SHOFU INC.
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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

Shigeyuki Komatsu
General Manager of
Quality Assurance

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