

## 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

**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 1.2 Rule 2 of Annex IX of MDD

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:** General Application Directives: Medical Device Directive, Council Directive 93/42/EEC of 14 June 1993 per Annex II Excluding Section 4 as amended by 2007/47/EC of September 2007

**Notified Body:** TÜV SÜD Product Service  
RIDLERSTRASSE 65, D-80339 MUNICH, Germany  
Number 0123

Conformity Assessment: Full Quality Assurance per Annex II MDD 93/42/EEC Excluding Section 4

EC Certificate No.: G1 045041 00 25 Rev. 00

Date CE mark was affixed: 29 April 2013

This Declaration is considered valid from the date of the signature below until May 26, 2024

Issued by Signature:  Date: May 08, 2023

Name: Anvitha Anand Rao  
Position: Regulatory and Quality Product Engineering Specialist

Approved by Signature:  Date: May 08, 2023  
Name: Sidra Hankins  
Position: VP of QA/RA

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 10993-1:2009 (ISO 10993-1:2009)  
EN ISO 15001:2011 (ISO 15001:2010)  
EN ISO 15002:2008 (ISO 15002:2008)