



2305 South 1070 West
West Valley, UT 84119

DOCUMENT NUMBER: R140P02-LCS

DOCUMENT TITLE: Label File, Max-550E External Medical Oxygen Sensor

DOCUMENT NOTES:

Document Information

Revision: G	Vault: Regulatory-rel
Doc Type: Labeling	Status: Release

Date Information

Effective Date: 13 Aug 2023	Next Review Date: 13 Aug 2025
Release Date: 13 Aug 2023	Expiration Date:

Control Information

Author: Regulatory Creator/Reviser	Previous Number:
Owner: Regulatory Creator/Reviser	Change Number: DC-0245-23

All dates and times are in US/Mountain

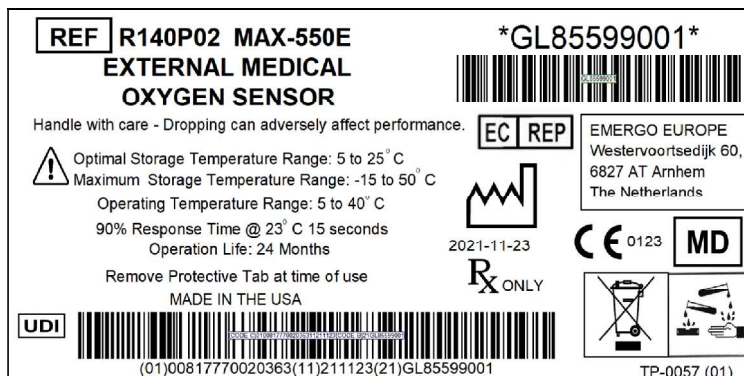
LABEL CONTROL SHEET

Revision # G
MAXTEC PART NUMBER: R140P02
DESCRIPTION: MAX-550E EXTERNAL MEDICAL OXYGEN SENSOR
Num. of Labels: 3
GTIN NUMBER SHOULD READ: 00817770020363
LABEL STOCK NUM: RP35P17-012
LABEL DESCRIPTION: 2.875 X 1.25 Sensor Label Stock
FILE PATH: Z:\LABEL FILE\ MAX-250 R140P02

TO PRINT LABEL CHANGE SERIAL NUMBER TO YMJJJXXSSS FORMAT, CHANGE MANUFACTURING DATE USING TODAY'S DATE AND YYYY-MM-DD SEQUENCE, CHANGE THE MANUFACTURING DATE IN THE BARCODE BY GOING INTO DATA SOURCE PROPERTIES AND CHANGING THE DIGITS AFTER THE(11) AND BEFORE THE (21) TO TODAYS DATE USING YYMMDD FORMAT AND USE THERMAL TRANSFER RIBBON


LABEL STOCK NUM: RP35P10-002
LABEL DESCRIPTION: 1.75 x 3.5 WHITE CARDSTOCK LABEL STOCK
FILE PATH: Z:\LABEL FILE\ MAX-250 R140P02 CARDSTOCK

TO PRINT LABEL CHANGE SERIAL NUMBER TO YMJJJXXSSS FORMAT, CHANGE MANUFACTURING DATE USING TODAY'S DATE AND YYYY-MM-DD SEQUENCE, CHANGE THE MANUFACTURING DATE IN THE BARCODE BY GOING INTO DATA SOURCE PROPERTIES AND CHANGING THE DIGITS AFTER THE(11) AND BEFORE THE (21) TO TODAYS DATE USING YYMMDD FORMAT AND USE THERMAL TRANSFER RIBBON



MAXTEC

OPERATIONAL PROCEDURE

IN-HOUSE LABEL TO BE PULLED AT TIME OF KITTING R137P11

UK	REP	Emergo Consulting (UK) Limited c/o Cr 360 - UL International, Compass House, Vision Park Histon, Cambridge CB24 9BZ, United Kingdom
TP-0148 Rev 02		

Released

FRM-0137 Rev. 01

2 of 2

Signature Manifest

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DC-0245-23 Medical Oxygen Sensors

Doc Control Review

Name/Signature	Title	Date	Meaning/Reason
Diana Larsen (DLARSEN)	Document Control Specialist	07 Aug 2023, 10:55:06 AM	Complete

Management Approval

Name/Signature	Title	Date	Meaning/Reason
Andrew Devlin (ADEVLIN)	Sr. Manufacturing Engineer	07 Aug 2023, 12:38:21 PM	Approved
Bret Nicholson (BRET)	Director Medical Devices Engineering	07 Aug 2023, 01:07:25 PM	Approved
Jake Freeman (JFREEMAN)	Senior Production Manager	08 Aug 2023, 08:44:43 AM	Approved
Sri Kadiyala (SKADIYALA)		08 Aug 2023, 09:42:23 AM	Approved
CHARLY DUFFY (CHARLY)	Director of Quality	09 Aug 2023, 08:21:48 AM	Approved
Brian Fagergren (BFAGERGREN)	Quality Engineer	10 Aug 2023, 10:31:30 AM	Approved

Quality Approval

Name/Signature	Title	Date	Meaning/Reason
Diana Larsen (DLARSEN)	Document Control Specialist	13 Aug 2023, 10:22:42 AM	Approved

Training/Disposition

Name/Signature	Title	Date	Meaning/Reason
Diana Larsen (DLARSEN)	Document Control Specialist	13 Aug 2023, 10:23:44 AM	Approved