

Producer : Kare Medical and Analytical Devices Ltd. Company

Head Office Address : Kültür mh. Ziya Gokalp Cd. 36/23 Çankaya / Ankara

Factory Address : Alcı OSB mh. 2017. CD. No: 24 Sincan / Ankara

Product Type : Oxygen Concentrator

Name of the product : Hikoneb Oxybreath 10L
Hikoneb Oxybreath Mini 5
Hikoneb Oxybreath Mini 3

Class : Ila Rule 11

GMDN Number : 12873

Medical Device Regulation : **93/42/EC Annex II.3**

Applicable Standards : TS EN ISO 13485 :2016
TS EN ISO 80601-2-69 :2014
TS EN ISO 14971+D1 :2016
TS EN 60601-1+A12 :2015
TS EN 60601-1-2 :2016
TS EN 60601-1-8/A11 :2017
TS EN 60601-11 :2015
TS EN 62366-1/AC :2016
TS EN 62304/A1 :2016
TS EN 1041+A1 :2014
TS EN ISO 15223-1 :2016

Notified Body : Kiwa Certification Services, Inc.
İtösb 9 Cad. No: 15 Tepeören Tuzla / İstanbul / Turkey
tel: +90 216 593 2575 fax: +90 216 593 2574

Identification No : 1984

EC Certificate : 1984- MDD-18-481 rev:2 14.12.2020

Certificate Release Date : 12.01.2018

Certificate Expiry Date : 27.05.2024

We, Kare Medical and Analytical Devices Ltd. Company declare that the Oxygen Concentrators fully comply with the essential safety and health requirements of the MDD 93/42 / EEC medical device directive (including 2007/47 / EC). Prepared Technical File and documents are under our responsibility. Our devices are not Life Support, Patient Monitoring devices or Sterile. It does not contain human blood and its derivatives, animal tissue, drugs and pharmaceutical ingredients.



Hasan Yavas
General Manager
29.12.20- Ankara