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DECLARATION OF CONFOMITY

The Manufacturer

Lumed Srl

Via Staffora 18/9 20073, Opera (MI) Italy

Declare under his own responsibility that the device

Nose Clip for Spirometry

Intended use

Nose clips for spirometry are devices used to ensure the perfect closure of the patient's nasal passages during any type of respiratory test.

Basic UDI-DI: 805750665 FT06 DW

Ref.	Risk Class
	(MDR 2017/745 – Annex VIII)
TSTRnnn/nn, TSTRnnn/nnn	I

It complies with the Essential Safety and Performance Requirements set forth in Annex I of EU Regulation 2017/745 on Medical Devices, and that the conformity assessment process referred to Annex II and Annex III of EU Regulation 2017/745 on Medical Devices was followed.

Opera, 26/05/2021

Place, Date

FABIO SANTAMARINA

CEO



Registro Imprese di Milano: 03050700966