Declaration of Conformity MDR ACM LSSC Add.SupportBelt/PressurePad

JBX.40047430.02 Page 1 of 2

We,

BSN medical GmbH Schützenstr. 1-3 22761 Hamburg Germany (SRN: DE-MF-000005787)

hereby declare under our sole responsibility, that this product family complies with the applicable requirements of the regulation (EU) 2017/745 of the European parliament and of the council on medical devices (MDR).

Product Name:

Actimove® Lumbar Sacral Support Comfort Additional

Support Belt, Pressure Pad

4042809400474309G Basic UDI-DI:

Intended purpose: Actimove® Lumbar Sacral Support Comfort Additional

Support Belt, Pressure Pad is intended to provide stabilization to the lumbar area. Application fields include:

Acute and chronic lower back pain
Degenerative changes in the lumbar area (e.g. Degenerative changes in the fullbar area (e.g. osteoporosis, osteochondrosis, spondylosis, spondylarthrosis, facet syndrome)
Lumbar instabilities (insufficiencies of muscles and ligaments, sprains and strains)
Lumbar disc protrusion
Post-traumatic and post-operative use (e.g. after intervertebral disc operations)

intervertebral disc operations)

Prevention of repetitive strain injuries

Conformity assessment route: Annex II+III

Classification rule:

Classification:

The Declaration of Conformity is performed in accordance with the quality management system according to EN ISO 13485, and fulfils the general safety and performance requirements of the regulation (EU) 2017/745.

Declaration of conformity issued: 08.02.2024

Compiled and released:

Hamburg, 08.02.2024 Martin Spengler

Director Regulatory Affairs Hamburg BSN medical GmbH

Madir Much



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JBX.40047430.02 Page 2 of 2

Article	Description	REF
75511-00013-00	ACTIMOVE LUMBAR SACRAL SUPPORT COMFORT ADDITIONAL SUPPORT BELT PRESSURE PAD 10"/25CM SMALL WHITE 1 AR ZH DA NL EN FI FR DE IT NO PT	75511-13
75511-00014-00	ACTIMOVE LUMBAR SACRAL SUPPORT COMFORT ADDITIONAL SUPPORT BELT PRESSURE PAD 10"/25CM MEDIUM WHITE 1 AR ZH DA NL EN FI FR DE IT NO PT	75511-14
75511-00015-00	ACTIMOVE LUMBAR SACRAL SUPPORT COMFORT ADDITIONAL SUPPORT BELT PRESSURE PAD 10"/25CM LARGE WHITE 1 AR ZH DA NL EN FI FR DE IT NO PT	75511-15
75511-00016-00	ACTIMOVE LUMBAR SACRAL SUPPORT COMFORT ADDITIONAL SUPPORT BELT PRESSURE PAD 10"/25CM EXTRA LARGE WHITE 1 AR ZH DA NL EN FI FR DE IT	75511-16
75511-00017-00	ACTIMOVE LUMBAR SACRAL SUPPORT COMFORT ADDITIONAL SUPPORT BELT PRESSURE PAD 10"/25CM EXTRA EXTRA LARGE WHITE 1 AR ZH DA NL EN FI FR	75511-17
75511-00018-00	ACTIMOVE LUMBAR SACRAL SUPPORT COMFORT ADDITIONAL SUPPORT BELT PRESSURE PAD 10"/25CM XXXL WHITE 1 AR ZH DA NL EN FI FR DE IT NO PT E	75511-18