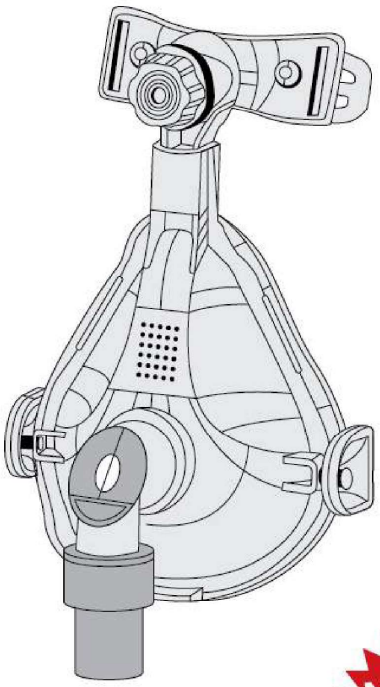
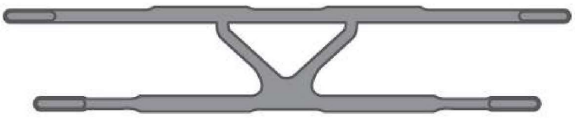
CPAP & BIPAP MASKELERİ / *CPAP & BIPAP MASKS*



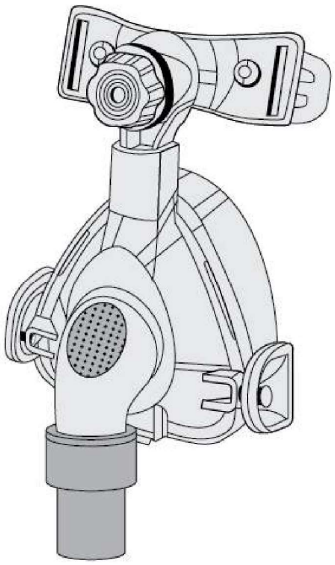
KOD / *CODE*	TİP / *TYPE*	KOLİ ADEDİ *QUANTITY PER BOX*
57814 L	CPAP/ BIPAP Ora-Nazal Maske Büyük *CPAP/BIPAP Ora-Nasal Mask Large*	25
57814 M	CPAP/ BIPAP Ora-Nazal Maske Orta *CPAP/BIPAP Ora-Nasal Mask Medium*	25
57814 S	CPAP/ BIPAP Ora-Nazal Maske Küçük *CPAP/BIPAP Ora-Nasal Mask Small*	25



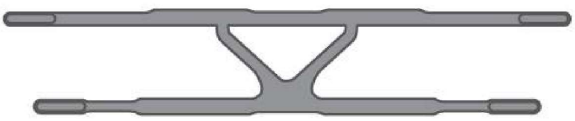
NEW
YENİ

- %100 anti-alerjenik kokusuz medikal silikon
- Kırılmaz esnek polikarbon gövde
- 360° dönebilen hortum konnektörü
- Kaçağı önleyen çift katlı silikon tasarımı
- Silikon yastıklı, ayarlanabilir alın desteği
- Dört noktadan kafa bandı bağlantısı
- Elastik ve ayarlanabilir kafa bandı
- Oksijen girişi
- Klips sistemi ile kolay montaj

- *100% anti-allergenic odorless medical silicone*
- *Unbreakable flexible polycarbonate body*
- *360° rotatable tube connector*
- *Prevent leakage double-layer silicone design*
- *Silicone cushion adjustable forehead support*
- *Four-point headband connection*
- *Elastic and adjustable headband*
- *Oxygen input*
- *Easy assembly by clip system*



KOD / *CODE*	TİP / *TYPE*	KOLİ ADEDİ *QUANTITY PER BOX*
57815 L	CPAP/ BIPAP Nazal Maske Büyük *CPAP/BIPAP Nasal Mask Large*	25
57815 M	CPAP/ BIPAP Nazal Maske Orta *CPAP/BIPAP Nasal Mask Medium*	25
57815 S	CPAP/ BIPAP Nazal Maske Küçük *CPAP/BIPAP Nasal Mask Small*	25



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

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.

Muhteşem Gökhan Yücel
Head of Notified Body

26 July 2019, Istanbul, Turkey

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

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: 05

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
Endotrakeal 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

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
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CERTIFICATE

Plasti-med®
"supporting healthy life"

PLASTİ-MED PLASTİK MEDİKAL ÜRÜNLER SANAYİ VE TİCARET LİMİTED ŞİRKETİ

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

with a scope of

Design, manufacture, sterilization and sale of Sterile and Non Sterile Respiratory and Anesthesia Products, Sterile Urology Products, Sterile and Non Sterile Aspiration and Drainage Systems, Sterile and Non Sterile Gynecology Products, Sterile and Non Sterile Disposable Oral Swab, Other Sterile Medical Devices (Camera Cover, Blood Gas Syringe, Extension Line, Sponge Swab, Umbilical Cord Clamp, Biopsy Punch), Other Non Sterile Medical Devices (Vomit Bag, Kidney Bowl, Enema Set, Sterile and Non Sterile IVD Devices; and the service of sub-contract Ethylene Oxide sterilization

Medical devices - Quality management systems - Requirements for regulatory purposes

"Following elements of the standard are excluded"
"7.5.3" "7.5.4" "7.5.9.2"

EN ISO 13485:2016

Certificate No	: M 10712
Initial Certification Date	: 21 June 2017
Certification Date	: 17 April 2020
Expiration Date	: 20 June 2021

General Manager

Kiwa Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

TÜRKAK
Medical Device Q.M.S.
TS EN ISO/IEC 17021-1
AB-0006-YS
TÜRKAK BDS NO
YS-EE43-3BBF

Last Modified: 17 April 2019 - R 02