



DECLARATION OF CONFORMITY

No. AFC-DOC-M20230901-01

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

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

Object of the declaration:

#	Name	Product code	IVDD Classification	IVDR Classification	Lot/Serial No.
1	ADAMS A _{1C} CONTROL	108931	General IVD	B	CTA2M94 and following

<IVD Directive / Regulation>

Conformity Assessment Route: ANNEX III Applied (Directive 98/79/EC concerning IVD)

This declaration of conformity is issued under the sole responsibility of ARKRAY Factory, Inc. We herewith declare that above-mentioned product meets the provisions of the Council Directive 98/79/EC for medical devices including additional requirement of IVDR Article 110 after 2022-05-26. All supporting documentation is retained on the premises of the manufacturer.

The object of the declaration described above is in conformity with the requirements of the following documents: EN ISO 13485: 2016, EN ISO 14971: 2012.

Notified Body: N/A

EC Certificate: N/A

Shiga, JAPAN

2023-09-01

Place and date

Shuzo Joko

Shuzo Joko
Person Responsible for Regulatory Compliance
ARKRAY Factory, Inc.