DECLARATION OF CONFORMITY

No. AFC-DOC-M20200206-01

Manufacturer: ARKRAY Factory, Inc.
Address: 1480 Koji, Konan-cho, Koka-shi, Shiga 520-3306, JAPAN

European Representative: ARKRAY Europe, B.V.
Address: Prof. J.H. Bavincklaan 2, 1183 AT Amstelveen, THE NETHERLANDS

Objects of the declaration:

Lactate Pro2 LT-1730	(Serial No.: 11941 and subsequent numbers)
Lactate Pro2 Test Strip	(Lot No.: M196B01L and subsequent lots)

<IVD Directive>

Classification: Self testing (Not included in Annex II of the Directive 98/79EC concerning IVD)
Conformity Assessment Route: Annex IV excluding (4,6) Applied (Directive 98/79/EC concerning IVD)

Product Category:
GMDN code: 35885, Lactate monitoring system IVD, home-use
GMDN code: 30208, Lactate electrode

We herewith declare that the above-mentioned products meet the provisions of the Council Directive 98/79/EC for medical devices. All supporting documents are 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, EN ISO 14971: 2012.

The Technical Documentation is subject to periodic surveillance by:

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65 · 80339 Munich · Germany
Identification No. 0123

EC Certificate: No. V1 027591 0045 Rev. 00

<RoHS Directive>

We also declare that the above-mentioned products meet the provisions of the Council Directive 2011/65/EU for RoHS directive and the objects of the declaration above are in conformity with the requirements of the documents, EN 50581:2012. All supporting documents are retained on the premises of the manufacturer.

Shiga, JAPAN

Feb. 06. 2020
Place and date

Hiroyuki Ono
Hiroyuki Ono
President & CEO
ARKRAY Factory, Inc.