SEKISUI

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 98/79/EC CONCERNING IN VITRO DIAGNOSTIC MEDICAL DEVICES

MANUFACTURER:	SEKISUI MEDICAL Co., LTD. 13-5, Nihonbashi 3-Chome, Chuo-ku, Tokyo 103-0027 Japan
EUROPEAN REPRESENTATIVE: EC REP	MEDICAL DEVICE SAFETY SERVICE GMBH(MDSS) SCHIFFGRABEN 41, D-30175 HANNOVER, GERMANY
PRODUCT:	Mediace TPLA Gen.2 Mediace TPLA Gen.2 Calibrator Set Mediace TPLA Gen.2 Control Set
CLASSIFICATION:	Other IVD
CONFORMITY ASSESSMENT ROUTE:	ANNEX III

We Sekisui Medical Co., Ltd. herewith declare that the above mentioned Product Meet the Provisions of Council Directive 98/79/EC on IN VITRO DIAGNOSTIC MEDICAL DEVICES.
All supporting documentation is retained at the premises of the MANUFACTURER.

STANDARDS APPLIED: See Annex 1

START of CE-Marking: April 27, 2015

PLACE, Date of Issue: Tokyo, Japan

SIGNATURE:
Name
Position

Kazunori Saito
Kazunori Saito
General Manager
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Sekisui Medical Co.,Ltd.

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CONFIDENTIAL

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Annex 1

List of Standards

(Mediace TPLA Gen.2, Mediace TPLA Gen.2 Calibrator Set, Mediace Gen.2 Control Set)

1. EN ISO 13485:2012
   Quality Management System for Medical Devices
2. EN ISO 14971:2012
   Application of risk management to medical devices
3. EN 13641:2002
   Elimination or reduction of risk of infection related to in vitro diagnostic reagents
4. EN ISO 18113-2:2011
   In vitro diagnostic medical Devices - Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
5. EN ISO 15223-1:2012
   Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
6. EN 13612:2002
   Performance evaluation of in vitro diagnostic medical devices
7. EN ISO 17511:2003
   In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
8. EN ISO 23640:2013
   In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents
9. Directive 67/548/EEC (2) Hazard labeling
   Classification, packaging and labelling of dangerous substances
10. Directive 88/379/EEC
    Dangerous Preparations Directive
11. EC 1272/2008 (CLP regulation)
    On the classification, labeling and packaging of substances and mixtures