Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 101021 0003 Rev. 01

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

Product Category(ies): **Dental Cement, Artificial Teeth, Dental Composite Restorative Materials, Dental Rotary Instruments, Dental Rotary Instrument Kits, Dental Materials for Crowns and Bridges, Dental Adhesives for CAD/CAM Hybrid Ceramic Restorations**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: **JN1420928**

Valid from: **2020-04-24**
Valid until: **2024-03-29**

Date, **2020-04-24**

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 101021 0003 Rev. 01

-/-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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.

SHOFU INC.
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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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Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

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

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
101021	JN200350003794	medical_devices@tuvsud.com		2024-06-26	1 of 9

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 101021 0005 Rev. 00

Reference: JN200350003794

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance 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 and has signed a written agreement in accordance with Section 4.3, second 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 and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 101021 0005 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-06-26

TÜV SÜD Product Service GmbH
Medical and Health Services

Hasegawa, Minoru
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Clara Höhneke
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 Super-Snap Basic UDI-DI 45481620087V	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 10102 1 0003 Rev.01; NB#0123
Device 2 Veracia / Veracia SA Basic UDI-DI 45481620107G	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 3 VINTAGE PRO Basic UDI-DI 45481620117J	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 4 CERARESIN BOND Basic UDI-DI 45481620127L	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 5 BEAUTIFIL II Basic UDI-DI 45481620077T	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 6 BEAUTIFIL Flow LM Basic UDI-DI 454816204787	☒ Class IIa	☒ Identification of the corresponding device under MDD/AIMDD BEAUTIFIL OPAQUERIndividual Article number: 1363, 1364 BEAUTIFIL FLOW Individual Article number: 1431,1432,1433,1434,1435, 1449,1451,1461,1462,1463, 1464,1465,1479,1482	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 7 FL-BOND III Basic UDI-DI 454816204889	☒ Class IIa	☒ Identification of the corresponding device under MDD/AIMDD FL-BOND II Individual Article number: 1306, 1307, 1308, 1309	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 8 BeautiLink SA	☒ Class IIa	☒ Identification of the corresponding device under MDD/AIMDD ResiCem	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI 45481620498B		Individual Article number: 3220, 3221, 3222, 3224, 3227, 3228 BeautiCem SA Individual Article number: 3213, 3214, 3215, 3216, 3217, 3218	
Device 9 BEAUTIFIL Flow Plus Basic UDI-DI 45481620137N	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 10 BeautiSealant Basic UDI-DI 45481620157S	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 11 BEAUTIFIL-Bulk Restorative Basic UDI-DI 45481620167U	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 12 BEAUTIFIL-Bulk Flowable Basic UDI-DI 45481620177W	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 13 GlasIonomer FX ULTRA Basic UDI-DI 45481620187Y	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 14 BEAUTIFIL II Enamel Basic UDI-DI 454816201982	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 15 BEAUTIFIL II Gingiva Basic UDI-DI 45481620207K	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 16 BEAUTIFIL II LS Basic UDI-DI 45481620217M	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 17 SHOFU Universal Primer Basic UDI-DI 45481620227P	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 18 BeautiCem Veneer Basic UDI-DI 45481620237R	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 19 BEAUTIFIL Flow Plus X Basic UDI-DI 45481620247T	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 20 CERAMAGE Basic UDI-DI 45481620257V	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 21 LITE ART Basic UDI-DI 45481620267X	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 22 SHOFU Universal Opaque Basic UDI-DI 45481620277Z	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 23 CERAMAGE UP Basic UDI-DI 454816202883	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 24 SHOFU RESIN GLAZE Basic UDI-DI 454816202985	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 25 VINTAGE PRIME PRESS Basic UDI-DI 45481620307N	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 26 VINTAGE ZR	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI 45481620317Q			
Device 27 VINTAGE Art Universal Basic UDI-DI 45481620327S	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 28 SHOFU DISK ZR Lucent / SHOFU DISK ZR Lucent Supra Basic UDI-DI 45481620337U	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 29 SHOFU BLOCK HC HARD Basic UDI-DI 45481620347W	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 30 SHOFU BLOCK HC / SHOFU DISK HC Basic UDI-DI 45481620357Y	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 31 GlasIonomer Cement CX-Plus Basic UDI-DI 454816203682	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 32 ROBOT POINTS PRO-CUT Basic UDI-DI 454816204583	☒ Class IIa	☒ Identification of the corresponding device under MDD/AIMDD SHOFU DIAMOND POINTS Individual Article number: , 0688, 07891, 07901, 07911, 07921, 07931, 08001, 08011, 08031, 08051, 08071, 08101, 08121, 08131, 08141, 08161, 08181, 08201, 08221, 08241, 08251, 08261, 08301, 08311, 08321, 08331, 08341, 08351, 08361, 08371, 08381, 08391, 08401, 08421, 08441, 08461, 08481, 08501, 08521, 08551, 08561, 08581, 08591, 08601, 08611, 08641, 08651, 08661, 08681, 08701, 08721, 08741, 08751, 08761, 08781, 08791,	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
		08801, 08811, 08821, 08831, 08851, 08861, 08881, 08901, 08911, 08921, 08931, 08941, 08951, 08961, 08971, 08981, 08991, 0900, 09011, 09031, 09051, 09071, 09091, 09111, 09131, 09151, 09171, 09191, 09211, 09231, 09251, 09271, 09291, 09311, 09331, 09351, 09371, 09391, 09411, 09431, 09441, 09451, 09461, 09471, 09481, 09491, 0950, 0955, 0956, 680C1, 680F1, 682C1, 682F1, 682S1, 684C1, 684F1, 684S1, 686C1, 686F1, 789V1, 790V1, 791V1, 792V1, 793V1, 808V1, 817C1, 820F1, 825V1, 826V1, 832F1, 832X1, 833V1, 835C1, 835F1, 835X1, 836V1, 839V1, 840C1, 840F1, 840V1, 840X1, 841V1, 842F1, 843V1, 845C1, 845X1, 846F1, 847F1, 848F1, 850F1, 850X1, 874V1, 875F1, 876X1, 880V1, 882V1, 883C1, 883F1, 883V1, 883X1, 889V1, 892X1, 893V1, 895C1, 895X1, 898X1, 899V1, C0611, C0621, C0631, C0811, C0821, C0831, C0841, C0851, C1011, C1021, C1031, C200, 0789-1, 0790-1, 0791-1, 0792-1, 0793-1, 0800-1, 0801-1, 0803-1, 0805-1, 0807-1, 0810-1, 0812-1, 0813-1, 0814-1, 0816-1, 0818-1, 0820-1, 0822-1, 0824-1, 0825-1, 0826-1, 0830-1, 0831-1, 0832-1, 0833-1, 0834-1, 0835-1, 0836-1, 0837-1, 0838-1, 0839-1, 0840-1, 0842-1, 0844-1, 0846-1, 0848-1, 0850-1, 0852-1, 0855-1, 0856-1, 0858-1, 0859-1, 0860-1, 0861-1, 0864-1, 0865-1,, 0866-1, 0868-1, 0870-1, 0872-1, 0874-1, 0875-1, 0876-1, 0878-1, 0879-1, 0880-1, 0881-1, 0882-1, 0883-1, 0885-1, 0886-1, 0888-1, 0890-1, 0891-1, 0892-1,	

