CERTIFICATE

KONFIDENCIALU

kiwa

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-19-631

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

Wellgo Medical Products GmbH

Buchenhofener Straße 21, 42329 Wuppertal, Germany

Products: Sterile Biopsy Needles and Sets, Sterile Needle Guide and Kit

The products defined at the enclosure which is the part of this certificate and contains 1 (one) page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.5567.01
Expiry Date: 27 May 2024

12 December 2019, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

KOPIJA TIKRA

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul,
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 7
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com

KONFIDENCIALU

kiwa

EC Sertifikatas

Visiškos kokybės užtikrinimo sistema pagal

medicininių prietaisų direktyvą 93/42/EEC Priedas II, skyrius 3

Sertifikato numeris: 1984-MDD-19-631

Mes patvirtiname, kad visiškai užtikrinama kokybės sistema ir laikomasi nacionalinių įstatymų reikalavimų, už kuriuos atsako žemiau pasirašęs asmuo, perkelta priede II (su išimtimis 4 skyrius) medicininių prietaisų Direktyvos 93/42/EEC. Mes sertifikuojame, kad visiškos kokybės sistema atitinka atitinkamas nuostatas.

Organizacija:

Wellgo Medical Products GmbH

Buchenhofener Strasse 21, 42329 Wuppertal, Vokietija

Produktai: Sterilios biopsinės adatos ir rinkiniai, sterilūs adatų nukreipėjai ir rinkiniai.

Produktai nurodomi šiame sertifikate. Sertifikatas galioja iki jo galiojimo datos. Dėl detalių susisiekite su Kiwa.

Pranešimo numeris: M.5567.01

Galioja iki: 2024 gegužės 27 d.

/Parašas/

Muhtesem Gokhan Yucel

2019 gruodžio 12 d., Istanbulas, Turkija

Sertifiktas galioja iki 2017 gegužės 26.

Dokumento numeris: M.4250.01

Vertimas tikras

Direktorė

Notified Body Confirmation Letter

Kiwa Belgelendirme Hizmetleri A.Ş.
İ.T.O.S.B 9. Cadde No: 15
Tepeören Mevkii PK 34959
Tuzla İstanbul
Türkiye

Tel. +90 216 593 25 75
Faks +90 216 593 25 74
posta@kiwa.com.tr
www.kiwa.com
www.1kiwa.com

Subject: Continuation of Surveillance Audits in the Context of MDD Certificate Extension

Date: 01.04.2024

Reference No: MY-24-002758

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, **Kiwa Cermet Italia S.P.A** a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0476** 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 **MDR Agreement No: CERBO0464922** in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer

WELLGO MEDICAL PRODUCTS GmbH
Buchenhofener str. 21, Wuppertal 42329 Germany

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 with-drawn, 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 in accordance with Article 59(1) of the MDR or
- provided evidence that a competent authority of a Member State had granted an exemption from the applicable conformity assessment procedure in accordance with Article 97(1) of the MDR respectively,

On **12.03.2024**, an application was submitted to our organization for MDD surveillance audits of the products specified in **Annex-I**, and the contract with Reference Number **QUO-198652-P8Q1D3** was signed on **26.03.2024** In this context, the company's audits will be continued by Kiwa Certification Services Inc. until **26.09.2024**.

KOPIJA TIKRA

Direktorė

Annex-I: Certificate Information

Notified Body	Products	Certificate Number	Valid Date	Regulation
Kiwa Belgelendirme Hizmetleri A.Ş.	**Sterile biopsy needles and sets;** -Percutaneous Access Needle -Semi-automatic Biopsy Needle -Automatic Biopsy Needle -Automatic Biopsy Instrument -Automatic Biopsy Instrument Needle -Breast Localization Neddle -Bone Biopsy Needle -Oocyte Aspiration Needle -Coaxial Needle -Seldinger Needle -Bone Marrow Biopsy Needle -Bone Marrow Aspiration Needle -Chiba Biopsy Needle -Tumor Marker Needle **Sterile biopsy needles and sets;** -Sterile Needle Guide and Kit	1984-MDD-19-631	27.05.2024	93/42/EEC

Kind Regards,
Deputy General Manager

Mehmet Fevzi Gülünay

, KİWA