

STATEMENT REGARDING
CE-MARKING OF INTEGRA BIOSCIENCES MANUAL AND ELECTRONIC PIPETTES
AS IN VITRO DIAGNOSTIC MEDICAL DEVICES

The purpose of this paper is to express the substantiated opinion of the authors, that the manual and electronic pipettes of Integra Biosciences are **products for general laboratory use and can be used to perform in vitro diagnostic procedures, but** do not fall under the scope of in vitro diagnostic medical devices in accordance to the In Vitro Diagnostic Directive 98/79/EC. Therefore, the products are not CE-marked according to the aforementioned directive.

In order to fall under the scope of the In Vitro Diagnostic Directive 98/79/EC, a product has to fulfill the definition of an in vitro diagnostic (IVD) device (Article 1, clause 2b):

“in vitro diagnostic medical device” means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- *concerning a physiological or pathological state, or*
- *concerning a congenital abnormality, or*
- *to determine the safety and compatibility with potential recipients, or*
- *to monitor therapeutic measures.*

(...)

Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;

Thus, products for general laboratory use are specifically excluded from the scope of IVD devices in the IVD Directive. The pure intention of the manufacturer to promote the use of a general laboratory use product as in vitro diagnostic medical device is not sufficient. The device must have a specific characteristic feature, which specifically qualifies the product for in vitro diagnostic use.

General laboratory equipment are products that can be used in a laboratory for essentially any purpose, including preparing samples. The current guidance document concerning the definition and borderline of in vitro diagnostic devices (MEDDEV 2.14/1) provides examples of general laboratory equipment (Section 1.4 - products for general laboratory use), clearly listing general purpose pipettes (e.g. single or multiple pipettes, plastic pipettes, Pasteur pipettes) under this category. What will bring these products into the scope of the IVD directive is the intended purpose in combination with specific characteristics, as for example blood coagulation pipettes with automatic timing being accessories of coagulometers. As the devices manufactured by INTEGRA Biosciences are multi-purpose pipetting products without a specific characteristic for the pipettes that would make them suitable for one or more identified in vitro diagnostic examination procedures, INTEGRA Biosciences pipettes are not in vitro diagnostic medical devices. The

regulation, on the other hand, also means that a user can utilize pipettes, which are not IVD products, for pipetting during an in vitro diagnostic procedure without changing the legal status of the pipette (no automatic off-label use).

In summary, the pipettes manufactured by INTEGRA Biosciences are not considered IVD medical devices within the European Union and do therefore not bear the CE-mark for demonstration of conformity with the IVD directive 98/79/EC. Nevertheless, usage of the devices during in vitro diagnostic procedures does not imply an off-label use by the laboratory.

Sources

European Commission Directive

- IVD Directive 98/79/EC

European Commission guidance document (MEDDEV)

- MEDDEV 2.14/1 IVD medical device borderline and classification issues

Authors

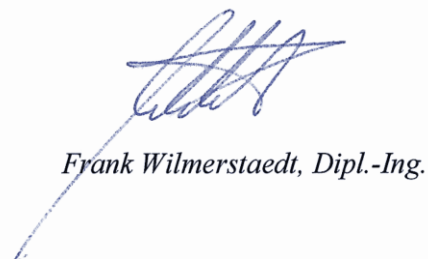
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