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
		0893-1, 0894-1, 0895-1, 0896-1, 0897-1, 0898-1, 0899-1, 0901-1, 0903-1, 0905-1, 0907-1, 0909-1, 0911-1, 0913-1, 0915-1, 0917-1, 0919-1, 0921-1, 0923-1, 0925-1, 0927-1, 0929-1, , 931-1, 0933-1, 0935-1, 0937-1, 0939-1, 0941-1, 0943-1, 0944-1, 0945-1, 0946-1, 0947-1, 0948-1, 0949-1, 680C-1, 680F-1, 682C-1, 682F-1, 682S-1, 684C-1, 684F-1, 684S-1, 686C-1, 686F-1, 789V-1, 790V-1, 791V-1, 792V-1, 793V-1, 808V-1, 817C-1, 820F-1, 825V-1, 826V-1, 832F-1, 832X-1, 833V-1, 835C-1, 835F-1, 835X-1, 836V-1, 839V-1, 840C-1, 840F-1, 840V-1, 840X-1, 841V-1, 842F-1, 843V-1, 845C-1, 845X-1, 846F-1, 847F-1, 848F-1, 850F-1, 850X-1, 874V-1, 875F-1, 876X-1, 880V-1, 882V-1, 883C-1, 883F-1, 883V-1, 883X-1, 889V-1, 892X-1, 893V-1, 895C-1, 895X-1, 898X-1, 899V-1, C061-1, C062-1, C063-1, C081-1, C082-1, C083-1, C084-1, C085-1, C101-1, C102-1, C103-1	
Device 33 Dura-Green DIA Basic UDI-DI 454816203988	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 34 SHOFU Vitrified Stones (Dura-Green Stones / Dura-White Stones / SHOFU Composite Finishing Kit) Basic UDI-DI 45481620407R	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 101021 0003 Rev.01; NB#0123
Device 35 SHOFU Silicone Abrasives **(**Brownie / Greenie / Supergreenie / Ceramiste / Composite / SHOFU Amalgam Polishing Kit /	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 1010210003 Rev.01; NB#0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
SHOFU Porcelain Laminate Polishing Kit) Basic UDI-DI 45481620417T			
Device 36 OneGloss Basic UDI-DI 45481620427V	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 1010210003 Rev.01; NB#0123
Device 37 Master Polisher (CeraMaster / CompoMaster / ZiLMaster) Basic UDI-DI 45481620437X	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #G1 1010210003 Rev.01; NB#0123

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified during application review)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
☒ N/A	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	**TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter**	**Action**
2024-06-26	JN200350003794	Initial issue