



Declaration of Conformity

The manufacturer, A&D Company, Limited, is exclusively responsible for this declaration of conformity.

Manufacturer's Name and Address:

A&D Company, Limited
1-243 Asahi, Kitamoto-shi,
Saitama-ken 364-8585 Japan

European Representative:

Emergo Europe B.V.
Westervoortsedijk 60,
6827 AT Arnhem,
The Netherlands

Product Category: Blood pressure monitor

Model Number: UM-212BLE

Classification/Rule: Ila/ Rule10

- ✓ **The product complies with the requirements of the Directive 93/42/EEC Annex I and the certified quality system according to Annex II excluding (4).**

Standards:

EN 60601-1:2006/A12:2014, EN 60601-1-2:2015, EN 60601-1-6:2010/A1:2015,
EN 62304:2006/A1:2015, EN 62366-1:2015, IEC 80601-2-30:2018,
ISO 81060-2:2018/A1:2020, ISO 10993-1:2018, EN ISO 14971:2019,
EN 1041:2008/A1:2013, EN ISO 15223-1:2016

Notified Body:

TÜV SÜD Product Service GmbH (0123)
Ridlerstraße 65 80339 MÜNCHEN, GERMANY

EC Certificate:

This declaration is valid until the expiration date of the MDD Annex II certificate No. G1 085349 0009 Rev. 00 issued by TÜV SÜD Product Service GmbH.

- ✓ **The product complies with the requirements of the Directive 2014/53/EU.**

Standard: EN 300 328 V2.2.2, EN 301 489-1 V2.2.3, EN 301 489-17 V3.2.4

Notified Body: Not Applied

- ✓ **The product complies with the requirements of the Directive 2011/65/EU and (EU)2015/863.**

Notified Body: Not Applied

Place / date: Saitama-ken, Japan / 12 May. 2023

Legally binding signature:

K. Murata
Name / Title: Kazuharu Murata / General Manager

Affiliation department: R&D Division 3, A&D Company, Limited

File number: 23051215