

EC Certificate

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

Certificate Number: 1984-MDD-12-159

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:

OCTAMED SAĞLIK ÜRÜNLERİ SANAYİ VE TİCARET ANONİM ŞİRKETİ

Aydınlı – Birlik OSB Mahallesi Doğu Cad. No: 15 Tuzla, İstanbul, Turkey

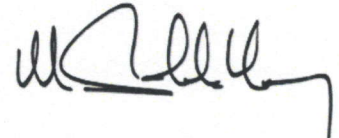
Products: Sterile Elastic Wound Dressing and I.V Fixation and First Aid Plasters, Sterile Adhesive Eye Pads, Sterile Hemodialysis Pressure Plasters, Sterile Absorbent Wound Pads, Sterile Transparent PU Wound Dressing, Sterile Transparent PU I.V. Fixation Dressing, Sterile Absorbent Gauze Sponges, Sterile Absorbent Sponges

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

Report Number: M.3722.09
Date of first issue: 30 April 2012
Date of last issue: 25 January 2021
Revision Number: 09
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 January 2021, İstanbul, Turkey