



Certifikat / Certificate

za
sistem menadžmenta

NIVA DOO ŽABALJ

Čuruška 54, 21230 Žabalj

Proizvodnja i promet medicinskih sredstava: medicinske vate, kaliko zavoja, pamučne gaze, papirne vate, proizvoda od gaze (sterilnih i nesterilnih), kompresa (sterilnih i nesterilnih), elastičnih gumenih zavoja, medicinskih gumenih čarapa, terapeutskih gaćica, prvog zavoja, trougle marame, flastera na kalem, adhezivnog flastera, kompresa sa RTG nitima (sterilnih i nesterilnih) i abdominalnih kompresa sa RTG nitima (sterilnih i nesterilnih), hirurške nesterilne maske, hirurškog nesterilnog mantila, hirurške nesterilne kape, hirurških nesterilnih kaljača, turban i mul zavoja, tupfera od gaze (nesterilni), hidrofilne kabel gaze, komprese za oko (nesterilne), abdominalnih kompresa od gaze (nesterilne), kompresa od netkanog materijala (sterilne i nesterilne), kompleti za prvu pomoć, izotermalnog prekrivača, zaštitnog sredstva za davanje veštačkog disanja, zakrivljenih makaza sa zaobljenim vrhom, esmarhove poveske.

*ima uspostavljen i održavan sistem menadžmenta,
koji ispunjava zahteve standarda*

ISO 13485:2016

Sertifikat broj / Datum sertifikacije

M-032/ 2010-05-26

Izdanje 14 / 2023-02-14 Važi do: 2025-04-30

Direktor SIQ Ljubljana

Gregor Schoss



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



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

Certificate

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

NIVA DOO ŽABALJ
Čuruška 54, 21230 Žabalj, Serbia

has implemented and maintains a
Medical devices - Quality System

for the following scope:

Manufacture and trading of medical devices: medical wadding, calico bandage, cotton gauze, paper wool, cotton gauze products (sterile and non-sterile), compresses (sterile and non-sterile), elastic rubber bandages, medical rubber socks, therapeutic pants, first aid bandage, triangular bandage, medical tape on dispenser, adhesive plaster, X-ray detectable compresses (sterile and non-sterile) and abdominal X-ray detectable compresses (sterile and non-sterile), surgical mask non-sterile, surgical gown non-sterile, surgical cap non-sterile, surgical shoe covers non-sterile, tubular and mull bandages, gauze balls (non-sterile), hidrofil cabel gauze, eye pad dressings (non-sterile), abdominal gauze compresses (non-sterile), nonwoven compresses (sterile and non-sterile), First Aid kits, isothermal blanket, First Aid artificial respiration mask, curved scissors with a rounded tip, esmarch bandages.

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

ISO 13485:2016

Issued on: **2023-02-14**
First issued on: **2010-05-26**
Expires on: **2025-04-30**

Registration Number: **SI - M-032**


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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