



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 as amended by 2007/47 EC, applicable standards and other normative documents.

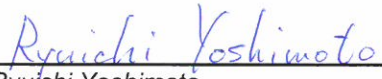
Product category: Cement, Dental, Resin Composite/ 16707 (according to UMDNS-list)
Device Name: BeautiCem SA
Class: IIa
Rule: 8
MDD Annex: Annex II
Notified Body: SGS United Kingdom Ltd. (Identification number is 0120)
Unit 202B, Worle Parkway, Weston-super-Mare, Somerset, BS22 6WA UK
European Representative: Shofu Dental GmbH, Am Brüll 17, 40878 Ratingen, Germany
Quality System: ISO 9001:2008 / EN ISO 13485:2012
Standards: ISO 4049:Dentistry-Polymer-based restorative materials
ISO 14971 : Medical devices - Application of risk management to medical devices
ISO 15223-1: Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1 : General requirements
ISO 10993-1: Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process
ISO 7405 : Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
IEC 62366 : Medical devices - Application of usability engineering to medical devices
EN 980 : Symbols for use in the labelling of medical devices
EN 1041 : Information supplied by the manufacturer of medical devices

This declaration of conformity content is confirmed at every placing on the market of a new device batch, manufactured since 2012/02/21 (Begin of the Validity).

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

Date of issue: March 10, 2017

This declaration is valid until March 20, 2020


Ryuichi Yoshimoto
General Manager of
Quality Assurance

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