

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

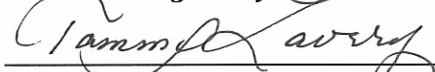
Each kind of medical device to which the system has been applied complies with the applicable provisions of the essentials principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

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

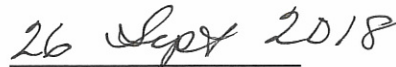
Standards Applied: EN 1041:2008
EN ISO 15223-1:2016
EN ISO 14971:2012
ISO 18562-1:2017
ISO 18562-2:2017
ISO 18562-3:2017
ISO 15001:2011
ISO 15002:2008

Authorized Signatory:



Tammy Lavery, Director RA/QA

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



Date: