

**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: PRESSAGE
Product Category: Non-active non-implantable dental materials / MDN 1209
DENTAL FLOSS AND OTHER DEVICES FOR ORAL HYGIENE (FOR
PROFESSIONAL USE) / Q019003 (according to EMDN list)
Basic UDI-DI: 45481620047M
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-051)
Common Specifications: Not applicable specifications

This declaration is valid until 2027-08-24

Date: 2022-11-15

Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro
General Manager of Quality Assurance Department



Device listing

(As of 2022-11-15)

Basic UDI-DI: 45481620047M

UDI-DI	REF	Product name	Product code
04548162308955	0574	PRESSAGE 40g 1pc	F847