



cactus dental technology

### **CDT 1.2.1 Declaration of Conformity**

This DAMAS Compliance System Manual specifies the Medical Device Regulation and DAMAS Quality Policy and objectives of:

**Cactus Dental Technology Limited, Lockhart House, Tulloch Street, Dingwall, IV15 9JY**

It has been complied to document and allow an understanding of how we manufacture custom made dental appliances in compliance with the Medical Device Regulation (MDR) and the Dental Appliance Manufacturers Audit Scheme (DAMAS) and to ensure that these custom-made dental appliances will conform with the relevant essential requirements of the MDR and the specified requirements of DAMAS.

The documented procedures described within are mandatory.

This manual is issued with my approval and all personnel working within this laboratory are directed to operate according to procedures defined within.

This document supersedes all previous issues of the MDT and DAMAS compliance system manual.

Sally Fraser has been named as the person responsible for regulatory compliance within Cactus Dental Technology Limited.

**Issued and approved by:**

**John Hewitt**  
**Manging Director**

**References:**

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements of the DAMAS Management System Specification.
- The Dental Laboratory Association Ltd – Dental Appliance Manufacturers Audit Scheme (DAMAS) Management System Specification.