EC Declaration of Conformity

For the following kit:

DR. MTBC Screen™ IVD Kit

(Product Name)

8D1026 (96 tests/kit with C-8 well)

(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, Article 3, AnnexⅢ

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

EN ISO15223-1:2012	**– Symbols to be used with medical device labels, labelling and information to be supplied.**
EN ISO18113-2:2011	**– In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.**
EN13640:2002	**– Stability testing of in vitro diagnostic reagents.**
EN13612:2002	**– Performance evaluation of in vitro diagnostic medical devices.**
ISO14971:2012	**– Medical devices - Application of risk management to medical devices.**
ISO13485:2012	**– Medical devices - Quality management systems - Requirements for regulatory purposes.**

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 — (Position/Title) — Enrico Brenti — (Legal Signature) — 30/06/2015 — (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. — (Position/Title) — Yong Yen-Chueh — (Legal Signature) — 2015. 6. 30 — (Date)

EC Declaration of Conformity

For the following kit:

DR.HPV-27 IVD C8 Kit

(Product Name)

8D1079 (96 tests/kit with C-8 well)

(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, Article 3, AnnexIII

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

EN ISO15223-1:2012	**– Symbols to be used with medical device labels, labelling and information to be supplied.**
EN ISO18113-2:2011	**– In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.**
EN13640:2002	**– Stability testing of in vitro diagnostic reagents.**
EN13612:2002	**– Performance evaluation of in vitro diagnostic medical devices.**
ISO14971:2012	**– Medical devices - Application of risk management to medical devices.**
ISO13485:2012	**– Medical devices - Quality management systems - Requirements for regulatory purposes.**

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 — (Position/Title) | Daniela Rossi — (Legal Signature) | 30/06/2015 — (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. — (Position/Title) | Yung Yen-Chueh — (Legal Signature) | 2015.6.30. — (Date)