Manufacturer : Modül Grup Mühendislik Elektronik Medikal İnş. Eğ. Ve Bilişim San.Tic. Ltd. Şti.
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EC DECLARATION OF CONFORMITY
Medical Device Directive, 93/42 / EEC

CE

Product Name	: Transport Lung Ventilator
Brand	Oxivent
Model	: OxiHome ,Oxi4 Plus ,Oxi5 ,Oxi5 Plus
Purpose of usage	: Of patients; an electrically operated device designed to provide automatic, alveolar breathing support during and in transit in and between hospitals. Typically; compact, lightweight, durable device with built-in batteries for energy during patient transport. Typically; it does not allow spontaneous breathing of the patient by providing mandatory breathing at a predetermined rhythm (control mode). Some types may have help / control modes and / or synchronized intermittent mandatory ventilation (SIMV) modes. Usually includes an airway pressure monitor and low / high pressure alarms, it can be used in ambulances and field hospitals.
GMDN No	: 41148-Portatif pnömatik ventilatör
Harmonized Standards	: TS EN ISO 13485:2016, TS EN ISO 14971:2012, TS EN ISO 15223-1:2014, TS EN 60601-1/A1 :2014, TS EN 60601-1-2:2016, TS EN 794-3 + A2 :2010, TS EN 62304/A1: 2016, TS EN 62366-1 :2015, TS EN 62366-1/AC:2016, TS EN 1041+A1: 2014
Class / Rules (MDD 93/42/EEC)	: IIb / Rules 11
Conformity Assessment	: Excluding part 4 of Annex II
Notified Body:	: Kiwa Belgelendirme Hizmetleri A.Ş.
Notified Body Id	: 1984
Notified Body Address	: İTOSB 9. Cadde No:15 Tepeören Tuzla İstanbul TÜRKİYE Tel: +90 216 593 25 75
Certificate Number	: 1984-MDD-19-616
First release date	: 10 Jully 2013
Effective date	: 27 May 2024
Declaration	: ***"Modül Grup Mühendislik Elektronik Medikal İnş. Eğ. Ve Bilişim San.Tic. Ltd. Şti." As above name, description, product model number, etc. The information states that the product is CE marked and meets the requirements of the Medical Devices Directive 93/42 / EEC + 2007/47 / EC (this directive permits the free movement and sale of the above-mentioned product in all European Union countries). All supporting documentation "Modül Grup Mühendislik Elektronik Medikal İnş. Eğ. Ve Bilişim San.Tic. Ltd. Şti." in the facilities of the company. This Compliance of all the above mentioned product model numbers of medical devices Modül Grup Mühendislik Elektronik Medikal İnş. Eğ. Ve Bilişim San.Tic. Ltd. Şti.". and is included in the certified Quality System Documentation..***
Date, Place	: 12.09.2019/ ANKARA
Sign	: Genel Müdür Oğuz Sahin

Digitally Signed by Turcanu Ștefan
Date: 2021.07.03 11:58:36 EEST
Reason: MoldSign Signature
Location: Moldova

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