



**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:** Dressings, Other / 15216 (according to UMDNS-list)  
**Device Name:** Dura-Polish  
**Class:** I  
**Rule:** 1  
**MDD Annex:** Annex VII  
**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 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

*This declaration of conformity content is confirmed at every placing on the market of a new device batch, manufactured since 2017/03/07 (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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