

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

The Electrotechnical Testing Institute 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.: 8190025

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: Závod Trhové Sviny
Továrni 560, 374 15 Trhové Sviny, Czech Republic

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

Manufacture and sale of medical devices and in vitro diagnostic medical devices.

complies with all requirements of the above mentioned Standard documented by the Report No.: 910467-01 of: 27.03.2019

The validity of the Certificate is limited till: 28.03.2022

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.

Certificate granted: 29.03.2019
Corrigendum: 05.06.2019

Prague

Ing. Radek Teufl
Deputy Head of Certification Body



910467-01