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September 11th, 2014

Statement – Stepper and Dispenser not CE marked

To Whom It May Concern,

This document is in response to the request for information regarding CE marking of Stepper and Dispenser.

Item number	Product Name
4421120	Finnpipette FP Dispenser 0,2-1 ml
4421130	Finnpipette FP Dispenser 0,4-2ml
4421140	Finnpipette FP Dispenser 1-5ml
4421150	Finnpipette FP Dispenser 2-10ml
4421160	Finnpipette FP Dispenser 5-30ml
4421170	Finnpipette FP Dispenser 10-60ml
4540000	Finnpipette FP-STEPPER 10ul-5ml
4540500	Finnpipette FP-Stepper MCP
9404170	Finntip Stepper 0.5 ml, 100/box
9404173	Finntip Stepper 0.5 ml, 50/box, sterile
9404180	Finntip Stepper 1.25 ml,100/box
9404183	Finntip Stepper 1.25 ml,50/box, sterile
9404190	Finntip Stepper 2.5 ml, 100/box
9404193	Finntip Stepper 2.5 ml, 50/box, sterile
9404200	Finntip Stepper 5.0 ml, 50/box
9404203	Finntip Stepper 5.0 ml, 25/box, sterile
9404210	Finntip Stepper 12.5 ml,50/box
9404213	Finntip Stepper 12.5 ml,25/box, sterile
9404220	Finntip Stepper 25 ml, 20/box
9404223	Finntip Stepper 25 ml, 10/box, sterile
9404230	Finntip Stepper 50 ml, 10/box
9404233	Finntip Stepper 50 ml, 10/box, sterile

Extract compiled from two reference documents :

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DOCUMENT 1

MANUAL ON BORDERLINE AND CLASSIFICATION IN THE COMMUNITY REGULATORY FRAMEWORK FOR MEDICAL DEVICES Version 1.16 (07-2014):

"PLEASE NOTE: THE VIEWS EXPRESSED IN THIS MANUAL ARE NOT LEGALLY BINDING; ONLY THE EUROPEAN COURT OF JUSTICE ("COURT") CAN GIVE AN AUTHORITATIVE INTERPRETATION OF COMMUNITY LAW. MOREOVER, THIS MANUAL SHALL ONLY SERVE AS "TOOL" FOR THE CASEBY- CASE APPLICATION OF COMMUNITY-LEGISLATION BY THE MEMBERSTATES. IT IS FOR THE NATIONAL COMPETENT AUTHORITIES AND NATIONAL COURTS TO ASSESS ON A CASE-BY-CASE BASIS. THE CONTENT OF THIS MANUAL AND ALL UPDATES ARE PRESENTED TO THE WORKING GROUP ON BORDERLINE AND CLASSIFICATION FOR CONSULTATION. THIS GROUP IS CHAIRED BY THE COMMISSION AND IS COMPOSED OF REPRESENTATIVES OF ALL MEMBER STATES OF EU, EFTA AND OTHER STAKEHOLDERS"

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"2.3. Single or multiple channel pipettes

The single or multiple channel pipettes are used for aspirating and dispensing specific volumes in the microlitre scale. The volume is set by rotating the thumbwheel or the push button. These pipettes have various laboratory purposes.

Unless the manufacturer's intended purpose falls within the definition of an in vitro diagnostic medical device, these pipettes must be regarded as a general laboratory product. The latter isexcluded from the IVDD by article 1 (2) b IVDD.

In addition, MEDDEV 2.14/1 rev.1 states in this context:

"*if, however, the product does not in fact possess specific characteristics that make it suitable for one or more* ***identified*** *in vitro diagnostic examination procedures, then the manufacturer is not free to bring it within the scope of the IVDD merely by affixing the CE marking to it. In other words, a manufacturer is not able to bring within the scope of the IVDD a product that,in reality, is a piece of general laboratory equipment simply by affixing the CE mark to it".*

Moreover, the MEDDEV 2.14/1 rev. 1 specifically refers to pipette. Under point 4 *"Products for general laboratory use"*, it is mentioned that pipettes are laboratory products that are not usually considered to fall within the scope of the IVD directive."

DOCUMENT 2

EUROPEAN COMMISSION
DIRECTORATE GENERAL for HEALTH and CONSUMERS
Consumer Affairs
Health technology and Cosmetics

MEDDEV 2.14/1 revision 2
January 2012

GUIDELINES ON MEDICAL DEVICES
IVD Medical Device Borderline and Classification issues
A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES

"This guideline is not legally binding, since only the European Court of Justice can give an authoritative interpretation of Community law. It has been elaborated by an expert group including experts from Member States' Competent Authorities, the Commission' services, as well as industry trade associations. It is therefore intended that the document will provide useful guidance which should assist common positions to be taken throughout the European Union."

1.4. Products for general laboratory use

Article 1(2) (b) of the IVDD states that:

"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."

The qualification provided for in the Directive is where, on the basis of its characteristics, a manufacturer specifically intends that the product should be used for *in vitro* diagnostic examination. In this case, the product becomes an *IVD* and must comply with the applicable essential requirements of the IVDD and therefore must be CE marked.

If, however, the product does not possess specific characteristics that make it suitable for one or more identified *in vitro* diagnostic examination procedures, then the manufacturer is not allowed to qualify its product as an IVD. A manufacturer is not allowed to affix the CE mark on a piece of general laboratory equipment as a marketing claim. Merely adding the statement "for *in vitro* diagnostic use" to a product is not sufficient to qualify a product as an IVD.

Products used *in vitro* in the preparation of samples that have been obtained for examination are considered neither as IVD nor as accessories and fall outside the scope of the Directive unless, based on their characteristics, they are specifically intended for a particular IVD test. The validation of this specific combination shall be clearly documented in the technical documentation.

***Examples** of product of general laboratory use and IVD medical devices:*

	Laboratory use product	Covered by IVD Directive
Centrifuges	General centrifuges, cytospin	Hematocrite centrifuge
Pipettes	General purpose pipettes (e.g. single or multiple pipettes, plastic pipettes, Pasteur pipettes)	Blood coagulation pipettes with automatic timing (Accessory of coagulometer)
Tubes and flasks	Erlenmeyers, plastic tubes	Blood collection tubes, urine sample containers
Plates	Empty ELISA plates, empty Petri dishes,	Coated microtiter plates for the diagnosis of Lyme's disease

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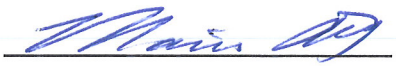

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