



DECLARATION OF CONFORMITY

No. AFC-DOC-M20220809-01

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

Objects of the declaration:

#	Name	Product code	IVDD Classification	IVDR Classification	Lot/Serial No.
1	GLUCOCARD S Test Strips	101471	List B	Class C	3AG2206 and subsequent numbers
2	GLUCOCARD S Test Strips	101472	List B	Class C	3AG2205 and subsequent numbers
3	GLUCOCARD S Test Strips	101473	List B	Class C	3AF2211 and subsequent numbers
4	GLUCOCARD S Control Solution (L)	103155	List B	Class C	01042AK0 and subsequent numbers
5	GLUCOCARD S Control Solution (N)	103156	List B	Class C	01042BK0 and subsequent numbers
6	GLUCOCARD S Control Solution (H)	103157	List B	Class C	01042CK0 and subsequent numbers

<IVD Directive / Regulation>

Conformity Assessment Route: ANNEX IV excl. section 4 and 6 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 products meet 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 objects of the declaration described above are in conformity with the requirements of the following documents: EN ISO 13485: 2016 and EN ISO 15197: 2015.

Notified Body: TÜV SÜD Product Service GmbH
Zertifizierstelle • Ridlerstraße 65 • 80339 München • Germany
Identification No. 0123

EC Certificate: V1 027591 0045 Rev. 02

<RoHS Directive>

We also declare that the above-mentioned product "GLUCOCARD S Test Strips" meets the provisions of the Council Directive 2011/65/EU for RoHS directive and is 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

2022-08-09

Place and date

Shuzo Joko

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