

EC Certificate

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

Certificate Number: 1984-MDD-21-733

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:

GENADYNE BIOTECHNOLOGIES, INC.

16 Midland Avenue Hicksville NY 11801 USA

Product: Negative Pressure Wound Therapy System

Models: XLR8, XLR8+, UNO

Product: Sterile Wound Care Dressings, Kits and Canisters

Models: XLR8, XLR8+, UNO

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

Report Number: M.5836.01

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



Muhtesem Gökhan Yücel
Head of Notified Body

25 January 2021, Istanbul, Turkey