

**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:* DirectDia Paste

*Product Category:* Non-active non-implantable dental materials / MDN 1209  
DENTAL ABRASIVE AND POLISHING MATERIALS / Q01010403  
(according to EMDN list)

*Basic UDI-DI:* 45481620027H

*Product Code:* Refer to appendix

*Classification, Rule:* Class I, Rule 5, 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 I, II and IV

*Applicable Standards:* Refer to applicable standard described in Technical Documentation (TED-078)

*Common Specifications:* Not applicable specifications

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

Date: 2022-12-28  
Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro  
General Manager of Quality Assurance Department



## Device listing

(As of 2022-12-28)

Basic UDI-DI: 45481620027H

UDI-DI	REF	Product name	Product code
04548162235572	0558	DirectDia Paste 3g	F975