



2305 South 1070 West  
West Valley, UT 84119

DOCUMENT NUMBER: DOS-0113

DOCUMENT TITLE: Memo, EyeMax2 Packaging Qualification and Shelf Life

DOCUMENT NOTES:

Part B Section 8

### Document Information

Revision: 01	Vault: Regulatory-rel
Doc Type: Dossier Documentation	Status: Release

### Date Information

Effective Date: 23 Apr 2019	Next Review Date:
Release Date: 23 Apr 2019	Expiration Date:

### Control Information

Author: DLARSEN	Previous Number:
Owner: DLARSEN	Change Number: DC-0179-19

All dates and times are in US/Mountain



S E N S I N G . A N A L Y S I S . D E L I V E R Y .

**MEMORANDUM**

To: EyeMax 2 Technical File #: Part B Section 8

From: Tammy Lavery, RA/QA Director

Date: 4/1/2019

Subject: Packaging Qualification and Shelf Life

The EyeMax2 packaging will not undergo a shipping test such as ASTM D4169. The EyeMax2 is comprised of fabrics that are not susceptible to breakage due to drop, vibration, or shock. The EyeMax2 Neonatal Eye protector is contained within a 2 mil. polypropylene fold over pouch, where twenty assemblies will be enclosed in a chip board box or zip lock bag, qualification will be based on shipment of product to a Maxtec Sales Representative and then returned for inspection. The results of this shipping test and subsequent inspection of product can be found in Appendix I.

At this time there is no shelf life per Test Report QD-0445 found in Appendix I.

DOS-0113 Rev. 01

2305 South 1070 West Salt Lake City, UT 84119 [www.maxtec.com](http://www.maxtec.com) 866.4.maxtec

**Signature Manifest****Document Number:** DOS-0113**Revision:** 01**Title:** Memo, EyeMax2 Packaging Qualification and Shelf Life

All dates and times are in US/Mountain.

**DC-0179-19 EyeMax2 Technical File DOS documents****Doc Control Review**

Name/Signature	Title	Date	Meaning/Reason
Diana Larsen (DLARSEN)	Document Control Specialist	23 Apr 2019, 01:29:04 PM	Complete

**Management Approval**

Name/Signature	Title	Date	Meaning/Reason
Robert Foret (BFORET)	Engineering Manager	23 Apr 2019, 03:00:40 PM	Approved
Tammy Lavery (TLAVERY)	QA/RA Director	23 Apr 2019, 05:28:58 PM	Approved

**Quality Approval**

Name/Signature	Title	Date	Meaning/Reason
Tammy Lavery (TLAVERY)	QA/RA Director	23 Apr 2019, 05:29:31 PM	Approved

**Training/Disposition**

Name/Signature	Title	Date	Meaning/Reason
----------------	-------	------	----------------