



# 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:**

TM-2657P(REF:TM-2657P-EX)

**Classification/Rule:**

II a/ 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/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010,  
EN 62304:2006, EN 62366:2008, IEC 80601-2-30:2009/A1:2013,  
EN ISO 10993-1:2009, EN ISO 14971:2012, EN 1041:2008, ISO 81060-2:2013  
EN ISO 15223-1:2016

**Notified Body:**

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

**Certificate number: G1 085349 0009 Rev. 00**

This declaration is valid until the expiration date of the MDD annex II certificate by TÜV SÜD Product Service GmbH.

- ✓ **The product complies with the requirements of the Directive 2011/65/EU.**

**Notified Body: Not Applied**

**Place and date:** Saitama, Japan, 25 Mar. 2019

**File number:** 19032518

**Minoru Saitou**

**Chief of Quality Control Office**

**A&D Company, Limited**