



NSAI

Quality System Approval Certificate

Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated
Notified Body, (identification number 0050), for the purposes of the European Communities
(Medical Devices) Regulations (S.I. No. 252 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Thermoplastic Comfort Systems

2619 Lime Ave
Signal Hill
CA 90755
USA

to the Product Family

**Denture based resins, thermoplastic (Tradenames: TCS
Unbreakable, IFlex by TCS, Karadent by TCS)**

GMDN Code: 58288

*on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices Annex V.
The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of
Conformance for this product family is hereby authorised.*

Registration Number:	252.995
Original Approval:	17 May 2016
Last Amended on:	23 July 2019
Remains valid until:	16 November 2019

Signed:

Approved by:
Geraldine Larkin
Chief Executive Officer, NSAI

Approved by:
Elaine Darcy
European Medical Device Operations Manager

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI
National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.**