Perma Pure
Breathe Easier. Be Healthier.

Date Issued: May 18, 2021
Supersedes any preceding for this medical device

DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer, Perma Pure, LLC, in compliance with Article 19 of EU MDR 2017/745. Perma Pure, LLC hereby declares that the medical device and product code listing specified below meets the provision of Annex IV of regulation EU MDR 2017/745 for medical devices.

Manufacturer's Name:	Perma Pure, LLC
Business Address:	1001 New Hampshire Ave., Lakewood, New Jersey 08701, USA
SRN #:	US-MF-000003962
Basic UDI DI #	08401069MESeriesJA
Medical Device Name:	Nafion Tube Dryer, ME Series
Models:	ME-050 (0.0366 – 0.0416 diameter), ME-060 (0.0438 – 0.0528 diameter), ME-070 (0.0488 – 0.0588 diameter), ME-110 (0.0698 – 0.0848 diameter)
Device Risk Classification:	EU Class I, Non-sterile, Non-measuring in accordance with Annex VIII of EU MDR 2017/745
GMDN Code and Term:	GMDN 45566 – Gas Sampling/Monitoring Respiratory Tubing, Single-Use
Conformity Assessment Route:	Annex IX, Conformity Assessment Based on a Quality Management System and on Assessment of Technical Documentation
EU Authorized Representative:	Emergo Europe B.V. Prinsessegracht 20, 2514 AP The Hague, The Netherlands
List of Standards:	EN ISO 10993-1-2020 EN ISO 14971:2012 ISO 14971:2019 EN ISO 13485:2016 ISO 13485:2016

May 18, 2021

Sidra Hankins
VP, Quality/Regulatory