

[EN] EU DECLARATION OF CONFORMITY
[IT] DICHIARAZIONE DI CONFORMITÀ UE
[DE] EU-KONFORMITÄTSERKLÄRUNG

[FR] DÉCLARATION DE CONFORMITÉ UE
[SI] IZJAVA EU O SKLADNOSTI
No. KV26/2024/05



[EN] According to REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
[IT] In accordo con il REGOLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO
[DE] Gemäß VERORDNUNG (EU) 2017/745 DES EUROPÄISCHEN PARLAMENTS UND DES RATES
[FR] Conformément au RÈGLEMENT (UE) 2017/745 DU PARLEMENT EUROPÉEN ET DU CONSEIL
[SI] V skladu z uredbo EVROPSKEGA PARLAMENTA IN SVETA (EU) 2017/745



MANUFACTURER FABBRICANTE HERSTELLER PRODUCTEUR PROIZVAJALEC KOVAL D.O.O.	REGISTERED OFFICE SEDE LEGALE SIÈGE SOCIAL REGISTRIERTES BÜRO NASLOV PODJETJA Loka pri Žusmu 9 3223 Loka pri Žusmu, SLOVENIA	SRN NUMERO DI REGISTRAZIONE UNICO EINMALIGE REGISTRIERUNGSNUMMER NUMÉRO D'ENREGISTREMENT UNIQUE ENOTNA REGISTRACIJSKA ŠTEVILKA SI-MF-000003206
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[EN] This declaration of conformity EU is issued under the sole responsibility of the manufacturer.
[IT] La presente dichiarazione di conformità UE è rilasciata sotto la responsabilità esclusiva del fabbricante.
[DE] Diese EU-Konformitätserklärung wird in der alleinigen Verantwortung des Herstellers ausgestellt.
[FR] Cette déclaration de conformité UE est émise sous la seule responsabilité du fabricant.
[SI] Za izdajo te EU izjave o skladnosti je odgovoren izključno proizvajalec.

Basic UDI-DI UDI-DI BASE BASIS-UDI- DI IUD-ID OSNOVNI UDI-DI 383007592KV26AA	PRODUCT NAME NOME DEL PRODOTTO PRODUKTNAME NOM DU PRODUIT IME IZDELKA MOVER	PRODUCT CODE CODICE DEL PRODOTTO PRODUKTCODE CODE PRODUIT KODA IZDELKA 11992***	RISK CLASS CLASSE DI RISCHIO RISIKOKLASSE CLASSE DE RISQUE RAZRED TVEGANJA I, rule 1 I, rule 13*
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(*) electric models | versioni elettriche | elektrische versionen | versions électriques | električni modeli

[EN] INTENDED USE	[IT] DESTINAZIONE D'USO	[DE] VERWENDUNGSZWECK	[FR] UTILISATION PRÉVUE	[SI] PREDVIDENA UPORABA
Patient transfer	Trasferimento del paziente	Patiententransfer	Transfert de patients	Mover

[EN] We hereby declare that the devices listed above comply with the essential safety and performance requirements of REGULATION (EU) 2017/745 (MDR).
[IT] Con la presente si dichiara che i dispositivi sopra elencati sono conformi ai requisiti essenziali di sicurezza e prestazione del REGOLAMENTO (UE) 2017/745 (MDR).
[DE] Hiermit erklären wir, dass die oben aufgeführten Geräte den grundlegenden Sicherheits- und Leistungsanforderungen der VERORDNUNG (EU) 2017/745 (MDR).
[FR] Nous déclarons par la présente que les dispositifs énumérés ci-dessus sont conformes aux exigences essentielles de sécurité et de performance du RÈGLEMENT (UE) 2017/745 (MDR) entsprechen.
[SI] Izjavljamo, da zgoraj naštetih naprav izpolnjujejo bistvene zahteve o varnosti in učinkovitosti UREDBE (EU) 2017/745 (MDR).

PRODUCTS WITH CODE

I, rule 1, (Regulation (EU) MDR 2017/745)	I, rule 13, (Regulation (EU) MDR 2017/745)
Mover (code: 11992121) Mover - Narrow (code: 11992123) Mover - Narrow - PRO (code: 11992124) Mover - Flexi (code: 11992145) Mover - Flexi - PRO (code: 11992146) Mover - Flexi - Maxi (code: 11992150)	Mover EL-EP-DR (code: 11992182)

[EN] Compliance is assessed in accordance with Annex IX by means of the applicable parts of the following standards:

[IT] La conformità è valutata in accordo all'allegato IX mediante le parti applicabili delle seguenti norme:

[DE] Die Einhaltung wird gemäß Anhang IX anhand der anwendbaren Teile der folgenden Normen bewertet:

[FR] La conformité est évaluée conformément à l'annexe IX au moyen des parties applicables des normes suivantes:

[SI] Skladnost se oceni v skladu s Prilogo IX z uporabo ustreznih delov naslednjih standardov:

EN ISO 10535:2021	Assistive products - Hoists for the transfer of persons - Requirements and test methods
EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
EN ISO 21856:2022	Assistive products - General requirements and test methods
EN 60601-1:2006/A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015+A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1+A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Date of issue: 05.02.2024

Place of issue: Loka pri Žusmu

Authorized signature:

Director: Zdravko Zidar

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