



















## Product Data Sheet

<b>1.0 Name of the product</b>	Comprilan®
<b>2.0 Product description</b>	
<b>2.1 Description</b>	Comprilan® is a short stretch bandage for support, relief and compression.
<b>2.2 Intended purpose</b>	Comprilan® is intended for phlebological and lymphological indications to support muscle pump action and improve the haemodynamics of venous return: varicosis, chronic venous insufficiency including venous varicose ulcer and venous oedema, thrombophlebitis, phlebothrombosis, after vein operations (stripping), after sclerosing obliteration, primary and secondary lymphatic oedemas.
<b>2.3 Instructions for use</b>	Yes
<b>2.4 Warnings and precautions for use</b>	<p><b>Cautions:</b></p> <ul style="list-style-type: none"> <li>• Weeping dermatosis</li> <li>• cutaneous infections</li> <li>• Open wounds must be covered with an appropriate dressing before compression bandaging is put on.</li> <li>• Severely compromised skin sensibility and impaired sensitivity of the limb</li> <li>• advanced peripheral neuropathy</li> <li>• conditions in which increased venous and lymphatic return is not desired.</li> </ul> <p>The attending physician decides whether compression in general can be applied to patients suffering from the following diseases:</p> <ul style="list-style-type: none"> <li>• rheumatoid arthritis</li> <li>• complex regional pain syndrome</li> <li>• CRPS (M. Sudeck)</li> <li>• malignant lymphedema</li> <li>• gangrene</li> </ul> <p>The attached fixation clips should not be used for fixation while the bandage is applied on a patient. Due to the risk of unintended injuries both clips are solely designed for transportation purpose.</p>

<b>2.5 Indications and Contraindications</b>	<p><b>Indications:</b> Compression bandages for phlebological and lymphological indications to support muscle pump action and improve the haemodynamics of venous return:</p> <ul style="list-style-type: none"> <li>• varicosis,</li> <li>• chronic venous insufficiency including venous varicose ulcer and venous oedema,</li> <li>• thrombophlebitis,</li> <li>• phlebothrombosis,</li> <li>• after vein operations (stripping),</li> <li>• after sclerosing obliteration,</li> <li>• primary and secondary lymphatic oedemas.</li> </ul> <p>Contraindications:</p> <ul style="list-style-type: none"> <li>• Incompatibility to fabric,</li> <li>• advanced peripheral arterial occlusive disease,</li> <li>• decompensated cardiac insufficiency,</li> <li>• septic phlebitis,</li> <li>• phlegmasia coerulea dolens.</li> </ul>																								
<b>2.6 Transport Precautions</b>	not applicable																								
<b>2.7 Duration of application</b>	Several days up to a week as determined by a licensed clinician																								
<b>2.8 Information on reusable/washable products</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #002060; color: white;"> <th colspan="6">Washing instructions</th> </tr> </thead> <tbody> <tr> <td style="width: 25%;">General instructions</td> <td colspan="5"> <ul style="list-style-type: none"> <li>• Washable up to 10 cycles per recommended procedure using a commercial laundry detergent.</li> <li>• Do not use fabric softener</li> </ul> </td> </tr> <tr> <td style="vertical-align: top;">Wash Instruction symbols according to ISO 3758:2012</td> <td style="text-align: center;"><b>Washing</b></td> <td style="text-align: center;"><b>Bleaching</b></td> <td style="text-align: center;"><b>Drying</b></td> <td style="text-align: center;"><b>Ironing and pressing</b></td> <td style="text-align: center;"><b>Professional textile care</b></td> </tr> <tr> <td></td> <td style="text-align: center;">  mild process                 </td> <td style="text-align: center;">  do not bleach                 </td> <td style="text-align: center;">  do not tumble dry    flat drying                 </td> <td style="text-align: center;">  do not iron                 </td> <td style="text-align: center;">  do not dry clean                 </td> </tr> </tbody> </table>	Washing instructions						General instructions	<ul style="list-style-type: none"> <li>• Washable up to 10 cycles per recommended procedure using a commercial laundry detergent.</li> <li>• Do not use fabric softener</li> </ul>					Wash Instruction symbols according to ISO 3758:2012	<b>Washing</b>	<b>Bleaching</b>	<b>Drying</b>	<b>Ironing and pressing</b>	<b>Professional textile care</b>		 mild process	 do not bleach	 do not tumble dry   flat drying	 do not iron	 do not dry clean
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**2.10 Product range**

Item No.	Bandages (= UoM) per Folding Box	Folding Boxes per Shrink Unit	Shrink Units per Shipper Case	Folding Boxes per Shipper Case	Bandages per Shipper Case	Folding Boxes per Transport Case
01026-00000-06	1	5	40	--	200	---
01026-00001-06	20	---	---	1	20	1680
01027-00000-07	1	5	34	--	170	---
01027-00001-07	20	---	---	1	20	1680
01028-00000-06	1	5	28	--	140	---
01028-00001-06	20	---	---	1	20	1200
01029-00000-06	1	5	24	--	120	---
01029-00001-06	20	---	---	1	20	1200
01030-00000-05	2	---	---	25	50	---
45381-00000-04	10	---	8	--	80	---
45382-00000-04	10	---	8	--	80	---
45383-00000-04	10	---	8	--	80	---
45384-00000-04	10	---	8	--	80	---
77187-00000-02	24	---	---	1	24	3648
77188-00000-02	20	---	---	1	20	960
77189-00000-02	20	---	---	1	20	840

