West Valley, UT 84119

DOCUMENT NUMBER: R140P02-001-LCS

DOCUMENT TITLE: Label File, Max-550E External Medical MaxBlend2 Sensor

DOCUMENT NOTES:

Document Information

Revision: F 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 #__F_

MAXTEC PART NUMBER: R140P02-001

DESCRIPTION: MAX-550E MAXBLEND EXTERNAL MEDICAL OXYGEN

SENSOR

Num. of Labels: 3

GTIN NUMBER SHOULD READ: 00817770020523

LABEL STOCK NUM: RP35P17-012

LABEL DESCRIPTION: 2.875 X 1.25 Sensor Label Stock

FILE PATH: Z:\LABEL FILE\ MAX-250 R140P02-001

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

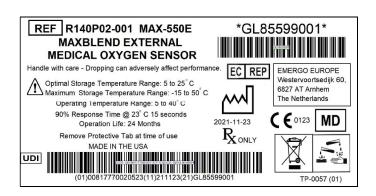


LABEL STOCK NUM: RP35P10-002

LABEL DESCRIPTION: 1.75 x 3.5 WHITE CARDSTOCK LABEL STOCK

FILE PATH: Z:\LABEL FILE\ MAX-250 R140P02-001 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



FRM-0137 Rev. 01

MAXTEC

OPERATIONAL PROCEDURE

IN-HOUSE REPRESENTATIVE LABEL TO BE PULLED AT 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



Signature Manifest

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Title: Label File, Max-550E External Medical MaxBlend2 Sensor

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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

Printed on: 19 Jun 2025, 11:42:55 am; Printed by: SKADIYALA.