

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® Rhizo Forte

Basic UDI-DI:

404280940049158A5

Intended purpose:

Actimove® Rhizo Forte is intended to provide immobilization of the thumb. The device is designed for single patient use.

Conformity assessment route: **Annex II+III**

Classification rule:

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Classification:

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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: 06.03.2024

Compiled and released:

Hamburg, 06.03.2024
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
76238-00000-03	ACTIMOVE RHIZO FORTE SMALL-RIGHT GREY 1 EN DE FR ES PT IT NL SV NO DA FI AR ZH	76238-00
76238-00001-03	ACTIMOVE RHIZO FORTE SMALL-LEFT GREY 1 EN DE FR ES PT IT NL SV NO DA FI AR ZH	76238-01
76238-00002-03	ACTIMOVE RHIZO FORTE MEDIUM-RIGHT GREY 1 EN DE FR ES PT IT NL SV NO DA FI AR ZH	76238-02
76238-00003-03	ACTIMOVE RHIZO FORTE MEDIUM-LEFT GREY 1 EN DE FR ES PT IT NL SV NO DA FI AR ZH	76238-03
76238-00004-03	ACTIMOVE RHIZO FORTE LARGE-RIGHT GREY 1 EN DE FR ES PT IT NL SV NO DA FI AR ZH	76238-04
76238-00005-03	ACTIMOVE RHIZO FORTE LARGE-LEFT GREY 1 EN DE FR ES PT IT NL SV NO DA FI AR ZH	76238-05
76238-00018-03	ACTIMOVE RHIZO FORTE SMALL-RIGHT BLACK 1 EN DE FR ES PT IT NL SV NO DA FI AR ZH	76238-18
76238-00019-03	ACTIMOVE RHIZO FORTE SMALL-LEFT BLACK 1 EN DE FR ES PT IT NL SV NO DA FI AR ZH	76238-19
76238-00020-03	ACTIMOVE RHIZO FORTE MEDIUM-RIGHT BLACK 1 EN DE FR ES PT IT NL SV NO DA FI AR ZH	76238-20
76238-00021-03	ACTIMOVE RHIZO FORTE MEDIUM-LEFT BLACK 1 EN DE FR ES PT IT NL SV NO DA FI AR ZH	76238-21
76238-00022-03	ACTIMOVE RHIZO FORTE LARGE-RIGHT BLACK 1 EN DE FR ES PT IT NL SV NO DA FI AR ZH	76238-22
76238-00023-03	ACTIMOVE RHIZO FORTE LARGE-LEFT BLACK 1 EN DE FR ES PT IT NL SV NO DA FI AR ZH	76238-23
76238-00048-03	ACTIMOVE RHIZO FORTE SMALL-RIGHT GREY 1 FR LPPR 76238-00-03	76238-48
76238-00049-03	ACTIMOVE RHIZO FORTE SMALL-LEFT GREY 1 FR LPPR 76238-01-03	76238-49
76238-00050-03	ACTIMOVE RHIZO FORTE MEDIUM-RIGHT GREY 1 FR LPPR 76238-02-03	76238-50
76238-00051-03	ACTIMOVE RHIZO FORTE MEDIUM-LEFT GREY 1 FR LPPR 76238-03-03	76238-51
76238-00052-03	ACTIMOVE RHIZO FORTE LARGE-RIGHT GREY	76238-52

Article	Description	REF
	1 FR LPPR 76238-04-03	
76238-00053-03	ACTIMOVE RHIZO FORTE LARGE-LEFT GREY 1 FR LPPR 76238-05-03	76238-53