

**SHOFU INC.**

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## *Declaration of Conformity*

**Manufacturer:** SHOFU INC.  
11 Kamitakamatsu-cho, Fukuine, Higashiyama-ku, Kyoto 6050983, Japan  
**SRN Number:** JP-MF-000015205  
**European Representative:** SHOFU DENTAL GmbH  
An der Pönt 70, 40885 Ratingen, Germany  
**SRN Number:** DE-AR-000004951  
  
**Device Name:** BeautiBond Xtreme  
**Product Category:** Non-active dental implants and dental materials / MDN 1103  
DENTAL BONDING AGENTS / Q01010104 (according to EMDN list)  
**Basic UDI-DI:** 45481620017F  
**Product Code:** Refer to appendix  
**Classification, Rule:** IIa, Rule Rule 8, 1st indent

**SHOFU INC.** declares sole responsibility that the product listed above complies with the following EU Regulation, applicable standards and other normative documents.  
The manufacturer is exclusively responsible for the declaration of conformity.

**Applicable Regulation:** Medical Devices Regulation (EU) 2017/745  
**MDR Annex:** Annex IX Chapters I and III (Class IIa)  
**Notified Body:** TÜV SÜD Product Service GmbH (Identification number is 0123)  
Ridlerstraße 65, 80339 Munich, Germany  
**Applicable Standards:** Refer to applicable standard described in Technical Documentation  
(TED-132)  
**Common Specifications:** Not applicable specifications  
  
**EC Certificate No.:** G10 101021 0004 Rev. 00

*This declaration is valid until 2027-08-24*

Date: 2023-11-22

Place: at SHOFU INC., Kyoto, Japan

  
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Hisaaki Tachidokoro  
General Manager of Quality Assurance Department



## Device listing

(As of 2023-11-22)

Basic UDI-DI: 45481620017F

UDI-DI	REF	Product name	Product code
04548162272683	YE2448	BeautiBond Xtreme Set	C261
04548162272690	YE2449	BeautiBond Xtreme 5mL Bottle 1pc	C262
04548162301314	YE2703	BeautiBond Xtreme 2mL Bottle 1pc	C267
04548162301321	YE2704	BeautiBond Xtreme 2mL Bottle 1pc (SAMPLE)	C268
04548162333018	YE2447	BeautiBond Xtreme Value Pack	C263