

**Änderungsnummer / Change Master: C2365\_210**


**Objektverknüpfungen / Object Links:**

JBX 40037492 000 01 MDR Co-Plus

**Dokumentenstückliste / Document Structure:**

Status		Responsible	Date
IE	in Erstellung	DEHNINA	15.02.2021
AF	Freigabeanford.	DEHOLHS	15.02.2021
FR	freigegeben	DEHNIPL	15.02.2021

## Product Data Sheet

<b>1.0 Name of the product</b>	Co-Plus®
<b>2.0 Product description</b>	
<b>2.1 Description</b>	Co-Plus® is an elastic cohesive bandage made of polyamide, polypropylene and polyurethane coated with natural rubber latex.
<b>2.2 Intended purpose</b>	Co-Plus® is intended for fixation of wound dressings of all types and sizes as well as devices such as splints, tubes and paddings, for short term application of compression and to provide general support. Co-Plus® is non-sterile, for single use on intact skin only. Intended users are healthcare professionals and patients. Use of the device is not restricted to specific populations.
<b>2.3 Instructions for use</b>	Instructions for use not necessary for class I/Is/IIa products. Product is well-known and self-explanatory. Pictograms and symbols on folding box are guiding to a safe use.
<b>2.4 Warnings and precautions for use</b>	Caution: This product contains natural rubber latex which may cause allergic reactions. Do not re-use. Upper limit of temperature 30°C.
<b>2.5 Contraindications</b>	Do not use Co-Plus® on patients with known intolerance to latex.
<b>2.6 Transport Precautions</b>	Not applicable
<b>2.7 Duration of application</b>	The bandages can be used from one day to several days depending on the treatment needs but cumulative use can be longer than 30 days. For single use on intact skin only.
<b>2.8 Information on reusable/ washable products</b>	 Do not re-use
<b>2.9 Composition</b>	62.5% Natural rubber compound 35.3% Polyamide/Polypropylene 2.2% Polyurethane yarn

<b>2.10 Product range</b>	Size	Color	Per flo w	Per folding box	Per shipper	Product code
	10cm x 3m (6.3m)	Flesh	1		18	72100-04
	15cm x 3m (6.3m)	Flesh	1		12	72100-05
	2.5cm x 3m (6.3m)	Flesh	5		60	72100-06
	5cm x 3m (6.3m)	Flesh	1		36	72100-08
	7.5cm x 3m (6.3m)	Flesh	1		24	72100-09
	10cm x 3m (6.3m)	White	1		18	72101-05
	5cm x 3m (6.3m)	White	1		36	72101-09
	7.5cm x 3m (6.3m)	White	1		24	72101-10
	10cm x 4.5m	White	1		16	72101-11 REPACK: 72101-14
	7.5cm x 4.5m	White	1		24	72101-12 REPACK: 72101-15
	5cm x 4.5m	White	1		36	72101-13 REPACK: 72101-16
	7cm x 3m	White	-	1	24	72101-27
	7cm x 3m	Flesh	-	1	24	72101-28
	10cm x 3.5m	White	-	1	18	72101-29
	10cm x 3.5m	Flesh	-	1	18	72101-30
	10cm x 3m (6.3m)	3x Purple 3x Blue 3x Green 3x Pink 3x Red 3x Light Blue	1		18	72102-02
	7.5cm x 3m (6.3m)	4x Purple 4x Blue 4x Green 4x Pink 4x Red 4x Light Blue	1		24	72102-03
	5cm x 3m (6.3m)	6x Purple 6x Blue 6x Green 6x Pink 6x Red 6x Light Blue	1		36	72102-04
	10cm x 3m (6.3m)	Green	1		18	72102-05
10cm x 3m (6.3m)	Blue	1		18	72102-23	

<b>2.11 Sizing Chart</b>	Please see 2.10
<b>2.12 Storage conditions</b>	Dry, clean and without exposure to direct sunlight. Max. storage condition: 30°C
<b>2.13 Shelf life/ Storage time</b>	The product has a shelf life of 3 years, if stored appropriately

**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.

<b>3.1 Components</b>	Raw materials used in product formulation	
	<b>Substance</b>	<b>Included in formulation</b>
	natural rubber Latex	Yes
	Lanolin and its derivatives	no
	Colophony	not intentionally added only rosin esters used
	Colophony derivatives	not intentionally added only rosin esters used
	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
	Raw materials used in the packaging	
	<b>Substance</b>	<b>Included in formulation</b>
	Polyvinylchloride (PVC)	no
	Natural rubber latex	no
	Recycled material	no
	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 GmbH cannot provide proof of absence.	

## History

Version/Date	Page /Item	Description of Change
01 / 24.06.2011	all	Set up new document 40014134 000 01
01 / 02.2021	all	Set up new document according to new template 40014134 000 01 will be replaced by 40047786
02 / 02.2021	Background data	Linked JBX