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, 171 02 Praha 8 - Troja

CE - CERTIFICATE

of full quality assurance system

No.: MED 050049

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

manufacturer **FOMA BOHEMIA spol. s r.o.**
ul. J. Krušinky 1604, 501 04 Hradec Králové, Czech Republic

for design, manufacture and final inspection of medical devices

Radiographic films

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. 503460-01/01-A of: 26.10.2005

In accordance with § 5 of Governmental Order No. 336/2004 (§ 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: 30.11.2010

The Certificate MED 050012 is cancelled hereby.

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV
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POD LISEM 129, PRAHA - TROJA

8.11.2005

Prague

Pavel Kučma
Certification and Inspection Manager

Stamp

* CE / MED 050049 *

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