Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

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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

-/-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

A&D Company, Limited
1-243 Asahi,
Kitamoto-shi, Saitama-ken
364-8585
Japan

05 Oct 2023

Notified Body Confirmation Letter

Reference: EU2023-607/631297

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

A&D Company, Limited
1-243 Asahi,
Kitamoto-shi, Saitama-ken
364-8585, Japan

SRN Number: JP-MF-000002158

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

NB 2797

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Digital Blood Pressure Monitor: UA-1200BLE	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UA-611Plus	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UA-651Plus	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UA-651SLPlus	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UA-651BLE	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UA-656BLE	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UA-767S	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UA-767S-W	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UA-767F	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123

NB 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Digital Blood Pressure Monitor: UA-1020	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UA-1020-W	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UA-704	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UB-525	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UB-533	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UB-543	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: SENDO ADVANCE 2	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: SENDO ADVANCE 3	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: SENDO SMART 2	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UM-102	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UM-211	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UM-212BLE	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: TM-2440	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: TM-2441	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123

NB 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Digital Blood Pressure Monitor: TM-2657P	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UB-522	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UB-1100BLE	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UA-767PBT-Ci	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UA-767PBT-Q	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: SENDO ECONOMY	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UA-767JP	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UA-654MR	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UB-533PGMR	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UA-611	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UA-651	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123
Digital Blood Pressure Monitor: UA-651SL	Class IIa	N/A	Certificate #G1 085349 0009 Rev. 00; NB #0123

NB 2797

Confirmation Letter Revision History

Date	Action
2023/05/23	Initial issue
2023/09/27	Addition of devices UA-611Plus, UA-651Plus, UA-651SLPlus, UA-651BLE, UA-656BLE, UA-767S, UA-767S-W, UA-767F, UA-1020, UA-1020-W, UA-704, UB-525, UB-533, UB-543, SENDO ADVANCE 2, SENDO ADVANCE 3, SENDO SMART 2, UM-102, UM-211, UM-212BLE, TM-2440, TM-2441, TM-2657P, UB-1100BLE, UA-767PBT-Ci, UA-767PBT-Q, SENDO ECONOMY, UA-767JP, UA-654MR, UB-533PGMR, UB-522 to the list
2023/10/05	Addition of devices UA-611, UA-651, UA-651SL to the list

NB 2797