Perma Pure
Breathe Easier. Be Healthier.

Date Issued: 03 June 2026

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 meet the provisions 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, United States
Manufacturer's SRN #:	US-MF-000003962
EU Authorized Rep. SRN#	NL-AR-000000116
Basic UDI DI #	08401069MESeriesJA
Medical Device Name:	Nafion™ Tube Dryer, ME Series
Models:	ME-050 (0.038 – 0.046 Inner Diameter), ME-060 (0.047 – 0.057 Inner Diameter), ME-070 (0.054 – 0.066 Inner Diameter), ME-110 (0.077 – 0.094 Inner Diameter)
Device Risk Classification:	EU Class I, Non-sterile, non-measuring in accordance with Annex VIII of EU MDR 2017/74
GMDN Code and Term:	GMDN 45566 – Gas Sampling/Monitoring Respiratory Tubing, Single-Use
Conformity Assessment Route:	Annex II Technical Documentation & Annex III Technical Documentation on Post-Market Surveillance
EC Certificate No.:	Not Applicable - Product is Self-certified

EU Authorized Representative:	Emergo Europe B.V. Westervoortsedijk 60, 6827 AT Arnhem The Netherlands

Issued by Signature: Anvitha AnandRao Digitally signed by Anvitha AnandRao Date: 2026.06.03 09:14:30 -05'00' Date: 03 June 2026
Name: Anvitha Anand Rao
Position: Regulatory and Quality Product Engineering Specialist

Approved by Signature: Rebecca Hudson Digitally signed by Rebecca Hudson Date: 2026.06.03 10:23:57 -04'00' Date: 03 June 2026
Name: Rebecca Hudson
Position: VP of QA/RA

List of Standards:
The referenced list of Common Specifications and harmonized standards for which documented evidence of compliance can be provided includes:

EN ISO 10993-1-2020
EN ISO 14971:2019 (ISO 14971:2019)
EN ISO 13485:2016 (ISO 13485:2016)
EU REACH 1907/2006
EU RoHS Directive (EU) 2015/863