EC Certificate Full Quality Assurance System: Certificate JP19/040508

The management system of

Tokuyama Dental Corporation

Head Office 38-9, Taitou 1-chome, Taitou-ku, Tokyo 110-0016 Japan

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 01 December 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 10 July 2012
and first certified by SGS Belgium NV since 31 October 2019

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered JP/YOK 8787

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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Tokuyama Dental Corporation

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 2

Detailed scope

Dental composite restorative materials, dental adhesives, dental cements, dental sealants

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

Kashima Factory **26 Sunayama, Kamisu-shi, Ibaraki, 314-0255 Japan**