Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City

CERTIFICATE OF MEDICAL DEVICE LISTING

Pursuant to Republic Act No. 3720 as per Republic Act 9711, the Food and Drug Administration (FDA) Act of 2009 and it's implementing Rules and Regulations (IRR), the medical device listing is hereby acknowledged,

Type of Listing	:	FOR CLINICAL TRIAL
CMDL Number	:	CDRRHR-CMDL-2020-004

Particulars of the Product/s

Brand Name	:	OSTREAVENT™
Product Name	:	MECHANICAL VENTILATOR
Code(s) / Size(s)	:	
Intended Use	:	Intended to be used among neonate to adults who need a mechanical ventilator. The Ostreavent is a pressure and volume controlled mechanical ventilator which can provide specific peak inspiratory pressure, post-expira tory end pressure, tidal volume, ventilator breaths and inspiratory time.
Quantity	:	

Particulars of the Manufacturer

Name and Address of the Manufacturer	:	Breath of Life Foundation - Unit 608-A Cityland 10 Tower, H.V. dela Costa, Makati City

Particulars of the Importer

Name and Address	:	NA
of the Importer	:	NA

This certification is being issued in compliance with A.O. 2018-002. This certificate is approved for one-time shipment only, and cannot be used for other purposes aside from what is declared. This certificate cannot be construed as an endorsement by the Center for Device Regulation, Radiation Health and Research.

This authorization is subject to suspension, cancellation, or recall should any violation of FDA laws, and its implementing rules and regulations, involving the product be committed.

Witness My Hand and Seal of this Office, this 8th day of March, 2021.

BY AUTHORITY OF THE DIRECTOR GENERAL

MARIA CECILIA C. MATIENZO
Director IV

DTN :20200527110508
O.R. No :1278180
Amount :P 510.00
Date Issued :10 June 2020
/crmt

FDA-0478549

MDL TABLE:

CLINICAL TRIAL:

QUANTITY	B/L. No / Air Waybill	Container Nos.	Packing List No. / Inv. No.	DATE/OR	Evaluator/Date