Art.-Nr. Item no.	Produktname; Variante; Beschreibung	Product Name, Version; Description	Risikoklasse EU Risk class EU	Klass.-Regel, Classifi-cation	UMDNS Code	GMDN Code	EMDN Code	Basis UDI-DI	UDI DI* [GTIN]	MDD [Ja/Nein]	MDR* [Ja/Nein]	DIMDI –Registrier-Nr. DIMDI Code
80.00.040	**ARTROMOT®-K1;** ARTROMOT®-K1 Standard; Bewegungstherapiegerät, passiv, kontinuierlich, Bein	**ARTROMOT®-K1;** ARTROMOT®-K1 Standard; Exercisers, Continuous Passive Motion, Lower Limb	IIa	9	17-138	36313	Z120616	0888912DJO000005966K	00888912403191	Ja	Nein	DE/CA39/662/A17
80.00.041	**ARTROMOT®-K1;** ARTROMOT®-K1 Standard Chip; Bewegungstherapiegerät, passiv, kontinuierlich, Bein	**ARTROMOT®-K1;** ARTROMOT®-K1 Standard Chip; Exercisers, Continuous Passive Motion, Lower Limb	IIa	9	17-138	36313	Z120616	0888912DJO000005966K	00888912403207	ja	Nein	DE/CA39/662/A17
80.00.042	**ARTROMOT®-K1;** ARTROMOT®-K1 Comfort; Bewegungstherapiegerät, passiv, kontinuierlich, Bein	**ARTROMOT®-K1;** ARTROMOT®-K1 Comfort; Exercisers, Continuous Passive Motion, Lower Limb	IIa	9	17-138	36313	Z120616	0888912DJO000005966K	00888912403214	Ja	Nein	DE/CA39/662/A17
80.00.043	**ARTROMOT®-K1;** ARTROMOT®-K1 Comfort Chip; Bewegungstherapiegerät, passiv, kontinuierlich, Bein	**ARTROMOT®-K1;** ARTROMOT®-K1 Comfort Chip; Exercisers, Continuous Passive Motion, Lower Limb	IIa	9	17-138	36313	Z120616	0888912DJO000005966K	00888912403221	Ja	Nein	DE/CA39/662/A17
80.00.044	**ARTROMOT®-K1;** ARTROMOT®-K1 Standard Basic; Bewegungstherapiegerät, passiv, kontinuierlich, Bein	**ARTROMOT®-K1;** ARTROMOT®-K1 Standard Basic; Exercisers, Continuous Passive Motion, Lower Limb	IIa	9	17-138	36313	Z120616	0888912DJO000005966K	00190446751823	Ja	Nein	DE/CA39/662/A17
80.00.045	**ARTROMOT®-K1;** ARTROMOT®-K1 Classic; Bewegungstherapiegerät, passiv, kontinuierlich, Bein	**ARTROMOT®-K1;** ARTROMOT®-K1 Classic; Exercisers, Continuous Passive Motion, Lower Limb	IIa	9	17-138	36313	Z120616	0888912DJO000005966K	00888912403238	Ja	Nein	DE/CA39/662/A17
80.00.047	**ARTROMOT®-K1;** ARTROMOT®-K1 Classic Basic; Bewegungstherapiegerät, passiv, kontinuierlich, Bein	**ARTROMOT®-K1;** ARTROMOT®-K1 Classic Basic; Exercisers, Continuous Passive Motion, Lower Limb	IIa	9	17-138	36313	Z120616	0888912DJO000005966K	00190446751830	Ja	Nein	DE/CA39/662/A17
80.00.070	**ARTROMOT® ACTIVE-K;** ARTROMOT® ACTIVE-K; Bewegungstherapiegerät, Sonstige, Bein	**ARTROMOT® ACTIVE-K;** ARTROMOT® ACTIVE-K; Exercisers, Other, Lower Limb	IIa	9	15-220	36313	Z120616	0888912DJO0000022155	00888912403283	Ja	Nein	DE/CA39/11/Ä064Ä2

