

DECLARATION OF CONFORMITY

MANUFACTURER: ARKRAY, Inc.
57 Nishi Aketa-cho, Higashi kujo, Minami-ku, Kyoto, 601-8045, Japan

EUROPEAN

REPRESENTATIVE : ARKRAY Europe, B.V.
Prof.J.H.Bavincklaan 5, 1183 AT Amstelveen, The Netherlands

PRODUCT CATEGORY: Instrument : Midium Automated Urine Analyser
Reagent : Urine Multi-constituent Test Strips
Urine control

PRODUCT: AUTION ELEVEN AE-4020
AUTION Sticks,
AUTION CHECK I, AUTION CHECK II

CLASSIFICATION: SELF DECLARATION

CONFORMITY ASSESSMENT ROUTE: ANNEX IV APPLIED

We herewith declare that the above mentioned products meet the provisions of the council directive 98/79/EC for medical devices. All supporting documentation retained under the premises of the manufacturer.

NOTIFIED BODY: N/A

EC CERTIFICATE: N/A

DECEMBER 2, 2005 Kyoto



SEIGI NONOGAKI, Director
ARKRAY, Inc.