

# DECLARATION OF CONFORMITY

No. AFC-DOC-20100316-13

Manufacturer name : ARKRAY Factory, Inc.

Address : 1480 KOJI, KONAN-CHO, KOKA-SHI, SHIGA, JAPAN

European representative : ARKRAY Europe, B.V.

Address : PROF.J.H. BAVINCKLAAN 5 1183 AT AMSTELVEEN, THE NETHERLANDS

Object of the declaration : ADAMS A1c HA-8180

Column unit 80

Eluent 80A

Eluent 80B

Hemolysis washing solution 80H

Control dilution set 80

Calibrator 80

CLASSIFICATION : NOT INCLUDED IN ANNEX II of The IVDD (Directive 98/79/EC concerning IVD)

CONFORMITY ASSESSMENT ROUTE : Annex III APPLIED (Directive 98/79/EC concerning IVD)

PRODUCT CATEGORY : Other RT\_CI Hardware + dedicated accessories + software (EDMA code: 21 07 10 09), Dedicated glycated haemoglobin/HbA1c system (GMDN code: 30838)

The object of the declaration described above is in conformity with the requirements of the following documents :

ISO13485:2003

ISO14971:2007

Additional information :

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



March 16, 2010

SEIGI NONOGAKI, President

ARKRAY Factory, Inc.