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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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Product Service

# 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

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

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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 extension

31 December, 2028 (Maximum)

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