



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:

UB-543

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 60601-1-11: 2010, EN 62304:2006, EN 62366:2008,
IEC 80601-2-30:2009/A1:2013, ISO 81060-2:2013, EN ISO 10993-1:2009,
EN ISO 14971:2012, EN 1041:2008, 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: 19032530

Minoru Saitou
Chief of Quality Control Office
A&D Company, Limited