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EXTRACT
from the
DRAFT SUMMARY RECORD
of the 1412th meeting of the PERMANENT REPRESENTATIVES COMMITTEE
held in Brussels on Friday 15 December 1989

Subject: AMENDED PROPOSAL FOR A COUNCIL DIRECTIVE ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO ACTIVE IMPLANTABLE ELECTROMEDICAL EQUIPMENT
AMENDED PROPOSAL FOR A COUNCIL DIRECTIVE ON THE APPROXIMATION OF THE LAWS OF THE
MEMBER STATES RELATING TO ACTIVE IMPLANTABLE ELECTROMEDICAL EQUIPMENT
8389/89 ECO 123, 10617/89 ECO 217 and 10618/89 ECO 218

The main conclusions reached by the Committee are set out in 10957/89.

The GR delegation submitted two specific requests relating to devices manufactured to order, namely that

- such devices should also carry the CE mark;

- the manufacturer should make the declaration referred to in Annex 5 before placing such devices on the market.

These two requests were not, however, supported by the other delegations and the Commission said it was unable to accept them.