



## EC DECLARATION OF CONFORMITY

issued in accordance with § 13 of the Act No. 22/1997 Sb., as later amended, in accordance with the Act No. 123/2000 Sb., as later amended, in accordance with the Government Ordinance No. 336/2004 Sb., as later amended, and in accordance with the Ordinance No. 93/42/EEC, as later amended concerning the medical devices.

**The manufacturer: SAFINA, a.s., Vídeňská 104, Jesenice, Vestec, Postal Code 252 42, Business ID: CZ45147868**

**is hereby confirming that in the case of the medical device, classified IIa, in particular:**

mercury used as a component of the dental amalgam, called

### **Dental Mercury**

the conformance evaluation has been carried out for the conformance of its characteristics to the safety requirements required by law and technical regulations, using the procedure defined in § 9 and Annex No.2 to the Government Ordinance No. 336/2004 Sb., on medical device technical requirements,

### **declaring,**

that the characteristics of the above medical device comply with all the basic requirements defined in the Annex No. 1 of the Government Ordinance No. 336/2004 Sb., that this medical device is safe, given its normal use, and that it is designed to be used once. The measures have been taken to secure the conformance of this medical device to the technical documentation kept by SAFINA, a.s., (Technical Section), Vídeňská 104, 252 42 Jesenice, Vestec.

**Purpose of use:** tooth fillings

### **Conformance evaluation procedure:**

By the Quality Full Assurance under § 9 and Annex No. 2 of the Government Ordinance No. 336/2004 Sb.

Notified body involved in conformance evaluation:

LRQA Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry, CV3 4FJ England.

Certificate No: LRQ 0955761/B, LRQA Notified Body Registration No: 0088, Certificate Expiry: 31 January 2012.

### **List of the technical regulations and technical standards used to evaluate the conformance:**

Directive No. 93/42/EEC, as later amended

Medical Devices Regulation 2002: 618

Act No. 22/1997 Sb., on product technical requirements, as later amended.

Act No. 123/2000 Sb., on medical devices, as later amended.

Government Ordinance No. 336/2004 Sb., on medical device technical requirements, as later amended.

ISO 9001: 2000, BS ISO 9001: 2000, ČSN EN ISO 9001: 2001 Quality Management Systems – Requirements.

ISO 13485: 2003 Quality systems – Medical devices – Particular requirement for the application of ISO 9001.

ČSN EN ISO 13485: 2003 Medical Devices – Quality Management Systems – Requirements for regulatory purposes.

ČSN EN ISO 14971: 2009 Medical Devices – Application of Risk Management to Medical Devices.

ČSN EN ISO 24234 Dental Materials – Mercury and alloys for dental amalgam .

ISO 13897 Dentistry – Amalgam Capsules.

Ing. Tomáš Plachý, MBA  
Managing Director

**EC declaration of conformity issued in Vestec on January 26, 2011**