



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-000024022	+31.70.326.2148 - phone info@medenvoyglobal.com

PRODUCT IDENTIFICATION		
Product Name	Product Code / Catalog Number	Basic UDI-DI
Disposable Nose Clip	166xxx	081708102166xxxVB
Intended Purpose	Photo	
The Foam and Rubber Padded Nose Clips are intended to seal the patient's nose during pulmonary function exercises to allow for more accurate pulmonary function test results.		

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	Common Specifications
Class <u> 1 </u> Rule <u> 1 </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: 11/08/2023