



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

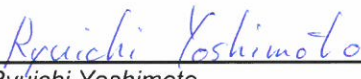
Product category: Restorative Materials, Dental/ 16188 (according to UMDNS-list)
Device Name: BEAUTIFIL-Bulk Restorative
Class: IIa
Rule: 8
MDD Annex: Annex II
Notified Body: SGS United Kingdom Ltd. (Identification number is 0120)
Unit 202B, Worle Parkway, Weston-super-Mare, Somerset, BS22 6WA UK
European 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 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
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
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 2012/12/21 (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

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