



CERTIFICATE



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, Endotracheal 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.

Report Number: M.3567.08
Date of first issue: 26 July 2011
Date of last issue: 26 July 2019
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.

Muhtesem Gökhan Yücel
Head of Notified Body

26 July 2019, Istanbul, Turkey



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Enclosure of the EC Certificate:

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Medical Devices Directive 93/42/EEC Annex-V

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Concerned medical devices;

Product Name	Types	Class
Pediatric Urine Bag	Pediatric Urine Bag Male	Is & Im
	Pediatric Urine Bag Female	Is & Im
Vaginal Speculum	Large, Medium, Screw Medium	Is
Camera Cover	170101	Is
Endotracheal Stylet	04-06-08-10-12-16 CH	Is
Spirometer Filter Accessories	Spirometer Mouth - 22-30-33 mm	Is
Vomit Bag	950021	Im
Respiratory Exercise Device	Three Balls	Im

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

26 July 2019, Istanbul, Turkey