

## 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:** 0853061002MAXFLOUK

**Product Name(s):** MaxFlo2 Mini (MaxMixing Block Family)

**Intended Purpose:** The MaxFLO2 Mini is designed to provide intermittent or continuous controlled flows of an air/oxygen gas mixture to infant, pediatric, and adult patients. The MaxFLO2 Mini is a restricted medical device intended for use by qualified trained personnel under the direction of a physician in institutional environments where delivery and monitoring of air/oxygen mixtures are required. *(This is not intended as a life supporting device)*

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**Risk Class & GMDN:** Class IIa 44225 – Oxygen/Air Breathing Gas Mixer, Hospital

**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: 17 July 2013

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

Issued by Signature: Anvitha Anand Rao Date: May 08, 2023

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

Approved by Signature: Sidra Hankins Date: May 08, 2023

Name: Sidra Hankins  
Position: VP of QA/RA

This Declaration supersedes any preceding Declaration of Conformity for the MaxFlo2 Mini (MaxMixing Block Family).

#### 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 14971:2019 (ISO 14971:2019)  
EN ISO 15223-1:2021  
EN ISO 20417:2021  
ISO 18562-2:2017  
ISO 18562-3:2017