

DECLARATION OF CONFORMITY

Manufacturer's Name: Maxtec, LLC
Address: 2305 South 1070 West
Salt Lake City, Utah 84119
USA

SRN: US-MF-000003961

European Representative: EMERGO EUROPE
Westervoortsedijk 60,
6827 AT Arnhem
The Netherlands

European Representative SRN: NL-AR-000000116

Basic UDI DI: 0817770022IN1ADAPTERHJ

Product Name(s): Muffled 2-in-1 Adapter

Part Number/ Identification
R219P50

Intended Purpose: Intended to thread onto the outlet of a flowmeter for connection to a 22mm male or 15mm female tube. The device also provides muffling of the noise produced by flowmeters when in use.

Risk Class & GMDN: Class IIa 44225 – Oxygen/air breathing gas mixer; Hospital
(Accessory)

Classification Criteria: Clause 4.1 Rule 1 of Annex VIII EU MDR 2017/745

This EU declaration of conformity is issued under the sole responsibility of the manufacturer. We herewith declare that the above mentioned products meet the provisions of the following EC Council Regulations, Common Specifications and Standards. All supporting documents are retained under the premises of the manufacturer and the European Representative.

Regulations: Medical Device Regulation 2017/745

Notified Body: N/A

Conformity Assessment: Annex II Technical Documentation & Annex III, Technical documentation on Post-Market Surveillance

EC Certificate No.: Product is Self-Certified

Date CE mark was affixed: 29 April 2013

This Declaration is considered valid from the date of the signature below.

Issued by Signature: _____ Date: 21 February 2025

Name: Anvitha Anand Rao

Position: Regulatory and Quality Product Engineering Specialist

Approved by Signature: _____ Date: 24 February 2025

Name: Rebecca Hudson

Position: VP, Regulatory Affairs and Quality Assurance

This Declaration supersedes any preceding Declaration of Conformity for the Muffled 2-in-1 Adapter.

Applied Common Specification and Standards

The referenced list of Common Specifications and harmonized standards for which documented evidence of compliance can be provided includes:

EN ISO 13485:2016 (ISO 13485:2016)

EN ISO 14971:2012 (ISO 14971:2017, Corrected version 2007-10-01)

EN ISO 20417:2021

EN ISO 15223-1:2021 EN ISO 15001:2011 (ISO 15001:2010)

EN ISO 18562-2:2020 (ISO 18562-2:2017)

EN ISO 18562-3:2020 (ISO 18562-3:2017)