

# 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

## CE - CERTIFICATE

of full quality assurance system

No.: MED 070018

The Electrotechnical Testing Institute, Notified Body No. 1014, has decided that Quality System applied by

manufacturer

**GAMA GROUP a.s.**  
**Mánesova 3/11, 370 67 České Budějovice**  
**závod 6, Ubušínská 20, 592 42 Jimramov, Czech Republic**

in manufacturing sites

**GAMA GROUP a.s.**  
**závod 6, Ubušínská 20, 592 42 Jimramov, Czech Republic**

for design, manufacture and final inspection of medical devices

**Medical devices class IIa - see enclosure**

complies with provisions of Annex 2 section 3 of Governmental Order No. 336/2004 Coll. (Annex II section 3 of the Council Directive 93/42/EEC) incl. amendments.

This decision is based on the results presented in report No. 604627-02 of: 04.01.2007

In accordance with Art. 5 of Governmental Order No. 336/2004 (Art. 17 of Directive 93/42/EEC), incl. amendments the above specified medical device must be labelled CE 1014.

The certified manufacturer is subject to a surveillance audit by the notified body in accordance with section 5 of Annex 2 of Governmental Order No. 336/2004 Coll. (Annex II section 5 of Directive 93/42/EEC) incl. amendments, and validity of the Certificate is subject to regular supervision. The manufacturer must inform the notified body about any intention resulting in significant modification of quality system or scope of included medical products. In the event that the conditions under which the Certificate has been issued are violated, the notified body may suspend the Certificate's validity or cancel the Certificate.

The validity of Certificate is limited to: 30.3.2012

30.3.2007

Prague

Pavel Kudrna  
Certification and Inspection Manager



Stamp



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