



# NSAI

## Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

**Thermoplastic Comfort System, Inc.**  
**2619 Lime Avenue**  
**Signal Hill, CA 90755**  
**USA**

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

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**The manufacture and distribution of dental resins, dental equipment and dental accessories for use in dental laboratories for the fabrication of removable dental appliances. The manufacture and distribution of dental cleansers for removable dental appliances.**

**Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.8020)**

Approved by:  
Geraldine Larkin  
Chief Executive Officer

Approved by:  
Susan Murphy  
European Medical Device  
Operations Manager

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Registration Number: MD19.8020  
Certification Granted: Sep 20, 2016  
Effective Date: Sep 16, 2018  
Expiry Date: Sep 15, 2021



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National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800



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## Annex to Certificate Number: MD19.8020

### Scope of Registration:

The manufacture and distribution of dental resins, dental equipment and dental accessories for use in dental laboratories for the fabrication of removable dental appliances. The manufacture and distribution of dental cleansers for removable dental appliances.

### Activity

### Location

Administration, Manufacturing,  
Distribution

Thermoplastic Comfort System, Inc.  
2619 Lime Avenue  
Signal Hill, CA 90755  
USA  
File No.: MD19.8020

Distribution

Thermoplastic Comfort System, Inc.  
2035 W. Wardlow Road  
Long Beach, CA 90810  
USA  
File No.: MD19.8020/A

**Verified by:**  
**Operations Manager**