# CEN/TC 55/WG 7 N 217

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## CEN/TC 55/WG 7 Steering Committee

**Notes of the meeting of Project Leaders held in Berlin on 21 May 2008**

1. The meeting was attended by Dr P Jacobsen, Mr J Nille, Prof K Dermann and Dr H-P Keller with the CEN Consultant Dr R Virefleau present.

2. The meeting was convened to consider the implications of the revision of the Medical Devices Directive (MDD) on the four harmonised dental standards EN 1639-42.

3. Documents had been issued by the CEN Technical Board providing advice to TC's on how to approach the changes and giving the timetable for action. TC 55 had already agreed to revise the four harmonised standards. Other documents had been prepared highlighting the changes in the MDD and comparing changes with the current MDD. There were also considerations in respect of the relationship of medical devices with the Machinery Directive and the Personal Protective Equipment Directive.

4. It was announced that the Commission intended to merge all three MDD's into a single document and was inviting public comment on this proposal. It was likely that this change would take several years.

5. The meeting agreed a strategy to be applied to all four standards, particularly with reference to the Annexes ZA:

   Normative references would remain undated
   Changes to the labelling clauses as suggested by BT
   User instructions to be dated and permitted to be published electronically
   Clinical evaluation to be required for all devices. Noted that "evaluation" did not mean "investigation".
   Clarification of "single use".
   Reference to phthalates and other biological hazards

6. Revision of EN 1641 materials would include orthodontic materials.

7. Each of the standards was edited in turn and new Annexes ZA were drafted.

8. The four standards would be completed by the three project leaders, (Mr J Nille, Prof K Dermann, Dr P Jacobsen), and circulated to the WG for finalisation at the next meeting in June.

Respectfully submitted

Peter Jacobsen

Convenor CEN/TC 55/WG 7