80.00.023	**ARTROMOT®-S3;** ARTROMOT®-S3 Standard; Bewegungstherapiegerät, passiv, kontinuierlich, Arm	**ARTROMOT®-S3;** ARTROMOT®-S3 Standard; Exercisers, Continuous Passive Motion, Upper Limb	IIa	9	17-139	36313	Z120616	0888912DJO0000004545W	00888912403108	Ja	Nein	DE/CA39/11/Ä062
80.00.024	**ARTROMOT®-S3;** ARTROMOT®-S3 Comfort; Bewegungstherapiegerät, passiv, kontinuierlich, Arm	**ARTROMOT®-S3;** ARTROMOT®-S3 Comfort Exercisers, Continuous Passive Motion, Upper Limb	IIa	9	17-139	36313	Z120616	0888912DJO0000004545W	00888912403115	Ja	Nein	DE/CA39/11/Ä062
80.00.084	**ARTROMOT®-S4;** ARTROMOT®-S4 Comfort; Bewegungstherapiegerät, passiv, kontinuierlich, Arm	**ARTROMOT®-S4;** ARTROMOT®-S4 Comfort; Exercises, Continuous Passive Motion, Upper Limb	IIa	9	17-139	36313	Z120616	0888912DJO0000002455K	00190446278764	Ja	Nein	DE/CA39/662/18
80.00.031	**ARTROMOT®-E2;** ARTROMOT®-E2; Bewegungstherapiegerät, passiv, kontinuierlich, Arm	**ARTROMOT®-E2;** ARTROMOT®-E2; Exercisers, Continuous Passive Motion, Upper Limb	IIa	9	17-139	36313	Z120616	0888912DJO0000005115H	00888912403139	Ja	Nein	DE/CA39/11/Ä065
80.00.033	**ARTROMOT®-E2;** ARTROMOT®-E2 Compact; Bewegungstherapiegerät, passiv, kontinuierlich, Arm	**ARTROMOT®-E2;** ARTROMOT®-E2 Compact; Exercisers, Continuous Passive Motion, Upper Limb	IIa	9	17-139	36313	Z120616	0888912DJO0000005115H	00888912403146	Ja	Nein	DE/CA39/11/Ä065
80.00.035	**ARTROMOT®-SP3;** ARTROMOT®-SP3 Standard; Bewegungstherapiegeräte, passiv, kontinuierlich, Bein	**ARTROMOT®-SP3;** ARTROMOT®-SP3 Standard; Exercises, passive, continuous, Lower Limb	IIa	9	17-138	36313	Z120616	0888912DJO0000056262	00888912403153	Ja	Nein	DE/CA39/11/Ä063
80.00.036	**ARTROMOT®-SP3;** ARTROMOT®-SP3 Standard Chip; Bewegungstherapiegeräte, passiv, kontinuierlich, Bein	**ARTROMOT®-SP3;** ARTROMOT®-SP3 Standard Chip; Exercises, passive, continuous, Lower Limb	IIa	9	17-138	36313	Z120616	0888912DJO0000056262	00888912403160	Ja	Nein	DE/CA39/11/Ä063
80.00.037	**ARTROMOT®-SP3;** ARTROMOT®-SP3 Comfort; Bewegungstherapiegeräte, passiv, kontinuierlich, Bein	**ARTROMOT®-SP3;** ARTROMOT®-SP3 Comfort; Exercises, passive, continuous, Lower Limb	IIa	9	17-138	36313	Z120616	0888912DJO0000056262	00888912403177	Ja	Nein	DE/CA39/11/Ä063
80.00.038	**ARTROMOT®-SP3;** ARTROMOT®-SP3 Comfort Chip; Bewegungstherapiegeräte, passiv, kontinuierlich, Bein	**ARTROMOT®-SP3;** ARTROMOT®-SP3 Comfort Chip; Exercises, passive, continuous, Lower Limb	IIa	9	17-138	36313	Z120616	0888912DJO0000056262	00888912403184	Ja	Nein	DE/CA39/11/Ä063

* Erklärung: Die **MDR**-Anforderung, einer eindeutigen Produktidentifizierbarkeit ist durch die **UDI-DI** gewährleistet /
Declaration: The **MDR** requirement of unique product identification is guaranteed by the **UDI-DI**.

UDI-DI [GTIN] Spezifikation ist in der VA ***7000.020*** definiert / **UDI DI** [GTIN] is specified in procedure ***7000.020***:

0 = Indikatorziffer / indicator prefix

0888912 = DJO Global, LLC - Firmenpräfix der GS1 Registierung / Company Prefix, registered under GS1 license / Ormed GmbH is a company of Enovis
0190446 = DJO Global, LLC – Firmenpräfix der GS1 Registrierung / Company Prefix, registered under GS1 license / Ormed GmbH is a company of Enovis

40319 = 5-stellige einmalige, unique Ziffer / 5-pattern unique sequence

0 = Prüfziffer / checksum

Die Produktrückverfolgbarkeit ist somit über UDI-DI [GTIN / Produkt SN und Herstell-Datum] gewährleistet; und ist auf dem Produkt Typenschild vorhanden.
The product traceability is guaranteed via UDI-DI [GTIN / Product SN und Manufacturing date]; therefore, check product labelling.

Vor der Verwendung der GTIN-Nummer war die Identifikation über die **EAN**-Nummer gewährleistet / Prior GTIN numbering, the unique product identification was guaranteed via an **EAN** number.

Freiburg, 2025-05-05

Bernhard Krohne, PRRC Ormed GmbH