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MEDICAL DEVICES IN ORTHODONTICS BETWEEN CLINICAL INVESTIGATION AND CLINICAL USE

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In Italy use and clinical investigation involving medical devices are regulated by law (e.g. Legislative Decree 25th January 2010, n. 37, Health Ministerial Circular 2nd August 2011, Health Ministerial Decree 12th March 2013). The manufacturer, or the established authorized representative in the European Community, of non-CE marked medical devices must send a communication to inform the Ministry of Health; this procedure is obligatory, even when the clinical investigation concerns medical device intended use that is different from those that have been the subject of CE mark. Clinical investigations using medical devices bearing CE marking require approval from Ethical Committee, while dental professionals may use in dental practice routinely these devices. In orthodontics, dental professionals may use medical devices "off label", for an indication not in the approved labelling: in such a case, if the intent is the practice of dentistry, and the medical device is not used in the context of a clinical investigation, it does not require the submission of a clinical study protocol to the Ethical Committee; dental professionals have the responsibility to base the use of the medical device on firm scientific rationale and on sound medical evidence, and to inform the patient and acquire his/her consent. When a dental professional uses medical devices (for clinical investigation or for clinical use, "off label" or not), adequate information on the prospects, limits and potential risks of the treatment must be given to the patient.

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