

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



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

Pod litem 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.: 8210099

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: GAMA GROUP a.s., závod Dalečín č.p. 36, 592 41 Dalečín, Czech Republic

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

Design, manufacturing and sale of medical devices class I – Urine bottle with cover (non-sterile, without measuring function, not reusable surgical instrument).

Design, manufacturing and sale of in vitro diagnostic medical devices – Urine conic container, Petri dish.

complies with all requirements of the above mentioned Standard documented by the Report No.: 212469-01 of 23.11.2021

First certification granted: 17.12.2021

The validity of the Certificate is limited till: 16.12.2024

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: 17.12.2021

Date of issue: 17.12.2021

Ing. Radek Teufl
Head of Certification Body



212469-01