maxtec

SENSING. ANALYSIS. DELIVERY.

DECLARATION OF CONFORMITY

Manufacturer's Name: Address:	Maxtec, LLC 2305 South 1070 West Salt Lake City, Utah 84119 USA
SRN:	US-MF-000003961
European Representative:	EMERGO EUROPE Prinsessegracht 20 2515 AP The Hague The Netherlands
Basic UDI DI:	Pending Assignment
Product Name(s):	Air Oxygen Blenders (MicroMax Low Flow, MicroMax High Flow)
Intended Purpose:	The MicroMax is intended to dispense a continuous and precise blend of medical air and USP oxygen via outlet ports to infant, pediatric and adult patients.
Risk Class & GMDN:	Class IIb 36327 – Mixer, Gas Breathing
Classification Criteria:	Clause 3.2 Rule 11 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: 15 August 2012

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

Signature: _____ Date: 5/25/2021

Name: Sidra Hankins
Position: VP of QA/RA

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 14971:2007, Corrected version 2007-10-01)
EN 1041:2008
EN ISO 15223-1:2016 (ISO 15223-1:2016, Corrected version 2017-03)