



**SHOFU INC.**

HEAD OFFICE : 11 KAMITAKAMATSU-CHO, FUKUINE HIGASHIYAMA-KU, KYOTO, 605-0983 JAPAN  
TEL : 81-75-561-0411 FAX : 81-75-561-0412

## Declaration of Conformity

### European Community Council Directive 93/42/EEC

**SHOFU INC.** declares sole responsibility, that the product listed below complies with the essential requirements of the Medical Devices Directive 93/42/EEC and 2007/47 EEC, applicable standards and other normative documents.

**Product category:** Composite Restorative Material Kits, Dental, Light-Cured/ 16736

(according to UMDNS-list)

**Device Name:** Solidex

**Class:** IIa

**Rule:** 5

**MDD Annex:** Annex II

**Notified Body:** TÜV NORD CERT GmbH (Identification number is 0044)  
Langemarckstraße 20 D-45141 Essen

**Quality System:** ISO 9001:2000 / EN ISO 13485:2003

**Standards:** ISO 10477: Dentistry-Polymer-based crown and bridge materials  
EN 1441 : Medical devices - Risk analysis  
ISO 15223-1 :Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

*This declaration of conformity content is confirmed at every placing on the market of a new device batch, manufactured since 1997/03/20 (Begin of the Validity).*

*The Technical File required by this Directive is maintained at the manufacture's address below.*

Date of issue : April 7, 2009

This declaration is valid until March 20, 2012

Shigeyuki Komatsu  
General Manager of  
Quality Assurance

**Address:** 11 Kamitakamatsu-cho,  
Fukuine, Higashiyama-ku,  
Kyoto 6050983,  
Japan