

# ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



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

Pod Lisem 129, 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, grants the

## CERTIFICATE

No.: 8100167

for the Quality System in accordance with

### EN ISO 13485:2003

to the Firm

### GAMA GROUP a.s.

Mánsova 11/3b, 370 67 České Budějovice, Czech Republic  
Factory: GAMA GROUP a.s závod 9, Tovární 560, 374 15 Trhové Sviny

because it ascertained that the Quality System of the Firm in the field:  
**manufacture and sale of medical devices and in vitro diagnostic medical devices**

in the following locations: -

complies with all requirements of the above mentioned Standard documented by the Report No.: 002978-01 of: 30.09.2010

The validity of the Certificate is limited till: 30.9.2013

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: 30.9.2010

Prague

  
Miroslav Sedláček  
Certification and Inspection Manager



002978-01