

DECLARATION OF CONFORMANCE

Manufacturer: Tokuyama Dental Corporation
Address: 38-9, Taitou 1-Chome, Taitou-Ku, Tokyo 110-0016, Japan

European representative: Tokuyama Dental Italy S.r.l.
Address: Via Chizzalunga, 1, 36066 Sandrigo, Vicenza, Italy

Product name: OMNICHROMA
, including the following 2 products.
OMNICHROMA SYRINGE
OMNICHROMA PLT

Reference No.: OC01

Classification (MDD, Annex IX): Class IIa (Rule 8)

First Shipment Date: 5 November, 2019
First lot Number: see attached sheet 1

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

DIRECTIVES and REGULATION

General applicable directive and regulation:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC as amended by 2007/47/EC

Regulation concerning the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH), 1907/2006/EC

Standards: see attached sheet 2

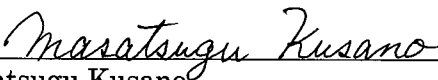
Notified Body: Notified Body Number 1639
SGS Belgium NV

Address: SGS House Noorderlaan 87 2030 Antwerp Belgium
Certificate: JP19/040508 (Annex II (excluding Section 4) MDD)

Place: 38-9, Taitou 1-Chome, Taitou-Ku, Tokyo 110-0016, Japan

Date: 1 April 2022

Signature



Masatsugu Kusano
Factory Manager

First lot number for refill:

Article	First lot number in EU market	First shipment date	Article number	
			Importer	
			Tokuyama Dental Italy S.r.l.	Tokuyama Dental Deutschland GmbH
OMNICHROMA SYRINGE	017EY9, 021EY9	5 November 2019	10110	10112
OMNICHROMA TRIAL SYRINGE	020EZ1	20 December 2021	10142	10143
OMNICHROMA PLT	009EY9, 019EY9	5 November 2019	10120	10122
OMNICHROMA PLT TRIAL KIT	002E12	3 February 2022	10152	10153

Standards applied to this product are listed below.

Standard	Published year
EN ISO 10993-1	2009
EN ISO 10993-3	2014
EN ISO 10993-5	2009
ISO 10993-10	2010
EN ISO 10993-11	2018
EN ISO 10993-12	2012
EN ISO 10993-18	2020
ISO 7405	2008
EN ISO 13485	2016
EN ISO 14971	2012
EN 1041	2008
EN 1641	2009
EN ISO 15223-1	2021
ISO 4049	2019