
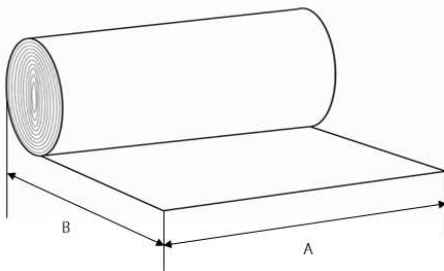


	TECHNICAL DATA SHEET OF MEDICAL DEVICE			TD-45-I.1.1-1.1.2	
	in accordance with Regulation (EU) 2017/745			edition: I	
	device: elastoBAND FLEX Elastic supporting bandage, woven, non-sterile			date: 2021-05-26	
	general group name: non-sterile elastic bandages			amendment of: N/A	

INFORMATION ON THE MEDICAL DEVICE						
name of device	elastoBAND FLEX Elastic supporting bandage, woven, non-sterile					
device identification (models, sizes, catalogue numbers)	REF	model			dimensions	
	OE08400-E	elastoBAND FLEX Elastic supporting bandage, woven, non-sterile			8 cm x 4 m	
	OE10400-E	elastoBAND FLEX Elastic supporting bandage, woven, non-sterile			10 cm x 4 m	
	OE12400-E	elastoBAND FLEX Elastic supporting bandage, woven, non-sterile			12 cm x 4 m	
	OE15400-E	elastoBAND FLEX Elastic supporting bandage, woven, non-sterile			15 cm x 4 m	
	OE08500-E	elastoBAND FLEX Elastic supporting bandage, woven, non-sterile			8 cm x 5 m	
	OE10500-E	elastoBAND FLEX Elastic supporting bandage, woven, non-sterile			10 cm x 5 m	
	OE12500-E	elastoBAND FLEX Elastic supporting bandage, woven, non-sterile			12 cm x 5 m	
	OE15500-E	elastoBAND FLEX Elastic supporting bandage, woven, non-sterile			15 cm x 5 m	
	OE08400P-E	elastoBAND FLEX Elastic supporting bandage, woven, non-sterile			8 cm x 4 m	
	OE10400P-E	elastoBAND FLEX Elastic supporting bandage, woven, non-sterile			10 cm x 4 m	
	OE12400P-E	elastoBAND FLEX Elastic supporting bandage, woven, non-sterile			12 cm x 4 m	
	OE15400P-E	elastoBAND FLEX Elastic supporting bandage, woven, non-sterile			15 cm x 4 m	
	OE08500P-E	elastoBAND FLEX Elastic supporting bandage, woven, non-sterile			8 cm x 5 m	
	OE10500P-E	elastoBAND FLEX Elastic supporting bandage, woven, non-sterile			10 cm x 5 m	
	OE12500P-E	elastoBAND FLEX Elastic supporting bandage, woven, non-sterile			12 cm x 5 m	
	OE15500P-E	elastoBAND FLEX Elastic supporting bandage, woven, non-sterile			15 cm x 5 m	
manufacturer	ZARYS International Group sp. z o.o. sp.k.					
manufacturer's address	ul. Pod Borem 18, 41-808 Zabrze, Poland		SRN	PL-MF-000000410	website	www.zarys.com
classification	class	II	rule	1		
EC Certificate Number (if applicable)	n/a		Notified Body involved in conformity assessment (if applicable)	n/a		
Notified Body number	n/a					
microbiological status	non-sterile		type of sterilisation	n/a	standard	n/a
Basic UDI-DI	59079968M03040201HJ		EMDN code	M03040201	GMDN code	61223
applicable current technical standards	n/a					

