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: Ashwini Kadam Digitally signed by Ashwini Kadam Date: 2026.10.07 13:05:04 +05'30' Date: 07/10/2026

Name: Ashwini Kadam
Position: Regulatory Specialist

Approved by Signature: Rebecca Hudson Rebecca Hudson (Oct 8, 2026 14:19:47 EDT) Date: Oct 8, 2026
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
IEC 60601-1-6:2010/AMD1:2013
EN ISO 10993-1:2018
IEC 62366-1:2015
ISO 15001:2010

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Final Audit Report 2026-10-08

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