Flow chart for the conformity assessment procedures provided for in Directive 90/385/EEC on active implantable medical devices Manufacturer's declaration No CE (Annex 6) marking + technical file Custom made devices and devices for clinical investigations Type of product MANUFACTURER EC declaration of conformity (complete quality assurance system + product design file (Annex 2)) NB issues an EC design examination certificate (Annex 2, para. 4) NB assesses and monitors the All other manufacturer's quality system EC declaration of conformity devices MODULE Hbis (*) to type (production quality Manuassurance (Annex 5)) facturer's NB assesses and monitors the choice manufacturer's quality system MODULE D (*) EC type-examination Manu-(Annex 3) facturer's choice MODULE B (*) EC verification (Annex 4) NB verifies and certifies that products conform to the type MODULE F (*)

These procedures were approved before the adoption of Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.

Zdroj: Príloha č.8 príručky pre implementáciu smerníc nového prístupu a globálneho prístupu

Diagramy sú upravené.

nnnn je číslo notifikovanej osoby pridelené Európskou komisiou.