



*Certifikat / Certificate*

za  
sistem vodenja

**TOSAMA d.o.o.**

Vir, Šaranovičeva cesta 35, 1230 Domžale

Razvoj, proizvodnja, pakiranje in prodaja nesterilnih in sterilnih proizvodov iz gaze in netkanega materiala, medicinskih obližev, setov, operacijskih setov, vpojnih oblog, sterilnih proizvodov z medicinskim medom, zaščitnih izdelkov za paciente in osebje, vate za medicinsko rabo, povojev, lepilnih trakov, kompletov prve pomoči in higienskih tamponov v Tosama d.o.o. in pakiranje higienskih tamponov v Intos d.o.o.

*ima vzpostavljen in ustrezno vzdrževan sistem vodenja,  
ki izpolnjuje zahteve standarda*

**ISO 13485:2016**

*Certifikat št. / Datum certifikacije*

**M-045/ 2010-12-17**

*Izdaja 08 / 2023-01-31 Velja do: 2026-01-31*

*Direktor SIQ Ljubljana*

*Gregor Schoss*



**SLOVENSKA  
AKREDITACIJA**  
SIST EN ISO/IEC 17021-1  
**CS-001**



SIQ Ljubljana, Mašera-Spasičeva ulica 10, 1000 Ljubljana, Slovenija

# Certificate

**SIQ Ljubljana** has issued an IQNET recognized certificate that the organization:

**TOSAMA d.o.o.**  
**Vir, Šaranovičeva cesta 35, 1230 Domžale, Slovenia**

has implemented and maintains a  
**Medical devices - Quality System**

for the following scope:

**Design, production, packaging and sales of non sterile and sterile products from gauze and nonwoven, medical plasters, sets, surgical procedure packs, absorbent dressing pads and sterile products with medical honey, protective products for patients and personnel, medical wadding, bandages, adhesive tapes, first aid kits and hygienic tampons at Tosama d.o.o. and packaging of hygienic tampons at Intos d.o.o.**

which fulfils the requirements of the following **standard**:

**ISO 13485:2016**

Issued on: **2023-01-31**  
First issued on: **2010-12-17**  
Expires on: **2026-01-31**

Registration Number: **SI - M-045**



**Alex Stoichitoiu**  
President of IQNET



**Gregor Schoss**  
Managing director of SIQ Ljubljana



This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

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**LSQA** Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria**  
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