



EC Certificate

Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-19-571

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:

İNOFAB SAĞLIK TEKNOLOJİLERİ ANONİM ŞİRKETİ

Head-office: Üniversiteler Mahallesi İhsan Doğramacı Bulvarı No:19
Çankaya, Ankara, Turkey

Warehouse / Production: Üniversiteler Mahallesi İhsan Doğramacı Bulvarı No:29
Çankaya, Ankara, Turkey

Product: Spirohome Ultrasonic Spirometer

Types: Personal, Clinic

Product: Spiroway Mouthpiece

Types: Reusable Mouthpiece, Disposable Mouthpiece

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.5063.01

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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

04 July 2019, Istanbul, Turkey

CERTIFICATE