

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® Sling Comfort – On a Roll .**

Basic UDI-DI:

**4042809400344728Y**

Intended purpose:

**Actimove® Sling Comfort – On a Roll 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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Compiled and released:

Hamburg, 07.07.2023  
Dr. Thomas Mehler  
Global Quality Director Medical  
BSN medical GmbH



| Article        | Description  | REF      |
|----------------|--|----------|
| 72859-00018-05 | ACTIMOVE SLING COMFORT DISPENSER<br>UPPER EXTREMITY 5.5CMX12M UNIVERSAL<br>BLUE 2 AR ZH DA NL EN FI FR DE IT JA NO PT<br>ES SV | 72859-18 |