



Certifikat / Certificate

za
sistem vodenja

TOSAMA d.o.o.

Vir, Šaranovičeva cesta 035, 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 osebe, 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 07 / 2020-01-31 Velja do: 2023-01-31

Direktor SIQ Ljubljana

Igor Likar



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

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



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

SIQ Ljubljana has issued an IQNet recognized certificate that the organization:

TOSAMA d.o.o.

Vir, Šaranovičeva cesta 035, 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

First issued on: 2010-12-17

Issued on: 07 | 2020-01-31 Expires on: 2023-01-31

*This attestation is directly linked to the IQNet Partner's original certificate
and shall not be used as a stand-alone document*

Registration Number: SI – M-045



Alex Stoichitoiu
President of IQNet

Igor Likar
Managing Director of SIQ Ljubljana



IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com