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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 101021 0004 Rev. 00

Manufacturer:

SHOFU INC.
11 Kamitakamatsu-cho, Fukuine
Higashiyama-ku
Kyoto
605-0983 JAPAN

SRN Manufacturer: **JP-MF-000015205**

Authorized Representative:

SHOFU DENTAL GmbH
An der Pönt 70, 40885 Ratingen, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 101021 0004 Rev. 00

Report No.: **JN1605483**

Valid from: **2022-08-25**
Valid until: **2027-08-24**

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-08-25

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 101021 0004 Rev. 00

Classification:	IIa
Device Group:	Q010101 - DENTAL RESTORATION DEVICES
Intended Purpose:	-/-
The validity of this certificate depends on conditions and/or is limited to the following:	**- none -**

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TÜV®

SHOFU INC.
HEAD OFFICE : 11 KAMITAKAMATSU-CHO, FUKUINE, HIGASHIYAMA-KU, KYOTO 605-0983, JAPAN
TEL : 81-75-561-0411 FAX : 81-75-561-0412

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	SHOFU INC.
Manufacturer address and contact details	11 Kamitakamatsu-cho, Fukuine, Higashiyama-ku, Kyoto, Japan
Single Registration Number (SRN) (if available)	JP-MF-000015205

Authorised Representative name (if applicable)	SHOFU DENTAL GmbH
Authorised Representative address and contact details	An der Pönt 70, Ratingen, 40885, Germany
Single Registration Number (SRN) (if available)	DE-AR-000004951

Notified body name (if applicable)	See attached schedule
Notified body number (if applicable)	See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	See attached schedule
End date of extended validity/transition period	See attached schedule

We, as the manufacturer declare under our sole responsibility:

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Expired/expires *after* 20 March 2023:

Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

SHOFU INC.

Kyoto, Japan & Date

Signature,

2024-04-22

Hisaaki Tachidokoro, General Manager of Quality Assurance Department

Contact information: h-tachidokoro@shofu.co.jp

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
CERARESIN BOND	No. G1 101021 0003 Rev. 01	2024-03-29	TÜV SÜD Product Service GmbH	TÜV SÜD Product Service GmbH, CE0123	2028-12-31	NA
BEAUTIFIL II	The same above	The same above	The same above	The same above	The same above	NA
BEAUTIFIL OPAQUER	The same above	The same above	The same above	The same above	The same above	BEAUTIFIL Flow LM
BEAUTIFIL FLOW	The same above	The same above	The same above	The same above	The same above	BEAUTIFIL Flow LM
FL-BOND II	The same above	The same above	The same above	The same above	The same above	FL-BOND III
ResiCem	The same above	The same above	The same above	The same above	The same above	BeautiLink SA
BeautiCem SA	The same above	The same above	The same above	The same above	The same above	BeautiLink SA
BEAUTIFIL Flow Plus	The same above	The same above	The same above	The same above	The same above	NA
BeautiSealant	The same above	The same above	The same above	The same above	The same above	NA
BEAUTIFIL-Bulk Restorative	The same above	The same above	The same above	The same above	The same above	NA
BEAUTIFIL-Bulk Flowable	The same above	The same above	The same above	The same above	The same above	NA
Glasionomer FX ULTRA	The same above	The same above	The same above	The same above	The same above	NA

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

BEAUTIFIL II Enamel	The same above	The same above	The same above	The same above	The same above	NA
BEAUTIFIL II Gingiva	The same above	The same above	The same above	The same above	The same above	NA
BEAUTIFIL II LS	The same above	The same above	The same above	The same above	The same above	NA
SHOFU Universal Primer	The same above	The same above	The same above	The same above	The same above	NA
BeautiCem Veneer	The same above	The same above	The same above	The same above	The same above	NA
BEAUTIFIL Flow Plus X	The same above	The same above	The same above	The same above	The same above	NA
CERAMAGE	The same above	The same above	The same above	The same above	The same above	NA
LITE ART	The same above	The same above	The same above	The same above	The same above	NA
SHOFU Universal Opaque	The same above	The same above	The same above	The same above	The same above	NA
CERAMAGE UP	The same above	The same above	The same above	The same above	The same above	NA
SHOFU RESIN GLAZE	The same above	The same above	The same above	The same above	The same above	NA
VINTAGE PRIME PRESS	The same above	The same above	The same above	The same above	The same above	NA
VINTAGE ZR	The same above	The same above	The same above	The same above	The same above	NA
VINTAGE PRO	The same above	The same above	The same above	The same above	The same above	NA
VINTAGE Art Universal	The same above	The same above	The same above	The same above	The same above	NA
SHOFU DISK ZR Lucent/SHOFU DISK ZR Lucent Supra	The same above	The same above	The same above	The same above	The same above	NA
Veracia / Veracia SA	The same above	The same above	The same above	The same above	The same above	NA
SHOFU BLOCK HC HARD	The same above	The same above	The same above	The same above	The same above	NA
SHOFU BLOCK HC / SHOFU DISK HC	The same above	The same above	The same above	The same above	The same above	NA

