

DECISION BT 41/2015

Subject: Harmonization of Annexes ZA required for publishing references of Harmonized Standards in the OJEU - Implications for Medical Devices

BT,

- having noted
 - the proposal of the Commission regarding implications for the Annex ZA/ZZ of Harmonized Standards resulting from the implementation of the New Legislative Framework (NLF) in the revised/recast New Approach Directives (see the EC letter dated 2015-05-29 in BT N 10072);
 - that acceptance of such provisions would have implications for the drafting of Annexes ZA in the field of Medical Devices;
 - Decision BT C34/2015 'Medical Harmonized Standards – Proposal for an Annex ZA format and for a practice of dating normative references';
 - that DG GROW.D.4 'Health Technology and Cosmetics' stated that the new Annex ZA template, if adopted by BT, would be acceptable to them, provided the four Notes adopted through BT C34/2015 are kept;
- adopts the Annex ZA templates for the three Medical Devices Directives as presented in Annexes 1, 2 and 3 to BT N 10135;
- agrees to immediately start applying the templates for new drafts;
- decides to allow TCs to replace the current lay out of Annex ZA/ZZ for those drafts currently under FV with the new one after the FV;
- asks CCMC to instruct all relevant CEN/TCs to use those templates when developing Harmonized Standards in support of a Medical Devices Directive.