We,

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

Prduct Name:	**Actimove® Professional Line Umerus Comfort Comfort Shoulder Immobilizer**
Basic UDI-DI:	**4042809400344718W**
Intended purpose:	**The product is intended to provide support to the arm, elbow and shoulder. Application fields include:** **- Postoperative use (e.g. after rotator-cuff-rupture)** **- Fracture management (e.g. clavicle, scapular, humeral, and greater tuberosity fractures)** **- Joint distortions (sprains) and dislocations (e.g. acromioclavicular & sternoclavicular dislocations, shoulder luxation)** **- Inflammatory diseases (e.g. calcific tendinitis of the rotator cuff)** **- Minor instability of the shoulder (e.g. dorsal instability)** **- Support for hemiplegic patients** **- Support while wearing a cast or splint** **- Temporary arm stabilization in emergency/paramedic care**
Conformity assessment route:	**Annex II+III**
Classification rule:	**1**
Classification:	**I**

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.

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Dr. Thomas Mehler
Global Quality Director Medical
BSN medical GmbH

Article	Description	REF
72819-00039-04	ACTIMOVE UMERUS COMFORT IMMOBILISER -37 CM SMALL BLACK/BLUE 1 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72819-39
72819-00040-04	ACTIMOVE UMERUS COMFORT IMMOBILISER 37-40 CM MEDIUM BLACK/BLUE 1 AR ZH DA NL EN FI FR DE IT NO PT ES SV	72819-40
72819-00041-04	ACTIMOVE UMERUS COMFORT IMMOBILISER 40-43 CM LARGE BLACK/BLUE 1 AR ZH DA NL EN FI FR DE IT NO PT ES SV	72819-41
72819-00042-04	ACTIMOVE UMERUS COMFORT IMMOBILISER >43 CM EXTRA LARGE BLACK/BLUE 1 AR ZH DA NL EN FI FR DE IT NO PT ES SV	72819-42
72819-00094-04	ACTIMOVE UMERUS COMFORT IMMOBILISER <33CM EXTRA SMALL BLUE 1 AR ZH DA NL EN FI FR DE IT NO PT ES SV	72819-94
73423-00003-04	ACTIMOVE UMERUS COMFORT IMMOBILISER SMALL BLACK/BLUE 1 AR ZH DA NL EN FI FR DE IT NO PT ES SV LPPR 72819-39-04 33-38CM	73423-03
73423-00004-04	ACTIMOVE UMERUS COMFORT IMMOBILISER MEDIUM BLACK/BLUE 1 AR ZH DA NL EN FI FR DE IT NO PT ES SV LPPR 72819-40-04 37-43CM	73423-04
73423-00005-04	ACTIMOVE UMERUS COMFORT IMMOBILISER LARGE BLACK/BLUE 1 AR ZH DA NL EN FI FR DE IT NO PT ES SV LPPR 72819-41-04 42-48CM	73423-05
73423-00006-04	ACTIMOVE UMERUS COMFORT IMMOBILISER EXTRA LARGE BLACK/BLUE 1 AR ZH DA NL EN FI FR DE IT NO PT ES SV LPPR 72819-42-04 >48CM	73423-06
73423-00011-04	ACTIMOVE UMERUS COMFORT IMMOBILISER EXTRA SMALL BLUE 1 AR ZH DA NL EN FI FR DE IT NO PT ES SV 72819-94-04 LPPR <33CM	73423-11