

## 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

SRN: NL-AR-000000116

Basic UDI DI: 0853061002MAXFLOUK

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

Part Number/ Identification
R223P08
R223P14-001

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)*

GMDN: 44225 – Oxygen/Air Breathing Gas Mixer, Hospital

Risk Class & Classification Criteria: Class IIa Clause 1.2 Rule 2 of Annex IX of MDD  
Class IIa Clause 4.2 Rule 2 of Annex VIII 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: 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

Extension Confirmation Letter: CL 045041 0026

Date CE mark was affixed: 17 July 2013

This Declaration is considered valid from the date of the signature below until December 31, 2028.

Issued by Signature: \_\_\_\_\_ Date: 23 January 2025

Name: Anvitha Anand Rao

Position: Regulatory and Quality Product Engineering Specialist

Approved by Signature: \_\_\_\_\_ Date: Jan 27, 2025

Name: Rebecca Hudson

Position: VP, Regulatory Affairs and Quality Assurance

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 18561-1:2017  
ISO 18562-2:2017  
ISO 18562-3:2017