EC Declaration of Conformity

For the following kit:

DR. AiM™ Reader

(Product Name)

8C3003

(Model,Designation)

is herewith confirmed to comply with the requirement set out in the Council Direction on the harmonization of the Laws of the Member States concerning

In Vitro Diagnostic Medical Device Directive 98/79/EC

and in conformity with the following standard(s) or other normative documents(s)

EN61010-1:2001 - Safety requirements for electrical equipment for measurement control and laboratory use Part 1: General requirements.

EN61010-2-101:2002 - Safety requirements for electrical equipment for measurement control and laboratory use Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.

EN60601-1-2:2001 - EMC/EMI.

The following representative/importer is responsible for the declaration:

Delta Biologicals S.r.l. - Subsidiary of Erba Diagnostics, INC.

(Company Name)

Via Nicaragua 12-14 - 00071 Pomezia (Roma) - ITALY

(Company Address)

GM | Daniela Bruni | 30/06/2015

(Position/Title) | (Legal Signature) | (Date)

Manufacturer responsible for marking this declaration:

DR. Chip Biotechnology Incorporation Science Park Branch

(Manufacturer Name)

No.31 Ke-Jung Rd., Hsinchu Science Park,Chu Nan, Miao-Li ,Taiwan

(Place, Manufacture Address)

C. A. O. | Yang Yen-Chueh | 2015. 6. 30

(Position/Title) | (Legal Signature) | (Date)