5. Austria

	G4 Comment
Excerpt from the Austrian proposals of 7 June 2004 for the revision of Directive 93/42/EEC	The comments from Austria reflected the CETF comments and were agreed in full and hence are not reproduced here. Two issues not put forward from the Austrian proposal are commented upon here.

The following proposals to Annex I try to strengthen the clinicals, esp. the clinical benefits and the favourable risk/benefit-ratio, in the Essential Requirements and are intended to underpin the proposals of the CETF.

Annex I			**G4 Comment**
To strengthen the clinical benefits in the ER, where applicable	Annex I.I.3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.	Annex I.I.3. The devices must be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer and must achieve the safety, quality, performance and, where applicable, effectiveness according to the state of the art.	This overlaps with other sections of Annex I, I were state of the art, performance and safety are already mentioned. The terms 'effectiveness' and 'quality' (of devices) would be new concepts to the directive and would require further discussion.

Annex I			**G4 Comment**
To stress the importance of a favourable risk/benefit-ratio	Annex I.I.6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.	Annex I.I.6 Any side-effects and residual risks must constitute a favourable risk/benefit-ratio according to the state of the art when weighed against the performances achieved.	Agree, with the exception of the term 'state of the art' and we believe that the concept is contained within the current text.