SPECIFICATION OF THE MEDICAL DEVICE						
intended purpose	Device intended for holding dressings and for supporting and compressing body parts to treat sprains and strains, lymphoedema and to strengthen skin layers after surgery.					
nature of body contact (invasiveness of the device)	non-invasive device – surface-contacting medical device					
site of contact (organs/tissues/body fluids with which the device comes into contact)	undamaged skin surface					
maximum service life	up to 3 days					
frequency of use	reusable product - replacement and frequency of use according to the procedures of the medical institution					
shelf-life	5 years - from date of manufacture					
purpose of use	for holding dressings and for supporting and compressing body parts to treat sprains and strains, lymphoedema and to strengthen skin layers after surgery					
patient population	patients regardless of gender and age					
target group of users	professional user - medical staff					
patient selection criteria	patients requiring dressing support and to support and compress body parts to treat sprains and strains, lymphoedema and to strengthen skin after surgery					
indications for use	for holding dressings and for supporting and compressing body parts to treat sprains and strains, lymphoedema and to strengthen skin layers after surgery					
contraindications for use	damaged, irritated skin at the place of application					
warnings	do not apply directly on wounds or under Plaster of Paris bandages					
principle of operation and use	Select the size of the bandage according to the place of application. Before use check the package for damage. Open the package and remove the bandage. Check that the device is not damaged or dirty. Apply a sterile dressing to the prepared and disinfected wound. Wrap the part of the body with the dressing with an elastic bandage and secure with a clip. If using a bandage in a situation other than to support the dressing, wrap the part of the body requiring application of the device and secure with a clip.					
novel features	none					
accessory	n/a					
products/ accessories intended to be used in combination with the device	n/a					

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	general group name: non-sterile elastic bandages				amendment of: N/A		
characteristics of compatibility with other products/ accessories	n/a						
possible configurations/ device variants	dimensions of elastoBAND FLEX: 8 cm x 4 m; 10 cm x 4 m; 12 cm x 4 m; 15 cm x 4 m; 8 cm x 5 m; 10 cm x 5 m; 12 cm x 5 m; 15 cm x 5 m; 8 cm x 4 m; 10 cm x 4 m; 12 cm x 4 m; 15 cm x 4 m; 8 cm x 5 m; 10 cm x 5 m; 12 cm x 5 m; 15 cm x 5 m						
features	<ul style="list-style-type: none">• elastic supporting bandage, woven• thanks to high content of cotton it is safe for skin and very well tolerated by people prone to allergies• delicate, light• stretchability min. 150%• adapts well to all body curves• can be sterilized – by steam under positive pressure, by ethylene oxide• equipped with fixing clip (width 15 cm equipped with 2 clips)• reusable						
diagram / photograph / drawing	 						
description of the key functional elements	part number	description of the device component		function of the part		material/ raw material	colour
	1	supporting bandage, woven		holding dressings and supporting and compressing body parts to treat sprains and strains, lymphoedema and to strengthen skin layers after surgery		55 % cotton yarn 43% polyamide yarn 2 % spandex	white
	2	clip		facilitates fastening, prevents the elastic bandage from unwinding or moving from its place of application		fixing part: aluminium 76% elastic part: polyester 20% + spandex 4%	white-grey
	part number	dimension			tolerance		
		REF	length (B)	width (A)	length after relaxation min.	length	width
	1	OE08400-E	4 m	8 cm	120 cm	± 0,2 m	± 0,5 cm
		OE10400-E	4 m	10 cm	120 cm	± 0,2 m	± 0,5 cm
		OE12400-E	4 m	12 cm	120 cm	± 0,2 m	± 0,8 cm
		OE15400-E	4 m	15 cm	120 cm	± 0,2 m	± 1 cm
		OE08500-E	5 m	8 cm	150 cm	± 0,2 m	± 0,5 cm
		OE10500-E	5 m	10 cm	150 cm	± 0,2 m	± 0,5 cm
		OE12500-E	5 m	12 cm	150 cm	± 0,2 m	± 0,8 cm
		OE15500-E	5 m	15 cm	150 cm	± 0,2 m	± 1 cm
		OE08400P-E	4 m	8 cm	120 cm	± 0,2 m	± 0,5 cm
		OE10400P-E	4 m	10 cm	120 cm	± 0,2 m	± 0,5 cm
		OE12400P-E	4 m	12 cm	120 cm	± 0,2 m	± 0,8 cm
		OE15400P-E	4 m	15 cm	120 cm	± 0,2 m	± 1 cm
		OE08500P-E	5 m	8 cm	150 cm	± 0,2 m	± 0,5 cm
		OE10500P-E	5 m	10 cm	150 cm	± 0,2 m	± 0,5 cm
		OE12500P-E	5 m	12 cm	150 cm	± 0,2 m	± 0,8 cm
		OE15500P-E	5 m	15 cm	150 cm	± 0,2 m	± 1 cm
materials, substances, gases coming into contact with the device during use	n/a						
compatibility with medicinal products administered by the device	n/a						
flow rate of substances administered to the patient	n/a						
content of carcinogenic substances	type of substance			n/a			
	substance concentration weight by weight (w/w)			n/a			
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			amendment of: N/A	

