

## EU declaration of conformity

Manufacturer:

Tokuyama Dental Corporation

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

Single registration number (SRN):

Not applicable. Requirements concerning SRN are not applied at this time pursuant to Article 123(3) of Regulation (EU) 2017/745 as amended by Regulation (EU) 2020/561.

Authorised representative:

Tokuyama Dental Italy S.r.l.

Via Chizzalunga, 1, 36066 Sandrigo, Vicenza, Italy

We herewith declare that the EU declaration of conformity is issued for the following product under our sole responsibility.

Product name:

SOFRELINER

, including the following products.

SOFRELINER TOUGH M

SOFRELINER TOUGH S

Reference number: SR02

Basic UDI-DI:

Not applicable. Requirements concerning Basic UDI-DI are not applied at this time pursuant to Article 123(3) of Regulation (EU) 2017/745 as amended by Regulation (EU) 2020/561.

Article number: See Attached sheet 1.

Classification (according to the classification rule in Annex VIII of MDR): Class I (Rule 5)

Common specifications (CS):

There is no CS which has been used or referred to declare conformity of the product.

### DIRECTIVES and REGULATION

General applicable directive and regulation:

Regulation (EU) 2017/745 on medical devices

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

Place of issue of the declaration: 38-9, Taitou 1-Chome, Taitou-Ku, Tokyo 110-0016, Japan



Masatsugu Kusano / Factory Manager

Name / function

19 May 2021

Date

Attached sheet 1

Article number		Article
Importer		
Tokuyama Dental Italy S.r.l.	Tokuyama Dental Deutschland GmbH	
23350	23352	Sofreliner Tough M Kit
23355	23357	Sofreliner Tough M Paste
23440	23442	Sofreliner Tough Primer
23400	23402	Sofreliner Tough S Kit
23410	23412	Sofreliner Tough S Paste
23380	23380	TD II Mixing Tip XS
23381	23381	TD II Mixing Tip S