




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	131 Business Park Loop	US-MF-000002004

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/fax/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	Product Code / Catalog Number	Basic UDI-DI
Disposable Rubber Mouthpiece	164900	0817081021649009N
Intended Purpose	Photo	
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.		

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	Common Specifications
Class 1 Rule 5	

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: 05/05/2021