

# CERTIFICATE



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

**Certificate Number: 1984-MDD-19-616**

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:**

**MODÜL GRUP MÜHENDİSLİK ELEKTRONİK MEDİKAL İNŞAAT  
EĞİTİM VE BİLİŞİM SANAYİ TİCARET LİMİTED ŞİRKETİ**

Alinteri Bulvarı Gül 86 Yapı Koop. C Blok No:1/75  
Ostim, Yenimahalle, Ankara, Turkey

**Products:** Portable Emergency Lung Ventilator, Portable Vacuum Aspirator

The products defined at the enclosure which is the part of this certificate and contains 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.4064.07  
**Expiry Date:** 27 May 2024

**Muhteşem Gökhan Yücel**  
Head of Notified Body

12 September 2019, Istanbul, Turkey

**Enclosure of the EC Certificate:**

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Concerned medical devices;

**Product:** Portable Emergency Lung Ventilator

Types	Model Name
Meventi	Basic, MT1, MT2, MT2 Plus, MT3, MT4, MT4 Plus, MT5, MT5 Plus, BabyLite, BabySmart, Life, MevHome
Medrag	Easy, MDR1, MDR2, MDR2 Plus, MDR3, Life, BabyLite, BabySmart, MDR4, MDR4 Plus, MDR5, MDR5 Plus, Medhome
Oxivent	Easy, OXI1, OXI2, OXI2 Plus, OXI3, Life, BabyLite, BabySmart, OXI4, OXI4 Plus, OXI5, OXI5 Plus, OXIHome

**Product:** Portable Vacuum Aspirator

Types	Model Name
Medrag	PVA01

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 September 2019, Istanbul, Turkey