

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



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

Pod lisem 129, 171 02 Praha 8 - Troja

CE - CERTIFICATE

of production quality assurance

No.: MED 070019

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 manufacture and final inspection of medical devices

Medical devices class I sterile - see enclosure

complies with provisions of Annex 5 section 3 of Governmental Order No. 336/2004 Coll. (Annex V 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 Council 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 4 of Annex 5 of Governmental Order No. 336/2004 Coll. (Annex V section 4 of Council 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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