
| | Sterilisation | Radiation with at least 25 kGy |
| | Available sizes | 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 |
| | Country of Origin | Austria |
| | Shelf life | 3 years |

| | | | | | |
|------------------------------|--|--------------------|--|------|-----------------|
| THICKNESS PROFILE AND LENGTH | Thickness Profile [mm] measured in single layer in the palm area | | | | |
| | | | Specified values | | Typical values* |
| | | Thickness Finger | max. 0.27 | 0.23 | |
| | | Thickness Palm | 0.215 ± 0.025 | 0.21 | |
| | | Thickness Cuff | min. 0.17 | 0.21 | |
| | *Lot specific data according to Lot 17A0065 | | | | |
| | Total length [mm] | | | | |
| | | Total length | 5.5–6.5: min. 270 mm 7.0–8.0: min. 280 mm 8.5–9.0: min. 285 mm | | |
| | | Palm width typical | 95 (size 7.5) | | |

| | | | | | | |
|---------------------|------------------------------------|-------|---|-----|--------------------------------------|-----|
| PHYSICAL PROPERTIES | | | Standard requirement before / after aging | | Typical values before / after aging* | |
| | Force at break as per EN455-2 | [N] | >9 | >9 | 18 | 15 |
| | Tensile strength as per ASTM D3577 | [Mpa] | 24 | 18 | 30 | 26 |
| | Elongation as per ASTM D3577 | [%] | 750 | 560 | 909 | 867 |
| | Weight of product size 7.5 | [g] | n/a | | 12.1 | |
| | Dexterity level as per EN 420 | | acc. EC type examination | | level 5 | |

*Lot specific data according to Lot 17A0065

This is a summary of product relevant data and does not replace the respective applicable product specification available at the Sempermed Distributor login: www.sempermed.com/en/distributor-login/sempermed/product-specifications
Results of single production lots through independent institutes and production control.

PRODUCT INFORMATION SHEET

sempermed® syntegra IR



| | | | | |
|---|---|-------------------------|-----------------------------|--|
| SKIN TOLERANCE | Protein typical / independent external lab Lot specific data. | | | n/a |
| | Frequency of tests external: n/a. Frequency of tests internal: n/a | | | |
| | | | Standard requirement | |
| | Residual powder for powder free gloves | [mg / glove] | 2 | 0.28 Lot specific data according to Lot 17A0065 |
| | Powder content | [mg / dm ²] | n/a | n/a |
| | Pyrogene level | [EU / pair] | n/a | 0.83 Lot specific data according to Lot 12A0709 |
| | AQL freedom from holes as per EN455-1 | final product | 1.5 | 0.65 |
| | Accelerators | | | CAS number |
| | Tetramethylthiurammonosulfide (TMTM) | | | 97-74-5 not used |
| | Thirame; Tetramethylthiuramedisulfide (TMTD) | | | 137-26-8 not used |
| | Disulfirame; Tetraethylthiuramedisulfide (TETD) | | | 97-77-8 not used |
| | Bis(piperidinothiocarbonyl)disulfide; Dipentamethylthiuramedisulfide (DPTD) | | | 94-37-1 not used |
| | Zirame; Zinkdimethyldithiocarbamate (ZDMC) | | | 137-30-4 not used |
| | Zinkbis(diethyldithiocarbamate); Zinkdiethyldithioarbamate (ZDC, ZDEC) | | | 14324-55-1 not used |
| | Zinkbis(dibutyldithiocarbamate); Zinkdibutyldithiocarbamate (ZBC, ZDBC) | | | 136-23-2 not used |
| | Zinkbis(N-ethyl-N-phenyldithiocarbamate); Zinkethylphenyldithiocarbamate (ZEPC) | | | 14634-93-6 not used |
| | Zinkbis(piperidin-1-carbodithioat); Zinkpentamethylendithiocarbamate (ZPD) | | | 13878-54-1 not used |
| | Zinkbis(dibenzylthiocarbamate); Zinkdibenzylthiocarbamate | | | 14726-36-4 not used |
| | Natriumdibutyldithiocarbamate (NBC) | | | 136-30-1 not used |
| | Xanthogonate | | | used |
| Zinkdiisononyldithiocarbamate ZDNC | | | 84604-96-6 used | |
| 1,3-dibutyl-2-Thiourea; Dibutylthiourea (DBTU) | | | 109-46-6 not used | |
| 1,3-diethyl-2-thiourea; Diethylthiourea (DETU) | | | 105-55-5 not used | |
| 1,3-diphenyl-2-thiourea; Diphenylthiourea (DPTU) | | | 102-08-9 not used | |
| Imidazolidin-2-thion; N,N'-ethylen-thiourea; Ethylen-thiourea (ETU) | | | 96-45-7 not used | |
| Benzimidazol-2-thiole | | | 583-39-1 not used | |
| Benzothiazol-2-thiole; Mercaptobenzothiazol (MBT) | | | 149-30-4 not used | |
| Zinkdi(benzothiazol-2-yl)disulfide; Zinkmercaptobenzothiazole (ZMBT) | | | 155-04-4 not used | |
| 2-(morpholinothio)benzothiazole; Morpholinylmercaptobenzothiazole (MOR, MBS) | | | 102-77-2 not used | |
| Di(benzothiazole-2-yl)disulfide; Dibenzothiazylsulfide (MBTS) | | | 120-78-5 not used | |
| N-cyclohexyl-benzothiazole-2-sulfenamide; N-cyclohexyl-2-benzothiazylsulfenamide (CBS) | | | 95-33-0 not used | |
| N-Isopropyl-N'-phenyl-p-phenyldiamine (IPPD) | | | 101-72-4 not used | |
| N,N'-Diphenyl-p-phenyldiamine (DPPD) | | | 74-31-7 not used | |
| 1,3-Diphenylguanidine | | | 102-06-7 not used | |
| Hydroquinone | | | 123-31-9 not used | |
| Biphenyl-4,4'-diol | | | 92-88-6 not used | |
| Methenamine | | | 100-97-0 not used | |
| N-(cyclohexylthio)phthalimide | | | 17796-82-6 not used | |

