



# Declaration of Conformity

The manufacturer, A&D Company, Limited, is exclusively responsible for the 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.  
Prinsessegracht 20,  
2514 AP The Hague,  
THE NETHERLANDS

**Product Category:** Blood pressure monitor

**Model Number:** UA-656BLE

**Classification/Rule:** Iia/ 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 60601-1-11:2015, EN 62304:2006/A1:2015, EN 62366-1:2015,  
IEC 80601-2-30:2018, ISO 81060-2:2018/A1:2020, EN ISO 10993-1:2018,  
EN ISO 14971:2012, 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 / 2 Aug. 2021

**Legally binding signature:**

Name / Title: Kazuharu Murata / Deputy General Manager

Affiliation department: R&D Headquarters 3 Division 2 A&D Company, Limited

**File number:** 21080204