

CE - DECLARATION OF CONFORMITY

World Headquarters

Lafayette Instrument Company 3700 Sagamore Parkway North

Lafayette, IN 47904

U.S.A.

Authorized Representative

AJW Technology Consulting GmbH

Breite Str. 3

40213 Düsseldorf Germany

SRN: US-MF-000041816

Product/Trade Name: Latex-Free Non- Metallic Pneumograph

Model Designations: 76513NM10A PNEUMOGRAPH NONMETALIC W/10' TUBING

76513NM10P PEDIATRIC NON-METALIC PNEUMO-CHEST
76513NM12M NONMETALLIC PNEUMO 12' W/ CONNECTOR
76513NM89A PNEUMOGRAPH NONMETALIC W/89" TUBING
76513NM89P PEDIATRIC NONMETALIC PNEUMO 89"TUBE

Basic UDI: 0855170007NMPNEUMOGRAPHU9

RISK CLASS: 1 UMDNS Code: 17239

Conformity Assessment Route: EU MDR 2017/745 Annex IX

The above listed devices are hereby confirmed to conform to the essential requirements of the European Union Medical Device Regulations (EU 2017/745)

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Effective Date: April 17, 2024

Expiration date: This declaration of conformity expires 3 years from the signature date limited by the issuance of a new declaration of conformity after the addition/subtraction of product or a change in the scope of the conformity assessment route.

Person responsible for making this declaration:

Name: Brent E. Smitley

Position/Title: Quality and Compliance Manager, Lafayette Instrument Company

Place: Lafayette, Indiana U.S.A.

Legal Signature: