

Decision No. 16/2002

**of the Joint Committee established under the Agreement on Mutual Recognition
between the European Community and the United States of America**

on amending the Sectoral Annex for Medical Devices

THE JOINT COMMITTEE

Having regard to the Agreement on Mutual Recognition between the European Community and the United States of America and in particular Articles 14(4)(b) thereof;

Whereas, pursuant to Article 21(2), any Sectoral Annex may, through the Joint Committee, be amended in writing by the Parties;

Noting, on the one hand, the progress that has been made in carrying out the confidence building activities provided for by the Sectoral Annex on Medical Devices;

Recognising, on the other hand, that as more time is necessary to finalise remaining confidence building activities, the transition period must be extended.

HAS DECIDED AS FOLLOWS

1. The Sectoral Annex on Medical Devices is amended according to the following:

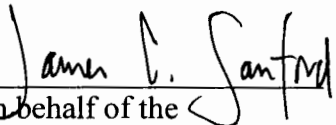
- (a) The first sentence of Article 5 of the Sectoral Annex on Medical Devices is deleted in its entirety and replaced with the following:

“There shall be a five year transition period immediately following the date of entry into force of the Agreement. Based on progress made during the transition period, and in particular when the Parties consider that a representative number of Conformity Assessment Bodies are listed in Appendix 5, according to Article 9, the Joint Committee may decide to end the transition period and proceed to the operational period.”

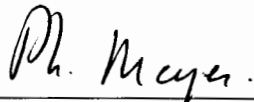
- (b) The first sentence of Article 9 of the Sectoral Annex on Medical Devices is deleted in its entirety and replaced with the following:

“Prior to the start of the operational period, the Parties shall proceed to a joint assessment of the equivalence of the CABs that participated in the confidence building activities.”

This Decision, done in duplicate, shall be signed by representatives of the Joint Committee who are authorised to act on behalf of the Parties for purposes of amending the Agreement. This Decision shall be effective from the date of the later of these signatures.


On behalf of the
United States of America
Signed in Washington D.C. on

APR - 4 2002


On behalf of the
European Community
Signed in Brussels on

16 April 2002