[EN] EU DECLARATION OF CONFORMITY
[IT] DICHIARAZIONE DI CONFORMITÀ UE
[DE] EU-KONFORMITÄTSERKLÄRUNG
[FR] DÉCLARATION DE CONFORMITÉ UE
[SI] IZJAVA EU O SKLADNOSTI
No. KV22/2025/05

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	**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
383007592KV22A2	**SHOWER TROLLEY**	**10068962**	**I, rule 13**

[EN] **INTENDED USE**	[IT] DESTINAZIONE D'USO	[DE] VERWENDUNGSZWECK	[FR] UTILISATION PRÉVUE	[SI] PREDVIDENA UPORABA
Shower trolleys	**Barella doccia**	**Duschwagen**	**Chariot douche**	**Vozički za tuširanje**

[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 13, (Regulation (EU) MDR 2017/745)
Shower Trolley L2-R-T1-EL (code: 10068962)

[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 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**
ISO 17966:2016	**Assistive products for personal hygiene that support users - Requirements and test methods**
EN ISO 21856:2022	**Assistive products - General requirements and test methods**
IEC 60601-1:2005+A1:2012	**Medical electrical equipment - Part 1: General requirements for basic safety and essential performance**
IEC 60601-1-2:2014+A1:2020	**Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests**
IEC 60601-1-6:2010+A1:2013	**Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability**

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Place of issue: Loka pri Žusmu

Authorized signature:

Director: Zdravko Zidar

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