



# Certificate of Verification

MDSS GmbH hereby declares

that an Authorized Representative's Mandate according to the EU Regulation 2017/745 (MDR) is in place and that the following tasks have been carried out in accordance with the requirements of the MDR on behalf of the Manufacturer:

**Thermoplastic Comfort Systems, Inc.**

**2619 Lime Avenue  
Signal Hill, CA 90755  
USA**

MDSS verified that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

MDSS keeps available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities for the period referred to in Article 10(8);

MDSS complied with the registration obligations laid down in Article 123.3(d) and until Eudamed is fully functional, the corresponding provisions of Directives 90/385/EEC and/or 93/42/EEC have been applied.

Details of the device(s) covered by the Certificate are listed hereafter.

Issued: 2024-02-29  
(YYYY-MM-DD)

This Certificate is valid without signature. The document can be traced within MDSS' electronic system.

Certificate No.: 734577

This certificate is subject to the following terms and conditions:

It is only valid for the device(s) listed hereafter;

It is not a proof for compliance to CE marking;

The Manufacturer shall inform MDSS of any significant change(s) to the device(s) listed hereafter and MDSS will verify the change(s) and determine if a renewed certificate has to be issued;

As in accordance with the Directive 85/374/EEC Art. 1, the producer is liable for damages caused by a defect in his product(s). The Manufacturer in addition confirms that the requirements of Art. 10.16 of the MDR are fulfilled.

This Certificate of Verification is valid for 5 years or until expiry of the EU Declaration of Conformity or NB Certificate if applicable, whichever comes first.

Technical File	Generic Device Description/ Trade Name	GMDN or EMDN Code	Risk Class	EU Declaration of Conformity	NB Identification No. / NB Certificate No.	NB Cert. valid until YYYY-MM-DD	BfArM Registration Number*
Technical File for TCS Concentrated Dental Appliance Cleaner_ TF040317 Rev F	TCS Concentrated Dental Appliance Cleaner	35871	I	DOC-CE040317 Rev. D_Effective Signed on 2021-07-21	N/A	N/A	DE/CA09/00199298
TF-TCS Dental Resins – MDR	TCS Dental Resins	58288	I	DOC-CE/MDR Rev. NEW Signed on 10-31-2023	N/A	N/A	DE/CA09/00199293

\*The registration number has been issued by the German Competent Authority.