



# 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.*

<b>Registration Number:</b>	<b>252.995</b>
<b>Original Approval:</b>	<b>17 May 2016</b>
<b>Last Amended on:</b>	<b>24 September 2019</b>
<b>Remains valid until:</b>	<b>16 May 2024</b>

**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.**