



Declaration of Conformity

Manufacturer's Name and Address:

A&D Company, Limited
1-243 Asahi, Kitamoto-shi,
Saitama-ken 364-8585 Japan
SRN: JP-MF-000002158

European Authorised Representative:

Emergo Europe B.V.
Westervoortsedijk 60,
6827 AT Arnhem,
The Netherlands
SRN: NL-AR-000000116

We, A&D Company, Limited, herewith declare the following product meets the provisions of the (EU) 2017/745 and are exclusively responsible for this declaration of conformity.

Product Name: Digital Blood Pressure Monitor
Model Name: UM-212BLE
Basic UDI-DI: 4981046-UM-YP
Intended Use: To measure systolic and diastolic blood pressure and plus rate
Classification/Rule: Class IIa/ Rule10
Initial S/N: N/A (Device not yet assigned a serial number at the time of declaration.)

✓ The product complies with the requirements of the (EU)2017/745 Annex I .

Standards:

EN 60601-1:2006/A2:2021, EN 60601-1-2:2015/A1:2021,
EN 60601-1-6:2010/A2:2021, EN 62304:2006/A1:2015,
EN 62366-1:2015/A1:2020, EN IEC 80601-2-30:2019, EN ISO 81060-1:2012,
EN ISO 81060-2:2019/A1:2020, EN ISO 10993-1:2020, EN ISO 20417:2021,
EN ISO 15223-1:2021, EN ISO 14971:2019/A11:2021, EN IEC 81001-5-1:2022

Notified Body:

BSI Group The Netherlands B.V.
Say Building John M. Keynesplein 9 1066 EP Amsterdam
The Netherlands

Identification number : 2797

Certificate number: MDR 769411 R000

This declaration is valid until 30 Jul. 2030, the expiration date of the MDR Annex certificate No. MDR 769411 R000 issued by BSI Group The Netherlands B.V.

Conformity assessment procedure :

We, A&D Company, Limited, use the following procedures for the
CE-labeling of our products according to the Medical Devices
Regulation(EU)2017/745 and Annex IX.

- ✓ **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

- ✓ **The product complies with the requirements of the Regulation (EU)2023/1542.**

Notified Body: Not Applied

Place / date: Saitama-ken, Japan / 31 Oct. 2025

Legally binding signature: _____

Name / Title: Kazuharu Murata / General Manager

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

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