



NOVAK M d.o.o
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Izjava EU o skladnosti
(EU Declaration of conformity)
Referenčna oznaka (Form Reference): DoC_MTSE2021.2



Naziv proizvajalca (Manufacturer's Name): Novak M d.o.o.
Blagovna znamka (Trade mark): Novak M
Naslov proizvajalca (Manufacturer's Address): Pod smrekami 5, 1218 Komenda SLOVENIJA
SRN (Single Registration Number): SI-MF-000000876
Basic UDI-DI: 38300546420MTSEQP

Ime produkta (Name of the device)	Model (Model)	Klasifikacija (Classification)
Terapevtska miza S2 (Therapy table S2)	TTS2-E	Razred I (Priloga VIII, Pravilo 13) Class I (Annex VIII, Rule 13)
Terapevtska miza S2 – basic (Therapy table S2 – basic)	TTS2-B	

Postopek ugotavljanja skladnosti: Novak M d.o.o. uporablja naslednje postopke za označevanje svojih izdelkov z oznako CE v skladu z Uredbo MDR 2017/745: Priloga II in Priloga III (Tehnična dokumentacija)
Conformity assessment route: Novak M d.o.o. uses the following procedures for the CE-labelling of their products according the Regulation MDR 2017/745: Annex II and Annex III (Technical documentation)

Ta izjava o skladnosti je izdana izključno na odgovornost podjetja Novak M d.o.o. Izjavljamo, da zgoraj navedeni izdelki izpolnjujejo zahteve Uredbe (EU) MDR 2017/745 o medicinskih pripomočkih. Vsa podporna dokumentacija in seznam uporabljenih standardov so na vpogled na sedežu proizvajalca.
This declaration of conformity is issued under the sole responsibility of Novak M d.o.o.. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. All supporting documentation and list of applied standards are retained at the premises of the manufacturer.

Kraj in datum izdaje (Place and date of issue): Komenda, 14. 3. 2022

Podpis proizvajalca (Signed by the manufacturer):


Novak M d.o.o.
Pod smrekami 5, 1218 Komenda, Slovenija-EU

Ime in Priimek (Name and Surname):

Miha Novak, Managing Director