EC Certificate – Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V
Certificate No. MDD-010

Issued to:	NIVA DOO ŽABALJ Čuruška 54, 21230 Žabalj, Serbia
Place of production:	NIVA DOO ŽABALJ Čuruška 54, 21230 Žabalj, Serbia
Product category:	Sterile compresses and sterile cotton gauze, first aid bandages
GMDN:	/
Product category:	Sterile gauze I.V cannulas dressings, sterile eye pad dressings, sterile burns dressings, sterile cotton gauze balls, sterile abdominal gauze compresses
GMDN:	/
Product category:	Nonwoven compresses, sterile
GMDN:	/

SIQ has audited the quality system in accordance with MDD Annex V, restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions and found that the above-mentioned manufacturer's quality system meets the requirements of the Directive 93/42/EEC concerning medical devices Annex V, including all subsequent amendments. This certificate is based on

Audit report No.:
OSV 00200A/2019, 2019-05-20
OSV 00395/2020, 2020-06-29
OSV 00506/2020, 2020-05-26
OSV 01605/2020, 2021-01-29
OSV 00055/2021, 2021-03-31
OSV 00498/2021, 2021-05-17
OSV 00663/2021, 2021-05-25

See also decision of NB`s commission for medical devices.

This certificate remains valid as long as the Manufacturer's quality system is subject to periodical surveillance as referred to in Directive 93/42/EEC concerning medical devices Annex V (4), restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions, and continues to meet the above requirements.

Certification date: 2010-05-26

Issue: 06/2021-05-25

Valid until: 2024-05-26

SIQ Ljubljana
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