



Thermoplastic Comfort Systems, Inc.

TITLE: Declaration of Conformity (TR) - TCS Dental Resins - MDR

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Declaration of Conformity

Manufacturer:

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Manufacturing Facility:

Thermoplastic Comfort Systems, Inc.
2619 Lime Ave.
Signal Hill, CA 90755 USA

Thermoplastic Comfort Systems, Inc
647 E. Willow Street
Signal Hill, CA 90755 USA



Thermoplastic Comfort Systems, Inc.

Incorporated January 18, 2002
California, USA

Product Model No.:

(See attachment for catalog numbers and description)

Basic UDI-DI:

++D805TCSRESINSS8

Product Model Description:

TCS Dental Resins

Classification:

Class I per Annex VIII of the Medical Device Regulation (EU)
2017/745 (Non-sterile, Non-measuring)

Conformity Assessment Route:

Annex II and III of the Medical Device Regulation (EU)
2017/745

This EU Declaration of Conformity is issued under the sole responsibility of Thermoplastics Comfort Systems, Inc.

I, the undersigned, hereby declare and authorize to certify that the Medical Device(s) specified above meets the provisions of Medical Device Regulation (EU) 2017/745 which apply to them. All supporting documentation is retained at the premises of the manufacturer.

Place: Signal Hill, CA USA

Date: 12/12/2024

Name: Marilyn Posca
President, Thermoplastic Comfort
Systems, Inc.

Signature:

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