

We,

**BSN medical GmbH
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20253 Hamburg
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(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® TaloCast Air

Basic UDI-DI:

4042809400384169J

Intended purpose:

**The devices are intended to stabilize the ankle joint.
Application fields include:
- Ligament and capsule injuries at the upper ankle joint
(e.g. ligament ruptures, strains, distortions)
- Slight soft tissue injuries
- Chronic ankle instability
- Rehabilitation and prevention of ankle injuries
- Acute, chronic, and inflammatory edema**

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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Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
73119-00004-00	ACTIMOVE TALOCAST AIR TRAINER UNIVERSAL SMALL/MEDIUM 1 AR ZH DA NL EN FI FR DE IT NO PT ES SV	73119-04
73119-00005-00	ACTIMOVE TALOCAST AIR STANDARD UNIVERSAL LARGE/EXTRA LARGE 1 AR ZH DA NL EN FI FR DE IT NO PT ES SV	73119-05
73119-00006-00	ACTIMOVE TALOCAST AIR TRAINER UNIVERSAL SMALL/MEDIUM 1 FR 73119-04 LPPR	73119-06
73119-00007-00	ACTIMOVE TALOCAST AIR STANDARD UNIVERSAL LARGE/EXTRA LARGE 1 FR 73119-05 LPPR	73119-07