

NOTIFIED BCPY No. 1023
Institute for Testing and Certification, Inc., Zlin, Czech Republic

EC CERTIFICATE

No. 08 XXXX QS/NB

Issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the products, medico devices of Class B.

HF X-Ray Machines

(Model: Vision 100mA, Vision 500mA, Vision 800mA)

manufactured by company

VISION MEDICAID EQUIPMENTS PVT. LTD.

Survey No 139, A/P- Tathawade, Tal. Mulshi,
Pune -411 033, Maharashtra, India

is manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2 of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3 and 5 of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803600XXX/2008 which is enclosed to this Certificate,

This Certificate is issued under the following conditions:

- 1. It applies only to the quality system maintained in the manufacture of above mentioned models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
- 2. The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 17th November 2018 at the latest.*
- 3. The Certificate validity is conditioned by positive results of surveillance audits.*
- 4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the Notified Body according to this example:*



Issued in Zlin, on 18th November 2013

RNDr. Radomir Cevalik
Representative of the Notified Body No.1023