



## Declaration of Conformity

Manufacturer: *Thermoplastic Comfort System, Inc.*  
2619 Lime Ave.  
Signal Hill, CA 90755  
Telephone 562-426-2970 or 866-426-2970  
Fax 562-426-5154

Authorized EC Representative MDSS GmbH  
Schiffgraben 41  
30175 Hannover  
Germany  
Telephone:  
Tel. (+49-511-6262 8630)  
FAX (+49) -511-6262 8633

Manufacturing Facility: Manufacturing Site: same as above

Product Model No. (see attachment for model descriptions)

Conformity Assessment Route: Annex V of the Directive 93/42/EEC  
as amended by 2007/47/EC

Rule and Risk Classification: Rule 5, Class IIa

I, the undersigned, hereby declare and authorize to certify that the Medical Device(s) specified above meets the provisions of Directive 93/42/EEC (MDD) as amended by 2007/47/EC which apply to them, as transposed into the national laws of the EU member states. In addition, we declare that our product meets the provisions as laid out under Annex I of the Essential Requirements as required under the same directive.

Notified Body Name and Address: National Standards Authority of Ireland  
1 Swift Square  
Northwood, Santry  
Dublin 9, Ireland DOP A0E4

Notified Body EC Notification No.: 0050

This declaration is supported by the MDD, Annex V Certificate (Registration Number 252.995) issued by NSAI-Notified Body number 0050 on 17 May 2016.

Place: Signal Hill, CA USA

Date: 9.29.2020

Name: Marilyn Posca

Signature: 