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: 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


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.

EN 980:2008

IDENTIFICATION NUMBER

PLACE OF DECLARATION: Beverly, MA

SIGNATURE: Diarmaid Douglas Hamilton
V.P. of Regulatory Affairs