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, Endotrakeal Stylet, Spirometer Filter Accessories, Vomit Bag, Respiratory Exercise Device, I.V Flow Regulator

The products defined at the enclosure which is the part of this certificate and contains one (1) pages. 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:	09 June 2020
Revision Number:	06
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 and 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.

Muhteşem Gökhan Yücel
Head of Notified Body

09 June 2020, Istanbul, Turkey

Digitally signed by Prodan Sveatoslav
Date: 2021.12.30 13:10:58 EET
Reason: MoldSign Signature
Location: Moldova

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CERTIFICATE

Enclosure of the EC Certificate:

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

Certificate Number: 1984-MDD-11-104, Revision Number: 06

Concerned medical devices;

Product Name	Types
Pediatric Urine Bag	Pediatric Urine Bag Male
	Pediatric Urine Bag Female
Vaginal Speculum	Large, Medium, Screw Medium
Camera Cover	170101
Endotrakeal Stylet	04-06-08-10-12-16 CH
Spirometer Filter Accessories	Spirometer Mouth - 22-30-33 mm
Vomit Bag	950021
Respiratory Exercise Device	Three Balls
I.V Flow Regulator	-

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

09 June 2020, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

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