



BACTOSFERA LLC

8, Vaclav Havel Boulevard, Kyiv, Ukraine, 03124
tel.: +38 044 290 78 78 Email: info@bactosfera.ua

EU Declaration of Conformity

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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.
Hungary, 1071 Budapest, Damjanich u. 26/A, fszt 2
tel.: +36209906155
email: office@starimpex.hu

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



Declaration of Conformity

