



CERTIFICATE



EC Certificate

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

Certificate Number: 1984-MDD-20-657

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:

İNCELER MEDİKAL SAĞLIK HİZMETLERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ

İvedik Organize Sanayi Bölgesi Mahallesi 1472 Cadde No:120
Yenimahalle, Ankara, Turkey

Product: Intracorporeal Pneumatic Lithotripter System **Model:** Lithobox

Product: Intracorporeal combined Ultrasonic pneumatic kidney stone crushing device **Model:** Lithobox Zero

Product: Accessories **Types:** Hand Piece, Probe, Applicator

Product: Extracorporeal Shock Wave Lithotripter (ESWL) **Models:** Spark, Spark EM

Product: Extracorporeal Shock Wave Lithotripter (ESWL) Electrode

Product: Extracorporeal Shockwave Therapy (ESWT) **Models:** Modus, Modus ED

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

Report Number: M.4148.08

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Revision Number: 02

Expiry Date: 27 May 2024

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

07 May 2021, Istanbul, Turkey