



European Office of Crafts, Trades and Small and Medium-sized Enterprises for Standardisation  
Bureau Européen de l'Artisanat et des Petites et Moyennes Entreprises pour la Normalisation  
Europäisches Büro des Handwerks und der Klein- und Mittelbetriebe für die Normung

## EUROPEAN DENTAL ASSOCIATION PROPOSES NEWLY DEVELOPED ISO 9001 BASED QUALITY MANUAL FOR DENTAL LABS ACROSS EUROPE.

The UK Dental Laboratories Association ISO 9001 based Quality Management System offers full Patient Protection and meets the European Directive Regulations on medical devices.

The European Dental Association FEPPD with its UK member “Dental Laboratories Association” (DLA) has produced a simplified ISO 9001 Quality Manual. The sector specific DAMAS management and production system (Dental Appliance Manufacturers Audit Scheme, today used in 55 dental labs with 150 dental labs preparing for use) has been further developed to create a generic system that can be applied to all custom made devices that can be applied to dental prosthodontics, orthodontics, but also hearing aid inserts, prescribed orthopaedic footwear, ocular prostheses, external orthoses and prostheses, joint replacement implants. Customer care and satisfaction are naturally a prime concern in this field.

The simple guide takes the lab employee through each of the phases of the production process, but it also covers incoming material control, specifications and all the other aspects to be taken into account in a proper Quality Management system. It achieves prescriber satisfaction by preventing non-conformity at all stages of custom-made medical device manufacture.

By implementing the methodology, an organization can demonstrate that they can manufacture custom-made medical devices in compliance with the European Union Medical Devices Directive - Council Directive 93/42/EEC of 14 June 1993. This Manual can be used by dental laboratories but also by Certification Bodies as a way to assess the organisation's ability to meet customer and regulatory requirements.

Using the Manual is sufficient to make a lab comply with the Directive and other regulatory requirements which is very important for the labs with typically few employees. Equally important is that the quality requirements of the Manual are ISO 9001 level, guaranteeing the patient full satisfaction and protection.

The proposal was presented to FEPPD European Members in the September 2002 Forum on the Future. The aim of the Association was to try to adapt one single European standard for the sector which guarantees use in a harmonized way across Europe, so that one lab in one country can supply a lab in another country without breaking the MDD regulations valid in that country. That would take away a major barrier for such Small Enterprises and meets the European Commission aim of free trade across borders.

FEPPD has been paving the way ahead with their work on occupational standards, where they are actively working on the implementation across Europe and this Laboratory Quality Management Standard is a further step towards the goal of European uniformity across the countries. They do realise that still local regulations and laws on health and safety, employment, training, etc. exist and prevail in this area, where the personal wellbeing and health aspects are so important. But while they consider these present aspects important and to be considered on a country by country basis, their focus is on the future where these important issues can be taken care of by European harmonisation as discussed in this summary above.

Adoption of the Standard leads to the issue of a Certificate of Conformity, whereby the Laboratory concerned declares that – by using the Standard – they achieve and guarantee conformity with the provisions of Council Directive 93/42/EEC 14th June 1993 Concerning Medical Devices giving their product a European-wide recognisable Quality Certification level.