

## 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:  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

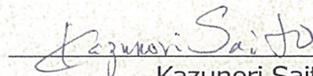
*We Sekisui Medical Co., Ltd. herewith declare that the above mentioned Product Meet the Provisions of Council Directive 98/79/EC on IN VITRO DIAGNOSTIC MEDICAL DEVICES.  
All supporting documentation is retained at the premises of the MANUFACTURER.*

STANDARDS APPLIED: See Annex 1

START of CE-Marking: April 27, 2015

PLACE, Date of Issue: Tokyo, Japan

SIGNATURE:  
Name  
Position

  
Kazunori Saito  
General Manager  
Compliance & Assurance Department  
Sekisui Medical Co.,Ltd.

## 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