[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

KOVAL
Your care, our mission

[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

CE

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**

[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***

(*) 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 si 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 naštete naprave 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

KOVAL d.o.o.
PROIZVODNJA IN TRGOVINA
LOKA PRI ŽUSMU 3223
SLOVENIJA