



Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
A-M Systems, LLC	131 Business Park Loop Sequim, WA 98382 USA	US-MF-000002004

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/fax/email
MedEnvoy Global B.V.	Prinses Margrietplantsoen 33 - Suite 123 2595 AM The Hague The Netherlands	NL-AR-000024028	+31.70.326.2148 - phone info@medenvoyglobal.com

PRODUCT IDENTIFICATION		
Product Name	Product Code / Catalog Number	Basic UDI-DI
Reusable Rubber Components	164xxx, 113xxx	081708102164xxxUV
Intended Purpose	Photo	
The Reusable Rubber components are intended to provide proper alignment of patient mouth to pulmonary testing device while maximizing airflow, preventing leakage, and providing patient comfort.		

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	Common Specifications
Class <u> 1 </u> Rule <u> 5 </u>	

A-M Systems declares that the above-mentioned products meet the provision of the following EU legislation:

- MDR (EU) 2017/745

COMPANY REPRESENTATIVE: Robert Thompson, Quality Manager

TITLE: Quality Manager

SIGNATURE:

PLACE: Sequim, WA USA

DATE: 09/18/2023