CERTIFICATE

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

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:

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

Certificate Number: 1984-MDD-19-631

Concerned medical devices;

Product: Sterile Biopsy Needles and Sets

Types
Percutaneous Access Needle
Semi-automatic Biopsy Needle
Automatic Biopsy Needle
Automatic Biopsy Instrument
Automatic Biopsy Instrument Needle
Breast Localization Needle
Bone Biopsy Needle
Oocyte Aspiration Needle
Coaxial Needle
Seldinger Needle
Bone Marrow Biopsy Needle
Bone Marrow Aspiration Needle
Chiba Biopsy Needle
Tumor Marker Needle

Product: Sterile Needle Guide and Kit

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel
Head of Notified Body

12 December 2019, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr