maxtec

SENSING. ANALYSIS. DELIVERY.

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURE

This is a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the **Australian Therapeutic Goods (Medical Devices) Regulations 2002** relating to the stated device(s):

Manufacturer's Name:	**Maxtec**
Business Address	**2305 South 1070 West Salt Lake City, Utah 84119 USA**
Medical Device(s):	**BlenderBuddy2**
Classification:	**Class IIa**
GMDN Code and Term:	**GMDN 36327 – Mixer, Gas Breathing (Accessory)**
Scope of Application:	**September 26, 2018 to December 18, 2021**

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essentials principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Full Quality Assurance Procedures Certificate:	**TÜV SÜD Product Service GMBH - CE-0123 RIDLERSTRASSE 65, D-80339 MUNICH GERMANY**
Annex II - EC Certificate No.:	**G1 16 10 45041 020**
Standards Applied:	**EN 1041:2008 EN ISO 15223-1:2016 EN ISO 14971:2012 ISO 18562-1:2017 ISO 18562-2:2017 ISO 18562-3:2017 ISO 15001:2011 ISO 15002:2008**

Authorized Signatory: Tammy Lavery

Tammy Lavery, Director RA/QA

Refer to TF0024 EU Declaration of Conformity (09/26/2018)

26 Sept 2018

Date: