[EN] DECLARATION OF CONFORMITY
[IT] DICHIARAZIONE DI CONFORMITÀ UE
[DE] EU-KONFORMITÄTSERKLÄRUNG
[FR] DÉCLARATION DE CONFORMITÉ UE
[SI] IZJAVA O SKLADNOSTI
No. KV24/2021/01

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	**REGISTERED OFFICE** SEDE LEGALE | SIÈGE SOCIAL| REGISTRIERTES BÜRO| NASLOV PODJETJA	**SRN** NUMERO DI REGISTRAZIONE UNICO | EINMALIGE REGISTRIERUNGSNUMMER | NUMÉRO D'ENREGISTREMENT UNIQUE | ENOTNA REGISTRACIJSKA ŠTEVILKA
KOVAL D.O.O.	**Loka pri Žusmu 9** **3223 Loka pri Žusmu, SLOVENIA**	**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	**PRODUCT NAME** NOME DEL PRODOTTO | PRODUKTNAME | NOM DU PRODUIT | IME IZDELKA	**PRODUCT CODE** CODICE DEL PRODOTTO | PRODUKTCODE | CODE PRODUIT | KODA IZDELKA	**RISK CLASS** CLASSE DI RISCHIO | RISIKOKLASSE | CLASSE DE RISQUE | RAZRED TVEGANJA
383007592KV24A6	**WALKING TROLLEY**	**11992***	**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
Walking trolleys	**Deambulatori**	**Gehwagen**	**Chariot de marche**	**Vozički za pomoč pri hoji**

[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).
[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)
Walking trolley (code: 11992002) **Walking trolley with IV pole (code: 11992005)** **Walking trolley - High (code: 11992010)** **Walking trolley 2-GS (code: 11992030)** **Walking trolley with Handbrake - high (code: 11992032)** **Walking trolley with Handbrake (code: 11992034)** **Walking trolley with Seat (code: 11992036)** **Walking trolley Maxi (code: 11992050)**	**Walking trolley Maxi - EL (code: 11992060)** **Walking trolley - EL (code: 11992100)** **Walking trolley with Handbrake - EL (code: 11992110)**

[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 12182:2012	**Assistive products for persons with disability - General requirements and test methods.**
EN ISO 15223-1:2017-02 (eq. EN ISO 15223-1:2016)	**Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied.**
SIST EN ISO 14971:2020 (eq. EN ISO 14971:2019)	**Medical devices - Application of risk management to medical devices.**
EN 60601-1:2007	**Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.**
EN 60601-1-2:2015	**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	**Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010).**

Date of issue: 20.5.2021

Place of issue: Loka pri Žusmu

Authorized signature:

Director: Zdravko Zidar

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LOKA PRI ŽUSMU 3223
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