

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÈQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod lisem 129/2, 171 02 Praha 8 - Troja

Elektrotechnický zkušební ústav, s. p., Certification Body No. 3004 for certification of management systems, accredited by the Czech Accreditation Institute, o.p.s. in accordance with ČSN EN ISO/IEC 17021-1, grants the

CERTIFICATE

No.: 8220011

for the Quality Management System in accordance with

EN ISO 13485:2016

to the Firm

GAMA GROUP a.s.

Mánesova 11/3b, 370 01 České Budějovice, Czech Republic

in localities: Plant Jimramov: Ubušínská 20, 592 42 Jimramov, Czech Republic

because it ascertained that the Quality Management System of the Firm in localities and processes:

- design and development, production and distribution of medical devices for infusion, transfusion, haemodialysis, blood-taking, venouse pressure measurement, suction and collection secretion, urodynamic, transfer and priming sets, catheters and currettes
- services in the field of sterilization of medical devices by the gaseous EO in keeping with requirements of EN ISO 11135:2014

complies with all requirements of the above mentioned Standard documented by the Report No.: 212865-01 of: 17.01.2022

First certification granted: 22.02.2022
The validity of the Certificate is limited till: 21.02.2025

The Certified Organization is subject to annual check-ups carried out by the Certification Body. Any change within the organization concerning the certification shall be followed up and approved by the Electrotechnical Testing Institute. The validity of this Certificate may be suspended or cancelled in the event of non-compliance with the Standard on the basis of which the Certificate was issued.

Certification decision: 22.02.2022
Date of issue: 22.02.2022

Ing. Radek Teufl
Head of Certification Body



212865-01