

**EU Declaration of Conformity**

| File №            | Effective Date | Version | Page | Language version |
|-------------------|----------------|---------|------|------------------|
| No. CE-DoC/001/21 | 15-06-2021     | A1      | 1/2  | Eng              |

**Manufacturer name and address:****BACTOSFERA LLC**

8, Vaclav Havel Boulevard, Kyiv, Ukraine, 03124

**Product:**

Ultraviolet germicidal devices TM «BactoSfera»

**Trade mark:**

BactoSfera

**Type/model:**

see the ANNEX 1

**Product Directives:**2014/35/EU Low Voltage Directive 2014/30/EU Electromagnetic Compatibility Directive  
Medical Device Regulation 2017/745**Applied standards:**

EN 61326-1:2013, EN 61010-1:2010, EN 60601-1:2006, EN 60601-1-2:2015

**Test report:**

№ 21-0123-01. Issued Date: 24.05.2021

№ 21-0123-02. Issued Date: 24.05.2021

**Name and contact  
address of the  
authorized  
representative:****STARIMPEX HUNGARY Kft.**  
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This Declaration of Conformity is issued under the full applicant responsibility in product verification confirmation for accordance to European Directives: European Parliament and of the Council of the European Union Low Voltage Directive 2014/35/EU, Electromagnetic Compatibility Directive 2014/30/EU and Medical Device Regulation 2017/745.

During the inspection, the most representative samples of the same product type was tested. The applicant ensures that all products that produced in a series meet the same standards as the test sample.

This document does not exempt the applicant from passing the check on compliance with other European Directives.

The validity of the Declaration of Conformity is unlimited. The Declaration of Conformity will be re-issued if the technical characteristics of the products mentioned in this document will be changed, as well as if will change the regulatory documents for the compliance which was the verification.

**Signatory on behalf of the manufacturer:****Morozova Olena, Director****Issued Date: 15.06.2021**