DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 98/79/EC OF 27 OCTOBER 1998 ON IN VITRO DIAGNOSTIC MEDICAL DEVICES

MANUFACTURER: Hamilton Thorne, Inc.
100 CUMMINGS CENTER, SUITE 465E, BEVERLY MA 01915 USA

EUROPEAN REPRESENTATIVE: EC REP *MR. ROBIN DOLAN*
21 RUE JOSEPH GUILLONNEAU
14100 LISIEUX, FRANCE

MEDICAL DEVICE: *IMSI STRICT SOFTWARE*

CLASSIFICATION : NOT LIST A OR B, *ARTICLE 9 – SELF DECLARE*

CONFORMITY ASSESSMENT ROUTE: IN VITRO MEDICAL DEVICE DIRECTIVE, DIRECTIVE 98/79/EC, ANNEX III (SELF-DECLARE)

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 98/79/EC OF 27 OCTOBER 1998 ON IN VITRO DIAGNOSTIC MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: ISO 13485:2003, EN ISO 18113-1:2011, EN ISO 18113-3:2011, EN 13612:2002, EN 62304: 2006, ISO 14971: 2007, EN 980:2008

IDENTIFICATION NUMBER CE

PLACE OF DECLARATION: *BEVERLY, MA*

SIGNATURE:

DIARMAID DOUGLAS HAMILTON
V.P. OF REGULATORY AFFAIRS