**2.11 Sizing Chart**

Item No.	Description	Length stretched [m]	Width [cm]
01026-00000-06	CL 6CM X 5MTR TA 1 INT.	5	6
01026-00001-06	CL 6CM X 5MTR TA 20 INT.	5	6
01027-00000-07	CL 8CM X 5MTR TA 1 INT.	5	8
01027-00001-07	CL 8CM X 5MTR TA 20 INT.	5	8
01028-00000-06	CL 10CM X 5MTR TA 1 INT.	5	10
01028-00001-06	CL 10CM X 5MTR TA 20 INT.	5	10
01029-00000-06	CL 12CM X 5MTR TA 1 INT.	5	12
01029-00001-06	CL 12CM X 5MTR TA 20 INT.	5	12
01030-00000-05	CL TA 2 INT.	5	10
45381-00000-04	CL 6CM X 5MTR TA 10 INT.	5	6
45382-00000-04	CL 8CM X 5MTR TA 1 INT.	5	8
45383-00000-04	CL 10CM X 5MTR TA 1 INT.	5	10
45384-00000-04	CL 12CM X 5MTR TA 10 INT.	5	12
77187-00000-02	CL 4CM X 5MTR STRETCHED 24 INT.	5	4
77188-00000-02	CL 10CM X 10MTR STRETCHED 20 INT.	10	10
77189-00000-02	CL 12CM X 10MTR STRETCHED 20 INT.	10	12

<b>2.12 Storage conditions</b>	Dry, clean, and without exposure to direct sunlight																																																							
<b>2.13 Shelf life/ Storage time</b>	Supplier guaranteed a minimum shelf life: 5 years																																																							
<b>2.14 Sterilization</b>	Product is <u>not sold</u> sterile.  But stable materials are used to maintain the therapeutically relevant material properties after common autoclavation processes																																																							
<b>2.15 Reimbursement Information</b>	<table border="1"> <thead> <tr> <th>REF</th> <th>Size</th> <th>PZN</th> </tr> </thead> <tbody> <tr><td>01026-00</td><td>6cm x 5m</td><td>2059664</td></tr> <tr><td>01026-01</td><td>6cm x 5m</td><td></td></tr> <tr><td>01027-00</td><td>8cm x 5m</td><td>2059670</td></tr> <tr><td>01027-01</td><td>8cm x 5m</td><td></td></tr> <tr><td>01028-00</td><td>10cm x 5m</td><td>2059687</td></tr> <tr><td>01028-01</td><td>10cm x 5m</td><td></td></tr> <tr><td>01029-00</td><td>12cm x 5m</td><td>2059693</td></tr> <tr><td>01029-01</td><td>12cm x 5m</td><td></td></tr> <tr><td>01030-00</td><td>10cm x 5m</td><td>2059701</td></tr> <tr><td>45381-00</td><td>6cm x 5m</td><td>4592575</td></tr> <tr><td>45382-00</td><td>8cm x 5m</td><td>4592581</td></tr> <tr><td>45383-00</td><td>10cm x 5m</td><td>4592598</td></tr> <tr><td>45384-00</td><td>12cm x 5m</td><td>4592606</td></tr> <tr><td>77187-00</td><td>4cm x 5m</td><td></td></tr> <tr><td>77188-00</td><td>10cm x 10m</td><td></td></tr> <tr><td>77189-00</td><td>12cm x 10m</td><td></td></tr> </tbody> </table>					REF	Size	PZN	01026-00	6cm x 5m	2059664	01026-01	6cm x 5m		01027-00	8cm x 5m	2059670	01027-01	8cm x 5m		01028-00	10cm x 5m	2059687	01028-01	10cm x 5m		01029-00	12cm x 5m	2059693	01029-01	12cm x 5m		01030-00	10cm x 5m	2059701	45381-00	6cm x 5m	4592575	45382-00	8cm x 5m	4592581	45383-00	10cm x 5m	4592598	45384-00	12cm x 5m	4592606	77187-00	4cm x 5m		77188-00	10cm x 10m		77189-00	12cm x 10m	
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### 3.0 Chemical substances of special concern to Essity

Essity has defined chemical substances that are of special concern and are subject to specific restrictions. A reference to the list of substances can be found in Annex A2 via the following link [www.essity.com/gss](http://www.essity.com/gss)

Deviations are covered in 3.1 Components.

### 3.1 Components

Raw materials used in product formulation

Substance	Included in formulation
natural rubber Latex	No
Lanolin and its derivatives	No
Colophony	No
Colophony derivatives	No
Bisphenol A (BPA)	No
Polyvinylchloride (PVC)	No
Methylmethacrylate	No
Butylacrylate	No
Microplastics (<5 mm)	No
Nanoparticles	No
Fragrance/parfum	No
Antibiotics	No
Triclosan	No
Chlorhexidine	No
Polyhexanide	No

Type of cotton used in the product: Standard Cotton

Raw materials used in the packaging

Substance	Included in formulation
Polyvinylchloride (PVC)	No
Natural rubber latex	No
Recycled material	Yes, folding box. Shipper case partly recycled material.

Raw materials used in the product formulation and in the packaging may contain small amounts of the substances listed above and not marked as included in formulation as well as amounts of other substances not listed above. As trace level analysis is not performed for each batch *BSN medical Inc.* cannot provide proof of absence.

## History

Version / Date	Page / Item	Description of Change
01 / 25.November 2021	All	Set up new document