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): 2-in-1 Muffled 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 I 44225 – Oxygen/air breathing gas mixer; Hospital

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:	Chapter I – Quality Management System and Chapter III – Administrative Provisions of Annex IX, including an assessment of the technical documentation as specified in Section 4 of Annex IX of at least one representative device per generic device group.
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: Ashwini Kadam Digitally signed by Ashwini Kadam Date: 2026.06.19 19:50:01 +05'30' Date: June 19, 2026

Name: Ashwini Kadam
Position: Regulatory Specialist

Approved by Signature: Rebecca Hudson Digitally signed by Rebecca Hudson Date: 2026.06.19 08:23:18 -04'00' Date: June 19, 2026

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 15223-1:2021EN ISO 15001:2011 (ISO 15001:2010)
EN ISO 18562-2:2020 (ISO 18562-2:2017)
EN ISO 18562-3:2020 (ISO 18562-3:2017)