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Glasionomer Cement CX-Plus	The same above	The same above	The same above	The same above	The same above	NA
SHOFU DIAMOND POINTS	The same above	The same above	The same above	The same above	The same above	ROBOT POINTS PRO-CUT
Dura-Green DIA	The same above	The same above	The same above	The same above	The same above	NA
SHOFU Vitrified Stones	The same above	The same above	The same above	The same above	The same above	NA
Super-Snap	The same above	The same above	The same above	The same above	The same above	NA
SHOFU Silicone Abrasives	The same above	The same above	The same above	The same above	The same above	NA
OneGloss	The same above	The same above	The same above	The same above	The same above	NA
CeraMaster / CompoMaster / ZiLMaster	The same above	The same above	The same above	The same above	The same above	NA

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Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
SI20240326	Minoru Hasegawa	minoru.hasegawa@tu	NA	2024-05-22	1 of 6

TÜV SÜD Product Service GmbH
Receipt of formal application

Reference: SI20240326

To whom it may concern,

Confirmation of the status of a formal application in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received **a formal application** in accordance with Section 4.3, first subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: JP-MF-000015205

The devices covered by the formal application mentioned above are identified in the Table below.

Please note that this letter only confirms the status of the formal application.
To benefit from the additional transitional provisions in the framework of Regulation EU 2023/607, TÜV SÜD Product Service GmbH and the manufacturer need to sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR latest until 26 September 2024.

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-05-22

TÜV SÜD Product Service GmbH
Medical and Health Services

Minoru Hasegawa 2024.05.22

Minoru Hasegawa
Conformity Assessment Responsible (CARE)

Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

Devices covered by the formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR

Device name or Basic UDI-DI (under MDR application)
Device 1 **Super-Snap** **Basic UDI-DI** **45481620087V**
Device 2 **Veracia / Veracia SA** **Basic UDI-DI** **45481620107G**
Device 3 **VINTAGE PRO** **Basic UDI-DI** **45481620117J**
Device 4 **CERARESIN BOND** **Basic UDI-DI** **45481620127L**
Device 5 **BEAUTIFIL II** **Basic UDI-DI** **45481620077T**
Device 6 **BEAUTIFIL Flow LM** **Basic UDI-DI** **454816204787**
Device 7 **FL-BOND III** **Basic UDI-DI** **454816204889**
Device 8 **BeautiLink SA** **Basic UDI-DI** **45481620498B**

Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

Device name or Basic UDI-DI (under MDR application)
Device 9 **BEAUTIFIL Flow Plus** **Basic UDI-DI** **45481620137N**
Device 10 **BeautiSealant** **Basic UDI-DI** **45481620157S**
Device 11 **BEAUTIFIL-Bulk Restorative** **Basic UDI-DI** **45481620167U**
Device 12 **BEAUTIFIL-Bulk Flowable** **Basic UDI-DI** **45481620177W**
Device 13 **Glasionomer FX ULTRA** **Basic UDI-DI** **45481620187Y**
Device 14 **BEAUTIFIL II Enamel** **Basic UDI-DI** **454816201982**
Device 15 **BEAUTIFIL II Gingiva** **Basic UDI-DI** **45481620207K**
Device 16 **BEAUTIFIL II LS** **Basic UDI-DI** **45481620217M**
Device 17

Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

Device name or Basic UDI-DI (under MDR application)
SHOFU Universal Primer **Basic UDI-DI** **45481620227P**
Device 18 **BeautiCem Veneer** **Basic UDI-DI** **45481620237R**
Device 19 **BEAUTIFIL Flow Plus X** **Basic UDI-DI** **45481620247T**
Device 20 **CERAMAGE** **Basic UDI-DI** **45481620257V**
Device 21 **LITE ART** **Basic UDI-DI** **45481620267X**
Device 22 **SHOFU Universal Opaque** **Basic UDI-DI** **45481620277Z**
Device 23 **CERAMAGE UP** **Basic UDI-DI** **454816202883**
Device 24 **SHOFU RESIN GLAZE** **Basic UDI-DI** **454816202985**
Device 25 **VINTAGE PRIME PRESS** **Basic UDI-DI**

Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

Device name or Basic UDI-DI (under MDR application)
45481620307N
Device 26 VINTAGE ZR Basic UDI-DI 45481620317Q
Device 27 VINTAGE Art Universal Basic UDI-DI 45481620327S
Device 28 SHOFU DISK ZR Lucent / SHOFU DISK ZR Lucent Supra Basic UDI-DI 45481620337U
Device 29 SHOFU BLOCK HC HARD Basic UDI-DI 45481620347W
Device 30 SHOFU BLOCK HC / SHOFU DISK HC Basic UDI-DI 45481620357Y
Device 31 Glasionomer Cement CX-Plus Basic UDI-DI 454816203682
Device 32 ROBOT POINTS PRO-CUT Basic UDI-DI 454816204583
Device 33 Dura-Green DIA Basic UDI-DI 454816203988
Device 34 SHOFU Vitrified Stones(Dura-Green Stones / Dura-White Stones / SHOFU Composite Finishing Kit)

Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

Device name or Basic UDI-DI (under MDR application)
Basic UDI-DI **45481620407R**
Device 35 **SHOFU Silicone Abrasives** **(Brownie / Greenie / Supergreenie / Ceramiste / Composite / SHOFU Amalgam Polishing Kit / SHOFU Porcelain Laminate Polishing Kit)** **Basic UDI-DI** **45481620417T**
Device 36 **OneGloss** **Basic UDI-DI** **45481620427V**
Device 37 **Master Polisher** **(CeraMaster / CompoMaster / ZiLMaster)** **Basic UDI-DI** **45481620437X**