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| MANUFACTURER | YILKAL MEDİKAL SAĞLIK ÜRÜNLERİ PAZARLAMA DAĞITIM SANAYİ VE TİCARET LTD. ŞTİ. |
| ADDRESS | Fevzi Çakmak Mah. 10670 Sokak No:26/B-1 Karatay Konya |
| PHONE | +90 332 346 44 40 |
| FAX | +90 332 346 00 22 |
| WEB | http://yikal.com/ |

As manufacturer, we guarantee our products against defects in materials and workmanship, and provide services based on the standard terms and conditions of our warranty policy. WE declare under our own responsibility, that the devices;

Medical Device: Disposable Medical Products
(Non sterile) Class IIa

| PRODUCT MODELS | PRODUCT CODE |
|--|---------------------|
| Masked Nebulizer Set - Newborn | 102 020 1 |
| Masked Nebulizer Set – Infant | 102 020 2 |
| Masked Nebulizer Set – Pediatric | 102 020 3 |
| Masked Nebulizer Set – Adult | 102 020 4 |
| Mouthpiece Nebulizer Set | 103 020 1 |
| T Piece Nebulizer Set | 111 020 1 |
| Oxygen Mask - Newborn | 101 020 1 |
| Oxygen Mask – Infant | 101 020 2 |
| Oxygen Mask – Pediatric | 101 020 3 |
| Oxygen Mask – Adult | 101 020 4 |
| High Concentration Oxygen Mask - Pediatric | 112 020 3 |
| High Concentration Oxygen Mask - Adult | 112 020 4 |
| Nasal Oxygen Cannula Newborn | 104 020 1 |
| Nasal Oxygen Cannula Infant | 104 020 2 |
| Nasal Oxygen Cannula Pediatric | 104 020 3 |
| Nasal Oxygen Cannula Adult | 104 020 4 |

• comply with the requirements of 93/42/EEC Directive, including amendments, are class IIa products and do not contain drug substances or elements of animal origin.

Yikal Medikal has followed the conformity assessment procedure described in Annex II of the above mentioned directive as described in the EC Certificate NO M.2019.106.11199 issued by UDEM International Certification Auditing Training Centre Industry and Trace Inc. Co. that the procedures of Yikal Medikal quality system management according to ISO 13485 have been followed Certificat of Registration No 4055 by IQR Uluslararası Belgelendirme Hizmetleri Ltd. Şti.

RELATED STANDARDS:

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|-------------------------|-------------------------|
| EN ISO 13485:2016 | EN ISO 15223-1:2016 |
| EN 1041:2008 + A1:2013 | EN ISO 10993-1:2018 |
| EN ISO 10993-10:2013 | ISO 14971:2019 |
| EN ISO 27427:2019 | EN ISO 10993-5:2009 |
| EN ISO 4135:2001 | EN 13544-2:2002+A2:2009 |
| EN 13544-1:2007+A1:2009 | MEDDEV 2.12-1 rev 8 |
| MEDDEV 2.7/1 rev 4 | ISO 18562-1:2017 |
| ISO 18562-2:2017 | ISO 18562-3:2017 |
| ISO 18562-4:2017 | |

NOTIFIED BODY : UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A. Ş.

APPROVED BODY NO : 2292

CE DOCUMENT PUBLICATION DATE : 22.01.2019

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CERTIFICATE NUMBER : M.2019.106.11199

CE MARK START DATE : 26.11.2014

CITY, ISSUE DATE : KONYA / 03.07.2024

APPROVED : Mustafa İNCE
General manage

YILKAL MEDİKAL SAĞLIK ÜRÜNLERİ PAZARLAMA
DAĞITIM SANAYİ VE TİCARET LİMİTED ŞİRKETİ
Fevzi Çakmak Mh. 2. Sokak No: 2/B, Karatay/KONYA
Tel: +90 332 346 44 40 Faks: +90 332 346 00 22
Selçuk V.D.:966 028 98 49 • Ticaret Sicil No: 272006