




**Declaration of Conformity**

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

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

<b>AUTHORIZED REPRESENTATIVE</b>			
<b>Name of Company</b>	<b>Address</b>	<b>SRN</b>	<b>Telephone/fax/email</b>
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

<b>PRODUCT IDENTIFICATION</b>		
<b>Product Name</b>	<b>Product Code / Catalog Number</b>	<b>Basic UDI-DI</b>
Disposable Rubber Mouthpiece	164900,164950	0817081021649009N
<b>Intended Purpose</b>	<b>Photo</b>	
The Disposable Rubber Mouthpiece is intended to provide proper alignment of patient mouth to Pulmonary testing device while maximizing airflow, preventing leakage, and providing patient comfort.		

<b>RISK CLASS FOR MEDICAL DEVICES</b>	
<b>Device Classification</b>	<b>Common Specifications</b>
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