

[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



[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



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|---|---|---|
| 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.

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| Basic UDI-DI UDI-DI BASE BASIS-UDI- DI IUD-ID OSNOVNI UDI-DI 383007592KV24A6 | PRODUCT NAME NOME DEL PRODOTTO PRODUKTNAME NOM DU PRODUIT IME IZDELKA WALKING TROLLEY | 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

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|-----------------------------|----------------------------|--------------------------|----------------------------|----------------------------------|
| [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 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).
[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) |
|---|---|
| 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:


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| 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). |

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Place of issue: Loka pri Žusmu

Authorized signature:

Director: Zdravko Zidar


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

KOVAL d.o.o.

Loka pri Žusmu 9

3223 Loka pri Žusmu

Slovenia

+ 386 3 747 19 14

koval@koval.si

www.koval.si

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