CERTIFICATE

kiwa

EC Certificate

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

Certificate Number: 1984-MDD-11-104

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:

PLASTİ-MED PLASTİK MEDİKAL ÜRÜNLER SANAYİ VE TİCARET LİMİTED ŞİRKETİ

Deri OSB Mahallesi Yan Sanayi Cad. No:13 Tuzla/İstanbul/Turkey

Products: Pediatric Urine Bag, Vaginal Speculum, Camera Cover, Endotrakeal Stylet, Spirometer Filter Accessories, Vomit Bag, Respiratory Exercise Device

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.

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Revision Number: 05
Expiry Date: 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements for Class Im devices and with securing and maintaining sterile conditions in accordance with MDD Annex V for Class Is devices covered by this certificate and found that the quality system meets the applicable requirements in MDD Annex V.

26 July 2019, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

Digitally signed by Rotari Vladimir
Date: 2022.05.05 10:33:36 EEST
Reason: MoldSign Signature
Location: Moldova

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr