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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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 035989 0072 Rev. 00

Manufacturer:

TANITA Corporation

1-14-2, Maeno-cho, Itabashi-ku

Tokyo

174-8630 JAPAN

Product Category(ies): Body Composition Analyzer

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.:

JAQ235039891

Valid from:

2020-01-08

Valid until:

2024-05-26

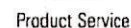
Date,

2020-01-08

Christoph Dicks

Head of Certification/Notified Body

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFICAT



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 035989 0072 Rev. 00

Facility(ies):

TANITA Corporation
1-14-2, Maeno-cho, Itabashi-ku, Tokyo, 174-8630
JAPAN

TANITA Corporation of AKITA LTD.
28-1, Aza-Shimotamogizoe, Horiminai, Daisen-shi,
Akita, 014-0113 JAPAN

-/-

TANITA

04/03/2025

To: Egidijus/Mingeda

Subject: Confirmation of MDD Class IIa Certification Validity and MDR Application

Dear Egidijus,

We would like to officially confirm the following regarding TANITA's medical device certification:

1. The MDD Class IIa certification remains valid until the MDR application process is completed which will be before the European deadline of 31 December 2028.
2. Attached, you will find the letter from our Notified Body, TÜV SÜD, which confirms that we have applied for MDR certification. This letter also verifies that the MDD certification remains valid.

This letter serves as an official confirmation from TANITA. Should you require any further clarification, please do not hesitate to contact us.

Best regards,

Signature:



Wilfrid NEAU
Inside Sales Representative
TANITA EUROPE B.V.
Hoogoorddreef 56e
1101 BE Amsterdam
The Netherlands
(+31) 6 34 63 33 23
wilfrid.neau@tanita.eu
www.tanita.eu





Add value.
Inspire trust.

TÜV SÜD Product Service GmbH · Germany

TANITA Corporation
1-14-2, Maeno-cho, Itabashi-ku
Tokyo
174-8630 JAPAN

Your reference/letter of
035989

Our reference/name
735004370 | JA2048276

Tel. extension/Email
medical_devices@tuvsud.com

Fax extension

Date
2024-06-17

Page
1 of 4

**TÜV SÜD Product Service GmbH
Confirmation Letter
CL 035989 0074 Rev. 00**

Reference: 735004370 | JA2048276

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 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have 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 above stated manufacturer with the following SRN Number:

SRN Number: JP-MF-000022755

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 TÜV SÜD Product Service GmbH 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 TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If 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

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH

Germany

tuvsud.com/ps
Hotline:





- 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.

The transition timelines in accordance Article 120 (3) of MDR 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, 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 (except 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, 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)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see [www.tuvsud.com/ps-cert?q=cert: CL 035989 0074 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:CL_035989_0074_Rev.00)

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-06-17

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in black ink, appearing to read 'Kazuya Ikemoto'.

Kazuya Ikemoto
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in black ink, appearing to read 'Olasunkanmi Egundeyi'.

18 June 2024

Olasunkanmi Egundeyi
Application Reviewer



Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 during application review)	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
Device 1 : Body Composition Analyzer: DC-240MA Body Composition Analyzer: MC-980MA-N plus Body Composition Analyzer: MC-780MA-N Body Composition Analyzer: DC-430MA Basic UDI-DI : 4904785BCA01RC	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1: G1 035989 0072 Rev.00 NB# 0123 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 during application review)	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
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Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/06/17	735004370 JA2048276	Initial issue