DECLARATION OF CONFORMITY

No. ADAMS_017-B-23138

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.

Shiga, JAPAN

2023-05-30
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	Lot/Serial number
1	Hemolysis Solution	109274	A	4987486BC0109274HC	W01019001	Next number from HAC3A01

< Intended purpose(s) >

1. Hemolysis Solution is intended for the dilution of whole blood samples for use with HA-8180V, HA-8180T or HA-8190V, which are intended for the quantitative measurement of HbA1c. For *in vitro* diagnostic use and professional use only.