





EC Certificate

Full Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 085349 0009 Rev. 00

Manufacturer:

A&D Company, Limited

1-243 Asahi, Kitamoto-shi

Saitama-ken 364-8585 JAPAN

EC-Representative:

Emergo Europe B.V.

Prinsessegracht 20. 2514 AP The Hague, THE NETHERLANDS

Product Category(ies): Blood Pressure Monitor,

Electronic Thermometers

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

JAQ235037508

Valid from:

2019-03-19

Valid until:

2023-10-31

Date,

2019-03-19

Stefan Preiß

1. Pumil

A4 / 07.17

TÜV SÜD



EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 085349 0009 Rev. 00

Facility(ies):

A&D Company, Limited

1-243 Asahi, Kitamoto-shi, Saitama-ken,

364-8585 JAPAN

KENSEI KOGYO Co., Ltd

4210-15 Takasai, Shimotsuma-shi, Ibaraki-ken,

304-0031 JAPAN

-/-

A&D Company, Limited



WEB: www.aandd.jp

November 16, 2023

Dear Customers,

Notification: MDD Extension for A&D products

1) Summary

We would like to inform you about the MDD extension regarding A&D's products. The expiration date of the certificates for MDD products was 31 October 2023. However, based on the REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 announced on 20 March 2023, we are pleased to report that we have prepared the following required documents and have completed the MDD extension procedure.

- Manufacturer's declaration
- Notified Body Confirmation Letter

Please see the following link for more detail.

URL: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0607

In addition, the expiration date of the current MDD Certificate will not be extended. (Expiration date remains expired.)

2) Applicable products

UA-1200BLE/UA-611Plus/UA-651Plus/UA-651SL Plus/UA-611/UA-651/UA-651SL/UA-651BLE/UA-656BLE/UA-767S/UA-767S-W/UA-767F/UA-1020/UA-1020-W/UA-704/UA-767PBT-Ci/UA-767PBT-Q/UA-767JP/UA-654MR/UB-522/UB-525/UB-533/UB-533PGMR/UB-543/UB-1100BLE/UM-102/UM-211/UM-212BLE/TM-2440/TM-2441/TM-2657P

The following products are going to be handled through the same procedure before the expiration of the MDD Certificate.

UT-801/UT-103/UT-113/UN-014/UN-019

3) Effective period of MDD extension31 December, 2028 (Maximum)

Thank you very much for your continued patronage of our products. Please contact our sales representative if you have any questions.