



EC Certificate – Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V
Certificate No. MDD-145

Issued to: NIVA DOO ŽABALJ
Čuruška 54, 21230 Žabalj, Serbia
Place of production: NIVA DOO ŽABALJ
Čuruška 54, 21230 Žabalj, Serbia
Product category: Sterile and non-sterile X-ray detectable gauze compresses
Sterile and non-sterile X-ray detectable abdominal gauze
compresses
GMDN: /

SIQ has audited the quality system in accordance with MDD Annex V 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 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) and continues to meet the above requirements.

Certification date: 2021-05-25

Issue: 1/2021-05-25

Valid until: 2024-05-26



Managing Director of SIQ

Gregor Schoss