



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 001231 0007 Rev. 00

Manufacturer:

YAMAKIN CO., LTD.

1090-3 Otani, Kamibun, Kagami-cho
Konan-shi, Kochi
781-5451 JAPAN

SRN Manufacturer - JP-MF-000011382

Authorized Representative:

MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7, 66386 St. Ingbert, 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_001231_0007_Rev._00

Report No.:

JN66871072

Valid from:

2024-02-20

Valid until:

2029-02-19

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-02-20



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlg.de
 BS-MDR-099



Product Service

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Classification: Class IIa
Device Group: Q010299 - PROSTHETIC DENTISTRY DEVICES - OTHER
Intended Purpose: -

Classification: Class 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-

Revision History:

Rev.	Dated	Report	Description
00	2024-02-20	JN66871072	Initial issuance