Change Master / Änderungsnummer: **C2365**_885

Object Links / Objektverknüpfungen:

JBZ 40044736 000 01 CH PFD MDR JOBST LYMPHCARE KIT NON-CE

Document Structure / Dokumentenstückliste:

Status	Responsible	Date
IE In preparation	USHPAHO	02/24/2023

BSN medical Inc.

Statement according Article 22 (Systems and procedure packs), Medical device Regulation 2017/745

Reference Documents
Product Family Description: ***JBZ 40044736_000_01***

Legal Manufacturer
BSN medical Inc.
5825 Carnegie Blvd.
Charlotte, NC 28209

EU Representative
BSN medical GmbH
Schützenstr. 1-3
Hamburg, Germany 22761

We, BSN Medical, Inc., hereby declare that we have verified the mutual compatibility of the devices within these systems and procedure packs in accordance with the individual manufacturer's instructions; have packaged the kits preserving the integrity of the individual devices; supplied relevant information for the user incorporating applicable instructions of the manufacturers and verify the activity is subject to all applicable methods of internal control and inspection according to an approved and controlled Quality System compliant to ISO 13485:2016, the Medical Device Regulation 2017/745 and FDA QSR 21CFR Part 820.

All products within the system/procedure pack bear the “CE” mark and are used within the limits of their intended purpose.

Component NART(s) within the System

NART	Qty.	Name	Legal Manufacturer	Packed by
JOBST Lymphcare Leg (Item No.: 78642-00000-02)				
02198-00000-07	1	Tricofix F7 10cm x 20cm	*LM BSN Medical, Inc. (CLT)*	*Schoepe Display Inc.*
02099-00000-03	1	Elastomull 4 cm x 4m	*LM BSN Medical GmbH (DE)*	
09046-00000-06	2	Artiflex 10cm	*LM BSN Medical, Inc. (CLT)*	
09047-00000-06	2	Artiflex 15cm	*LM BSN Medical, Inc. (CLT)*	
01756-00000-09	1	Leukoplast Hospital 1.25cm	*LM BSN Medical GmbH (DE)*	
01026-00000-06	1	Comprilan 6 cm x 5 m	*LM BSN Medical, Inc. (CLT)*	
01027-00000-07	1	Comprilan 8 cm x 5 m	*LM BSN Medical, Inc. (CLT)*	
01028-00000-06	3	Comprilan 10 cm x 5 m	*LM BSN Medical, Inc. (CLT)*	
01029-00000-06	4	Comprilan 12 cm x 5 m	*LM BSN Medical, Inc. (CLT)*	
78496-00010-00	1	Foam Rubber Pad 5cm x 9cm	*LM Lohmann & Rauscher*	
JOBST Lymphcare Lower Leg (Item No.: 78641-00000-02)				
02197-00000-07	1	Tricofix E6 8cm x 20cm	*LM BSN Medical, Inc. (CLT)*	*Schoepe Display Inc.*
02099-00000-03	1	Elastomull 4 cm x 4m	*LM BSN Medical GmbH (DE)*	
09046-00000-06	3	Artiflex 10cm	*LM BSN Medical, Inc. (CLT)*	
01756-00000-09	1	Leukoplast Hospital 1.25cm	*LM BSN Medical GmbH (DE)*	
01026-00000-05	1	Comprilan 6 cm x 5 m	*LM BSN Medical, Inc. (CLT)*	
01027-00000-06	1	Comprilan 8 cm x 5 m	*LM BSN Medical, Inc. (CLT)*	
01028-00000-05	3	Comprilan 10 cmx5 m	*LM BSN Medical, Inc. (CLT)*	
78496-00010-00	1	Foam Rubber Pad 5cm x 9cm	*LM Lohmann & Rauscher*	
JOBST Lymphcare Arm (Item No.: 78639-00000-02)				
02195-00000-07	1	Tricofix D5 6cm x 20cm	*LM BSN Medical, Inc. (CLT)*	*Schoepe Display Inc.*
02099-00000-03	1	Elastomull 4 cm x 4m	*LM BSN Medical GmbH (DE)*	
09046-00000-06	2	Artiflex 10cm	*LM BSN Medical, Inc. (CLT)*	
09047-00000-06	2	Artiflex 15cm	*LM BSN Medical, Inc. (CLT)*	
01756-00000-09	1	Leukoplast Hospital 1.25cm	*LM BSN Medical GmbH (DE)*	
01026-00000-05	1	Comprilan 6 cm x 5 m	*LM BSN Medical, Inc. (CLT)*	
01027-00000-06	1	Comprilan 8 cm x 5 m	*LM BSN Medical, Inc. (CLT)*	
01028-00000-05	5	Comprilan 10 cmx5 m	*LM BSN Medical, Inc. (CLT)*	
78496-00010-00	1	Foam Rubber Pad 5cm x 9cm	*LM Lohmann & Rauscher*	

Approved By: _____**Title**_____**Date**_____
Print/Sign **Director, Regulatory Affairs**

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HISTORY

Revision	Project/Change #	Description of Change	Change Request #	Release Date
02	C2365_885	To adapt Foam Pad NART from 78496-00000-03 to 78496-00010-00	N/A	See SAP release date
01	C2365_885	New Document	N/A	See SAP release date

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01029-00000-06	4	Comprilan 12 cm x 5 m	*LM BSN Medical, Inc. (CLT)*	
78496-00010-00	1	Foam Rubber Pad 5cm x 9cm	*LM Lohmann & Rauscher*	
JOBST Lymphcare Lower Leg (Item No.: 78641-00000-02)				
02197-00000-07	1	Tricofix E6 8cm x 20cm	*LM BSN Medical, Inc. (CLT)*	*Schoepe Display Inc.*
02099-00000-03	1	Elastomull 4 cm x 4m	*LM BSN Medical GmbH (DE)*	
09046-00000-06	3	Artiflex 10cm	*LM BSN Medical, Inc. (CLT)*	
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78496-00010-00	1	Foam Rubber Pad 5cm x 9cm	*LM Lohmann & Rauscher*	
JOBST Lymphcare Arm (Item No.: 78639-00000-02)				
02195-00000-07	1	Tricofix D5 6cm x 20cm	*LM BSN Medical, Inc. (CLT)*	*Schoepe Display Inc.*
02099-00000-03	1	Elastomull 4 cm x 4m	*LM BSN Medical GmbH (DE)*	
09046-00000-06	2	Artiflex 10cm	*LM BSN Medical, Inc. (CLT)*	
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78496-00010-00	1	Foam Rubber Pad 5cm x 9cm	*LM Lohmann & Rauscher*	

Andreas Matthies

Approved By: _____ Title_____ Date_____

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