

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

[FR] DÉCLARATION DE CONFORMITÉ UE
[SI] IZJAVA EU O SKLADNOSTI
No. KV42/2024/02



[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 383007592KV42A8	PRODUCT NAME NOME DEL PRODOTTO PRODUKTNAME NOM DU PRODUIT IME IZDELKA PATIENT TREATMENT CHAIR	PRODUCT CODE CODICE DEL PRODOTTO PRODUKTCODE CODE PRODUIT KODA IZDELKA 110004**	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 treatment chair	Poltrona per il trattamento del paziente	Patientenbehandlun gsstuhl	Fauteuil de traitement des patients	Stol za ambulantne posege

[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 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)
Patient Treatment chair - FIX (code: 11000400) Patient Treatment chair - HYD (code: 11000410)	Patient Treatment chair - EL - GS (code: 11000420) Patient Treatment chair - EL - EM (code: 11000430)

[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
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
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
EN 62366-1:2015+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices

Date of issue: 05.02.2024

Place of issue: Loka pri Žusmu

Authorized signature:

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