

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2094592-1

Certificate Holder: Kuraray Noritake Dental Inc.
1621 Sakazu, Kurashiki
Okayama
710-0801 Japan

Scope: Design and Development, Manufacture and Distribution of Dental cementing and bonding materials, Dental filling materials, Core build up materials, Pit and Fissure sealant materials, Tooth crown and bridge materials, Dental glazing materials, Denture base materials, Root canal post, Syringe for restorative materials, Caries detection materials and Desensitizers

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150296016-301

Effective date: 2024-11-04

Expiry date: 2027-11-03

Issue date: 2024-10-30

Replaces certificate SX 2094592-1 issued 2022-06-17

Furukawa Ryo

Ryo Furukawa

TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on <https://www.certipedia.com>

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Kuraray Noritake Dental Inc. Kurashiki Plant 1621 Sakazu, Kurashiki Okayama 710-0801 Japan	Activities related to communication process
/02	c/o Kuraray Noritake Dental Inc. Tokyo Office Tokiwabashi Tower, 2-6-4 Otemachi, Chiyoda-ku, Tokyo 100-0004 Japan	Aspects related to Design and Development, Distribution and Administration and activities related to management, quality assurance and regulatory affairs Aspect related to Distribution of Tooth crown materials including Dental alloys and Dental cement of Miyoshi Plant
/03	c/o Kuraray Noritake Dental Inc. Osaka Office Osaka Umeda Twin Towers North 8-1 Kakudacho Kita-ku, Osaka 530-0017 Japan	Aspect related to Distribution
/04	c/o Kuraray Noritake Dental Inc., Niigata Plant 2-28 Kurashiki-cho, Tainai, Niigata 959-2653 Japan	Aspect related to Design and Development, and Manufacture

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