This is a summary of product relevant data and does not replace the respective applicable product specification available at the Sempermed Distributor login: www.sempermed.com/en/distributor-login/sempermed/product-specifications
Results of single production lots through independent institutes and production control.

PRODUCT INFORMATION SHEET

sempermed® syntegra IR



Directives & Standards for medical gloves

Sempermed Syntegra is tested and manufactured to the following directives and standards:

DIRECTIVES AND STANDARDS

| | | | |
|--|---|--|---|
| 93/42/EEC Council Directive 93/42/EEC concerning medical devices. | ✓ | ASTM D 6978 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs | ✓ |
| EN 455-1 Medical gloves for single use – Part 1: Requirements and testing for freedom from holes | ✓ | ISO 10282 Single-use sterile rubber surgical gloves – Specification | ✓ |
| EN 455-2 Medical gloves for single use – Part 2: Requirements and testing for physical properties | ✓ | ISO 10993-10 Biological evaluation of medical devices – part 10: tests for irritation and skin sensitization | ✓ |
| EN 455-3 Medical gloves for single use – Part 3: Requirements and testing for biological evaluation | ✓ | ISO 11193-1 Single-use medical examination gloves – Part 1: Specification for gloves made from rubber latex or rubber solution | ✓ |
| EN 455-4 Medical gloves for single use – Part 4: Requirements and testing for shelf life determination | ✓ | ISO 11193-2 Single-use medical examination gloves – Part 2: Specification for gloves made from poly(vinyl chloride) | ✓ |
| ASTM D3577 Standard specification for rubber surgical gloves | ✓ | ISO 15223 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2012) – German version EN ISO 15223-1:2012 | ✓ |
| ASTM D3578 Standard specification for rubber examination gloves for medical application | ✓ | ISO 2859-1 Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection | ✓ |
| ASTM D6319 Standard specification for nitrile examination gloves for medical application | ✓ | ISO 2230 Rubber products – Guidelines for storage | ✓ |
| ASTM D5250 Standard specification for polyvinyl examination gloves for medical application | ✓ | ISO 22171 Medical gloves – determination of removable surface powder | ✓ |
| ASTM D5712 Standard test method for analysis of aqueous extractable protein in natural rubber and its products using the modified Lowry method | ✓ | ASTM F 1671 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System | ✓ |
| ASTM D6124 Standard test method for residual powder on medical gloves | ✓ | ASTM F 1670 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood | ✓ |

