



EU Declaration of Conformity

1. Product Identification

Product Name: **BluPAD Dual LED Blue/White Light Transilluminator**

Model / Type: **BP001CU, BP001CUN**

Product Type: **Electronic Laboratory Equipment**

Intended Use: **For laboratory research use only, not for medical or diagnostic purposes.**

Serial Number: **Refer to product label**

2. Manufacturer Information

Manufacturer: **Bio-Helix Co., Ltd.**

Address: **5F, No. 145, Section 3, Beixin Road, Xindian District, New Taipei City, Taiwan**

Country: **Taiwan**

3. Object of the Declaration

The object of the declaration described above is in conformity with the relevant Union harmonisation legislation, as demonstrated by the manufacturer's self-certification process in accordance with the applicable directives.

4. Relevant Union Harmonisation Legislation

This product is in conformity with the following EU Directives:

- 2014/35/EU - Low Voltage Directive (LVD)
- 2014/30/EU - Electromagnetic Compatibility Directive (EMC)
- 2006/25/EC - Artificial Optical Radiation Directive

5. Harmonised Standards Applied

The following harmonised standards have been applied:

- EN IEC 61010-1:2010/A1:2019 - Safety requirements for electrical equipment for measurement, control, and laboratory use
- EN IEC 61326-1:2021 - Electrical equipment for measurement, control and laboratory use - EMC requirements



- EN 62471:2008 - Photobiological safety of lamps and lamp systems

Verification: Product compliance with the relevant harmonised standards has been verified through third-party laboratory testing (Intertek).

Intertek Verification Numbers: 250100195TPE-001 (for Safety: EN 61010 series)

6. Additional Information

The technical documentation for the product is maintained at the manufacturer's premises and will be made available to the competent national authorities upon request.

7. The manufacturer does not have an authorised representative within the European Union.

EU importer information will be provided on the product label or accompanying documents, as required under Regulation (EU) 2019/1020.

8. Place and Date of Issue

New Taipei City, Taiwan

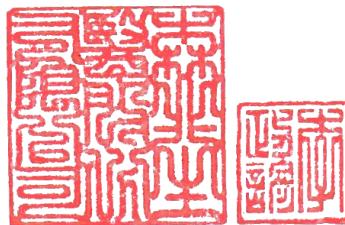
Date: 7 March 2025

9. Signed for and on behalf of:

Bio-Helix Co., Ltd.

Name: Kimi Lee

Position: CEO



Signature: _____