

CERTIFICATE



EC Certificate

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

Certificate Number: 1984-MDD-20-635

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:

MEDICALE GAZE SA

17, 22 rue du cuir, ZI Sidi Rezig, 2033, Megrine, Tunisia

Products: Dressing Set, Hemodialysis Kits (On/Off Kit & Connection/Disconnection Kit), Medical Gauze Compresses, Sterile Bandage (Elastic Bandages, Gauze Bandages, Tubular Bandages)

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

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Revision Number: 01
Expiry Date: 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions in accordance with MDD Annex V and found that the quality system meets the applicable requirements in MDD Annex V.

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

25 May 2021, Istanbul, Turkey