

Prejeto dne:

12. 04. 2018

**DOMEL<sub>3</sub>**

AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL  
DEVICES OF THE REPUBLIC OF SLOVENIA  
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Številka: 312-26/2018-4

Datum: 10.4.2018

**IZJAVA O PROSTI PRODAJI  
CERTIFICATE OF FREE SALE**

S to izjavo Javna agencija Republike Slovenije za zdravila in medicinske pripomočke zagotavlja, da se medicinski pripomočki v Republiki Sloveniji urejajo v skladu z Zakonom o medicinskih pripomočkih (Uradni list RS, št. 98/2009), ki povzema direktivo 98/79/EC. Usklajenost z direktivo 98/79/EC omogoča dajanje medicinskih pripomočkov v promet v Republiki Sloveniji, EU in EGP.

*The Agency for Medicinal Products and Medical Devices of the Republic of Slovenia hereby certifies, that medical devices in the Republic of Slovenia are regulated under the Act on Medical Devices of the Republic of Slovenia (OJ L no. 98/2009) which implements the directive 98/79/EC. Harmonization with the directive 98/79/EC enables marketing the medical devices in the Republic of Slovenia, in the EU and EEA.*

Naslednji medicinski pripomočki vpisani v register medicinskih pripomočkov na podlagi izdanih odločb za vlogo številka 310-74/2014,

*The following medical devices listed in register of medical devices based on decisions issued by the application number 310-74/2014,*

Ime medicinskih pripomočkov ali dodatkov

*Name of the medical devices or accessories*

**Priloga: seznam medicinskih pripomočkov**

*Attachment: list of medical devices*

proizvajalca:

*of manufacturer:*

**DOMEL, Elektromotorji in gospodinjski aparati, d.o.o., Otoki 21, 4228, Železniki, Slovenija**

*(podatki o proizvajalcu / identification of the manufacturer)*

so lahko na trgu Republike Slovenije.

*are eligible to be marketed in Republic of Slovenia.*

Ta izjava je veljavna do veljavnosti listin, ki so podlaga za izdajo te izjave. / *This certificate expires on the date of certificates, which are the basis for this statement.*



dr. Andreja Čufar  
Direktorica / Director  
*Andreja Čufar*

**Seznam IVD medicinskih pripomočkov**  
**List of IVD medical devices**

Generično ime: Univerzalna laboratorijska centrifuga  
*Generic name: Centrifuge, general-purpose laboratory*

Razvrstitev: razred IVD - Drugo  
*Classification: class IVD - Other/General*

Trgovsko ime <i>Commercial name</i>	Model <i>Model</i>
Centric 250 IVD	472.3.000/IVD (230V), 1472.3.000/IVD (115V)
Centric 350 IVD	473.3.000/IVD (230V), 1473.3.000/IVD (115V)
Centric 400	457.3.000
Centric 400 R	457.3.500

