Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

+44 (0) 20 3080 6000
gov.uk/mhra

Emergo Consulting (UK) Limited
Compass House, Vision Park Histon
c/o Cr360 – UL International
Cambridge
CB24 9BZ
England, United Kingdom

09 November 2021

Dear **Evangeline Loh**

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **15 October 2021** has been reviewed:

Application reference: **2021101501219022**

Manufacturer organisation: **Maxtec, LLC**
Address:
2305 South 1070 West
UT
Salt Lake City
84119
United States

Manufacturer registration status: **Registered**

Device(s):

GMDN term	Status	Comment
13538 - Respiratory oxygen sensor	Registered	
35219 - Respiratory oxygen monitor, line-powered	Registered	
46049 - Respiratory oxygen monitor, battery-powered	Registered	
61365 - Medical gas flowmeter, Thorpe tube	Registered	
44225 - Oxygen/air breathing gas mixer, hospital	Registered	
44225 - Oxygen/air breathing gas mixer, hospital	Registered	

Please note this letter does not represent any form of accreditation, certification or approval by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations, you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market UKCA or CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

1. **company/organisation information e.g. name and address**
2. **additional devices (GMDN code or term)**

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/ discontinuation of a device (GMDN) or product from your registration record, change of contact person, telephone number and/or email address, for which payment of our statutory fee does not apply.

Please note that the name and address of manufacturer, UK Responsible Person or Authorised Representative (Northern Ireland only) and devices that have been registered will be published on our Public Access Registration Database (PARD).

The account number for your company/organisation is **0000019385.**

Yours sincerely,

Ngozi Onyeukwu
Device registrations service
Devices division
MHRA