Flow chart of the procedure for assessment of conformity with the Technical regulation on medical devices as approved by Resolution No. 753 of the CMU of 2 October 2013 noDeclaration of conformity Sterility Module A, Annex 8 to TR Class I medical devices yes Product verification Module F, Annex 5 to TR Internal production At the choice Production quality assurance control At the choice of of the Module A. annex 8 Module D, Annex 6 to TR Class IIa medical manufacturer the manufacturer to TR devices Product quality assurance Module H Module E, Annex 7 to TR (full quality assurance) without design examination Annex 3 to TR Class IIb medical At the choice of devices the manufacturer Product verification Type examination Module B Module F. Annex 5 to TR. Annex 4 to TR Production quality assurance At the choice of the manufacturer Module D. Annex 6 to TR Product quality assurance Manufacturer Product type Module E, Annex 7 to TR Assessment concerns: - securing and maintaining of sterility - metrological aspects

notified body not involved

