

<b>Blue Sky Bio</b>	Issue Date	Document No.	Rev.
	06/26/2020	<b>BS-LS-0159-en</b>	0
Material Specification			
Title: <b>Blue Sky Bio Webpage “Agreement to Terms and Download”</b>	Previous Edition NEW	Page Page 1 of 3	

## 1.0 Item Description

Identification label for the Blue Sky Bio Agreement to Terms and Download

- 1.1 Material Type: Webpage <https://blueskybio.com/pages/download-planning-software>
- 1.2 Label Size: N/A
- 1.3 Font Style: N/A
- 1.4 Printing: See Addendum 1
- 1.5 Logo: N/A
- 1.6 Special Requirements: N/A

2.0 **Applicable Drawings** N/A

3.0 **Packaging** N/A

4.0 **Storage Conditions** N/A

5.0 **Sampling Requirements** N/A

## 6.0 Inspection Criteria

- 100% proofreading of text is required as a part of DCN implementation

## 7.0 Change History

DCN # BS-20-087	Rev 0	Replacing Rev 0 of BS-LS-0159
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## Addendum 1

### The user acknowledges prior to download and use that;

1. Blue Sky Plan® is available for download free of charge in many countries throughout the world.
2. the software is a medical device that can only be used by or under the direct supervision of a licensed practitioner.
3. that this software should not be utilized without careful review of the complete instructional manual located in the 'Help' section of the software.
4. periodic updates for the software may become available and it is the user's responsibility to inform Blue Sky Bio of email address changes. Users are further urged to check the Blue Sky Bio website for software upgrade announcements.
5. the hardware on which the software is installed conforms to the following minimum system requirements:
  - Operating System: Windows 10 Home/Professional 64 bit or OS X 10.10 (Yosemite) or newer
  - Processor: Quad Core Intel i7 or comparable
  - RAM: At least 16 GB
  - Video Card: dedicated NVidia or AMD card, at least 3 GB video RAM (e.g. NVidia GeForce GTX 650, AMD Radeon HD 7750, ...)
  - Monitor: 21 inch, resolution at least 1920x1080
  - Hard Disk: 5 GB of free space
6. By downloading the software and requesting a licensing code, the user agrees to use the email communication to attest to his/her agreement to the terms and conditions stated in the “Agreement to Terms and Download” and to the user “License Agreement”.
7. Aligner fabrication and use:
  - Aligners should be manufactured from Dentsply Essix Ace following the manufacturers instructions of use.
  - Dentist should provide the patient with no more than three aligners at each dental visit and very fit at the time of aligner delivery.
  - A licensed dentist must review and approve any digital treatment plan and monitor the progress of treatment
8. Dentist or user is required to notify Blue Sky Bio via plan@blueskybio.com as soon as possible if any adverse reaction is noticed or reported.
9. Blue Sky Plan is a medical device that has been cleared in the USA, Canada and the European Union. In other countries, it is the responsibility of the medical professional to verify that the software can be used following local regulatory requirements.

By receiving Blue Sky Plan® you agree to the terms and conditions listed above. After downloading please complete the registration form in the software to request your license code.

Blue Sky Bio, LLC is not affiliated with, nor warrants the products of other implant companies listed within Blue Sky Plan® software.

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mdi Europa GmbH  
Langenhagener Straße 71 D-30855 Langenhagen



A. **M** Blue Sky Bio, LLC , 800 Liberty Dr, Libertyville, IL 60030 USA

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