



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



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