content of mutagenic substances	type of substance	n/a
	substance concentration weight by weight (w/w)	n/a
content of substances toxic to reproduction	type of substance	n/a
	substance concentration weight by weight (w/w)	n/a
applied safeguards against unintentional ingress of substances into the device	n/a	
applied safeguards against unintentional cutting and pricking of the device	n/a	
applied safeguards to prevent use errors or interpretation of results	n/a	
measuring function	ensuring measurement precision and stability	n/a
	measurement accuracy limits	n/a
	units of measurement used	n/a
methods of effective disposal of the device after use	after use it should be disposed of in accordance with accepted procedures, recommended thermal disposal (incineration)	

description of packaging	type of packaging	packaging dimensions [mm]	packaging material	number of devices [pcs]	number of labels	print colour (PANTONE)
	unit packaging	OE08400-E	40x40x85mm	box – flat cardboard	1 pc.	1 label
OE10400-E		40x40x105mm				
OE12400-E		40x40x125mm				
OE15400-E		40x40x155mm				
OE08500-E		40x40x85mm				
OE10500-E		40x40x105mm				
OE12500-E		40x40x125mm				
OE15500-E		40x40x155mm				
OE08400P-E		145x150mm	polyethylene coated paper			
OE10400P-E		165x150mm				
OE12400P-E		185x150mm				
OE15400P-E		215x150mm				
OE08500P-E		150x160mm				
OE10500P-E		170x160mm				
OE12500P-E		190x160mm				
OE15500P-E		220x160mm				
transport packaging	OE08400-E	445x220x215mm		carton – corrugated cardboard	124 x 1 pc.	1 label
	OE10400-E	515x190x175mm	124 x 1 pc.			
	OE12400-E	265x260x330mm	108 x 1 pc.			
	OE15400-E	375x225x210mm	108 x 1 pc.			
	OE08500-E	350x260x265mm	96 x 1 pc.			
	OE10500-E	295x225x275mm	96 x 1 pc.			
	OE12500-E	265x260x330mm	72 x 1 pc.			
	OE15500-E	355x225x210mm	72 x 1 pc.			
	OE08400P-E	445x220x215mm	124 x 1 pc.			
	OE10400P-E	515x200x185mm	124 x 1 pc.			
	OE12400P-E	265x260x330mm	108 x 1 pc.			
	OE15400P-E	375x235x220mm	108 x 1 pc.			
	OE08500P-E	350x260x265mm	96 x 1 pc.			
	OE10500P-E	295x235x290mm	96 x 1 pc.			
	OE12500P-E	265x260x330mm	72 x 1 pc.			
	OE15500P-E	355x235x220mm	72 x 1 pc.			

markings used	list of the used markings is included in point I.2.a of the technical documentation - device label		
storage and transport conditions	temperature [°C]	-	humidity [%]
	other	keep away from sunlight; keep dry	

no.	date	scope of the amendments	approved by