

PRODUCTS WITH MEDICAL HONEY

Manufacturer:	TOSAMA Tovarna sanitetnega materiala d.o.o.
Address of registered place of business:	Vir, Šaranovičeva cesta 35 1230 Domžale, SLOVENIA
Single registration number of the manufacturer (SRN):	SI-MF-000003888

Basic UDI-DI:	383898546206M2
GMDN:	46206
Risk class (Annex VIII):	I (rule 1)
EMDN:	M9002
Trade name:	VIVAMEL SKIN BARRIER Skin renewal and protection ointment with chestnut honey, beeswax, and jojoba oil
Model/Type:	50 g (19731)

REMARK: Article numbers are in the brackets.

Used standards:

Reference number (ID: year)	Name of standard
EN ISO 13485:2016/ A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
IEC 62366-1:2015/AMD 1:2020	Medical devices - Part 1: Application of usability engineering to medical devices - Amendment 1
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Notified body:	/
Notified body ID number:	/
EU certificate:	/
Conformity assessment procedure:	/

TOSAMA d.o.o. under the sole responsibility of the manufacturer, with this EU declaration of conformity declares that the above-mentioned medical devices comply with relevant requirements of the Regulation (EU) 2017/745 on medical devices. Conformity assessment was performed in line with provisions of Annex II and III.

Place and date of issue of declaration:
Vir, 15.4.2024

For and on behalf of the manufacturer TOSAMA d.o.o.:

Person Responsible for Regulatory Compliance
Janez Obreza Msc, MPharm


TOVARNA SANITETNEGA MATERIALA d.o.o. / 11
ŠARANOVIČEVA CESTA 35, VIR
1230 DOMŽALE