PRODUCT INFORMATION SHEET

sempermed® syntegra IR



| DIRECTIVES AND STANDARDS | Directives & Standards for protective gloves | | | |
|---|---|---|---|---|
| | 89/686/EEC Council Directive 89/686/EEC relating to personal protective equipment. | | | ✓ |
| | EN 374-1 Protective gloves against chemicals and micro-organisms – Part 1: Terminology and performance requirements | | | ✓ |
| | EN 374-2 Protective gloves against dangerous chemicals and micro-organisms – Part 2: Determination of resistance to penetration | | | ✓ |
| | EN 374-3 Protective gloves against chemicals and micro-organisms – Part 3: Determination of resistance to permeation by chemicals | | | ✓ |
| | EN 420 Protective gloves. General requirements and test methods | | | ✓ |
| | EN 388 Protective gloves against mechanical risks | | | ✓ |
| | Corporate Social Responsibilities | | Quality | |
| | ISO 14001:2004 Environmental management system | ✓ | ISO 13485 Quality management system | ✓ |
| | BSCI Business Social Compliance Initiative | ✓ | ISO 9001 Quality management system | ✓ |
| OSHAS 18001:2009 Occupational Health & Safety | ✓ | | | |

| FINGER & CUFF LENGTH | Finger length [mm] | | | | | | | | |
|----------------------|-----------------------------|------------|------------|------------|------------|------------|------------|------------|------------|
| | | | | | | | | | |
| | Size | 5.5 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 |
| | Thumb finger | 49.5 ±2 | 51.5 ±2 | 55.5 ±2 | 58.0 ±2 | 62.5 ±2 | 65.0 ±2 | 67.0 ±2 | 72.0 ±2 |
| | Index finger | 63.0 ±2 | 64.0 ±2 | 65.5 ±2 | 67.0 ±2 | 71.5 ±2 | 76.0 ±2 | 82.0 ±2 | 85.0 ±2 |
| | Middle finger | 70.5 ±2 | 73.0 ±2 | 76.0 ±2 | 80.0 ±2 | 85.0 ±2 | 87.0 ±2 | 93.5 ±2 | 96.5 ±2 |
| | Ring finger | 62.5 ±2 | 65.0 ±2 | 72.0 ±2 | 75.5 ±2 | 81.0 ±2 | 85.0 ±2 | 88.5 ±2 | 93.5 ±2 |
| | Little finger | 47.0 ±2 | 48.5 ±2 | 54.5 ±2 | 57.0 ±2 | 60.0 ±2 | 64.5 ±2 | 66.5 ±2 | 70.5 ±2 |
| | Cuff length size 7.5 | 106.5 | | | | | | | |

PRODUCT INFORMATION SHEET

sempermed®  syntegra IR



| LOGISTIC DATA | Logistic data | | |
|---------------|---------------------------|------|-------------|
| | Dimension Dispenser | [mm] | 270x150x220 |
| | Dimension Transportcarton | [mm] | 478x283x450 |

| PACKAGING MATERIAL SPECIFICATION | All free of PVC | Yes |
|----------------------------------|---------------------------|-----------------------|
| | Material inner pouch | laminated paper |
| | Material pair pouch | PE/PET foil peel pack |
| | Material dispenser | corrugated carton |
| | Material transport carton | corrugated carton |
| | Material tape | paper adhesive tape |

| EAN CODES | EAN Codes | | | |
|-----------|-----------|---------------|---------------|------------------|
| | Size | Peel Pouch | Dispenser | Transport carton |
| | 5.5 | 9001570516848 | 9001570516855 | 9001570516862 |
| | 6.0 | 9001570515643 | 9001570515650 | 9001570515667 |
| | 6.5 | 9001570515636 | 9001570515674 | 9001570515681 |
| | 7.0 | 9001570515629 | 9001570515773 | 9001570515780 |
| | 7.5 | 9001570515612 | 9001570515698 | 9001570515704 |
| | 8.0 | 9001570515605 | 9001570515711 | 9001570515728 |
| | 8.5 | 9001570515599 | 9001570515735 | 9001570515742 |
| | 9.0 | 9001570515582 | 9001570515759 | 9001570515766 |



Find out more at www.sempermed.com

The information, classification and conformity to standards correspond to the latest status at date of issue. Technical details are average values from production or where indicated results of single production lots. The values may vary in individual cases. Please refer to the product specification for minimum values.

This is a summary of product relevant data and does not replace the respective applicable product specification available at the Sempermed Distributor login: www.sempermed.com/en/distributor-login/sempermed/product-specifications
Results of single production lots through independent institutes and production control.

Questions? Contact us!

Semperit Investments Asia Pte Ltd · 8 Jurong Town Hall Road · #29-03 to 06 JTC Summit
Singapore 609434

E-Mail: sempermed@semperitgroup.com · www.sempermed.com

Semperit Technische Produkte Gesellschaft m.b.H · Division Sempermed · Austria
1030 Vienna · Modecenterstrasse 22 · Tel.: +43-1-797 77-00 · Fax: +43 1 79 777-630

E-Mail: sempermed@semperitgroup.at · Internet: www.sempermed.com