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: 0853061002BLENDERBUDDY4U

Product Name(s): BlenderBuddy Family (BlenderBuddy, BlenderBuddy2)

Part Number/ Identification	
R219P20	R233P01-001
R219P20-001	R233P01-002
R219P20-002	R233P04-001
R219P20-003	R233P04-002
R219P20-004	R233P04-005
R219P20-006	R219P20-009
R219P20-007	

Intended Purpose: The BlenderBuddy Family are flowmeters intended for use with an air/oxygen blender and are to be used by physicians, respiratory therapists and other authorized hospital personnel to administer selected doses of medical gases to a patient The BlenderBuddy Family also contain a gas analysis port which may be used with a suitable oxygen analyzer to measure the gas concentration.

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

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
Date CE mark was affixed:	06 May 2009
Extension Confirmation Letter:	CL 045041 0026

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 13:06:52 +05'30' Date: 07/10/2026

Name: Ashwini Kadam
Position: Regulatory Specialist

Approved by Signature: Rebecca Hudson Rebecca Hudson (Oct 8, 2026 14:19:06 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 BlenderBuddy Family.

Applied Common Specifications 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
ISO 20417:2021
ISO 10993-1:2025
ISO 18562-1:2024
ISO 18562-2:2024
ISO 18562-3:2024

QR-0011 (23) BLENDERBUDDY FAMILY

Final Audit Report 2026-10-08

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