

DECLARATION OF CONFORMITY

No. ADAMS 002-E-23146

Manufacturer: ARKRAY Factory, Inc.
Address: 1480 Koji, Konan-cho, Koka-shi, Shiga 520-3306, JAPAN
Single Registration Number: JP-MF-000003008

Authorised Representative: ARKRAY Europe, B.V.
Address: Prof. J.H. Bavincklaan 2, 1183 AT Amstelveen, THE NETHERLANDS
Single Registration Number: NL-AR-000002056

Name(s) of the Device(s), Product code(s)/Catalogue number(s), Classification(s), Basic UDI-DI(s), EMDN code(s), Serial/Lot number(s), and Intended purpose(s): Refer to the attachment

<IVD Regulation>

Notified Body: N/A

Conformity assessment route: The following procedures are used for the CE-labeling of our products according to the Regulation IVDR 2017/746:
Class A:
ANNEX II and ANNEX III are applied

Common Specifications: N/A

EU Technical Documentation Assessment Certificate: N/A
EU Quality Management System Certificate: N/A

This declaration of conformity is issued under the sole responsibility of ARKRAY Factory, Inc. We hereby declare that the medical device(s) specified in the attachment meet(s) the provisions of the Regulation (EU) IVDR 2017/746 for in vitro diagnostic medical devices. This declaration is supported by the Quality System approval to EN ISO 13485: 2016 issued by TÜV SÜD Product Service GmbH. All supporting documentation is retained at the premises of the manufacturer.

<RoHS Directive>

We also declare that ADAMS A1c (HA-8190V) meet(s) the provisions of the Council Directive 2011/65/EU for RoHS directive and the device(s) above is/are in conformity with the requirements of the documents, EN IEC 63000: 2018. All supporting documentation is retained on the premises of the manufacturer.

Shiga, JAPAN

2023-06-09

Place and Date

Shuzo Joko

Shuzo Joko

Person Responsible for Regulatory Compliance
ARKRAY Factory, Inc.

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Attachment

< Device(s) information >

#	Name	Product code / Catalogue number	Classification	Basic UDI-DI	EMDN code	Serial/Lot number
1	ADAMS A1c (HA-8190V)	107366	A	4987486BC0107366H4	W0201050201	-
	ADAMS A1c (HA-8190V) Main body	107367	-	-	-	12306011 and following
	Sampler unit	107368	-	-	-	Next number from 62301035

< Intended purpose(s) >

1. The ADAMS A1c HA-8190V instrument is intended for the quantitative and automated measurement of HbA1c in whole blood and hemolysis samples. HbA1c measurements are used for screening, monitoring and as an aid to diagnosis of diabetes and prediabetes, for individuals diagnosed with or at risk of developing diabetes or prediabetes. For *in vitro* diagnostic use and professional use only.