



BACTOSFERA LLC

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

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.

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



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ANNEX 1

Type/model:

OBB 15P OZONE, OBB 15P OZONE FREE, OBB 15P ECO, OBB 15P-METAL OZONE, OBB 15P-METAL OZONE FREE, OBB 15P-METAL ECO, OBB 15S OZONE, OBB 15S OZONE FREE, OBB 15S ECO, OBB 30P OZONE, OBB 30P OZONE FREE, OBB 30P ECO, OBB 30S OZONE, OBB 30S OZONE FREE, OBB 30S ECO, OBB 36P OZONE, OBB 36P OZONE FREE, OBB 36P ECO, OBB 36S OZONE, OBB 36S OZONE FREE, OBB 36S ECO, OBB 25P ECO +100%, OBB 25P-METAL ECO+100%, OBB 25S ECO+100%, OBB 55P ECO+100%, OBB 55S ECO +100%, OBB 55S ECO+100%, OBB 75P ECO+100%, OBB 75S ECO+100%, ORBB 15x1 Gorizont, ORBB 15x2 Gorizont, ORBB 15x3 Gorizont MAX EFFECT, ORBB 15x1 Vertical, ORBB 15x2 Vertical, ORBB 15x3 Vertical MAX EFFECT, ORBB 30x1 Gorizont, ORBB 30x2 Gorizont, ORBB 30x3 Gorizont MAX EFFECT, ORBB 30x1 Vertical, ORBB 30x2 Vertical, ORBB 30x3 Vertical MAX EFFECT, ORBB 25x1 Gorizont+100%, ORBB 25x2 Gorizont+100%, ORBB 25x3 Gorizont MAX EFFECT+100%, ORBB 25x1 Vertical+100%, ORBB 25x2 Vertical+100%, ORBB 25x3 Vertical MAX EFFECT+100%, ORBB 55x1 Gorizont +100%, ORBB 55x2 Gorizont+100%, ORBB 55x3 Gorizont MAX EFFECT+100%, ORBB 55x1 Vertical+100%, ORBB 55x2 Vertical+100%, ORBB 55x3 Vertical MAX EFFECT+100%, EKCRAN Jalousie 15, EKCRAN Jalousie 15 FAN, EKCRAN Jalousie 15x2, EKCRAN Jalousie 15x2 FAN, EKCRAN Jalousie 30, EKCRAN Jalousie 30 FAN, EKCRAN Jalousie 30x2, EKCRAN Jalousie 30x2 FAN, EKCRAN Jalousie 25+100%, EKCRAN Jalousie 25 FAN+100%, EKCRAN Jalousie 25x2+100%, EKCRAN Jalousie 25x2 FAN+100%, EKCRAN Jalousie 55+100%, EKCRAN Jalousie 55 FAN+100%, EKCRAN Jalousie 55x2+100%, EKCRAN Jalousie 55x2 FAN+100%, SUN BABY, SUN UNIVERSAL, SUN POWER, QUARTZ 125 MULTIFIX, QUARTZ 125, QUARTZ 240, MININ MULTIFIX, MININ PORTABLE, MININ ELITE, MININ MULTIFIX IR, MININ PORTABLE IR, MININ ELITE IR, MED 15, MED 30, MED 30x2 EKCRAN, **MED 30x3**, MED 30x6, **MED 30x3 TIMER**, MED 30x6 TIMER, AMALGAM 360° 57, AMALGAM 360° 72, AMALGAM 360° 127, AMALGAM 360° 150

Signatory on behalf of the manufacturer:



Morozova Olena, Director

Issued Date: 15.06.2021



S/N: 001707

No.: **ICR Polska/VC/C210601**

Name and address of Applicant BACTOSFERA LLC
8, Vaclav Havel Boulevard, Kyiv, Ukraine, 03124

Name and address of manufacturer: BACTOSFERA LLC
8, Vaclav Havel Boulevard, Kyiv, Ukraine, 03124

Product name: Ultraviolet germicidal devices TM «BactoSfera»

Product types: see page 2/2

Product trademark: BactoSfera

This document confirms that the product sample meets the requirements of the following standards:

- Related with Directives 93/42/EEC, 2014/35/EU and 2014/30/EU:
EN 61326-1:2013
EN 61010-1:2010
EN 60601-1:2006
EN 60601-1-2:2015

The assessment process has been carried out in accordance with individual rules and conditions agreed with the applicant. Evaluation has been carried out in accordance with:

Test reports: 21-0123-01
21-0123-02

Tests conducted by: The State Enterprise "Certified- Metrological Test Center LORTA"

Issue date: 17.06.2021

Expiration date: 16.06.2026

Remarks:

Document refers to the above mentioned product and its conformity in regards of above mentioned standard(s) was proven on test sample

Document was issued on voluntary basis and does not imply meeting all essential requirements, assessment of the series-production or any other restricted Notified Bodies conformity assessment procedure appropriate for the product

Document status can be checked: <https://cert.icrpolska.com/>

CE marking remarks:

CE mark is not sanctioned by the following document

CE mark given here as reference, can be only use by the manufacturer after applying all essential requirements from relevant directives



S/N: 001707

No.: **ICR Polska/VC/C210601**

Product name: Ultraviolet germicidal devices TM «BactoSfera»

Product types:

OBB 15P OZONE, OBB 15P OZONE FREE, OBB 15P ECO, OBB 15P-METAL OZONE,
OBB 15P-METAL OZONE FREE, OBB 15P-METAL ECO, OBB 15S OZONE, OBB 15S OZONE FREE, OBB 15S ECO,
OBB 30P OZONE, OBB 30P OZONE FREE, OBB 30P ECO, OBB 30S OZONE, OBB 30S OZONE FREE,
OBB 30S ECO, OBB 36P OZONE, OBB 36P OZONE FREE, OBB 36P ECO, OBB 36S OZONE,
OBB 36S OZONE FREE, OBB 36S ECO, OBB 25P ECO +100%, OBB 25P-METAL ECO+100%,
OBB 25S ECO+100%, OBB 55P ECO+100%, OBB 55S ECO +100%, OBB 55S ECO+100%, OBB 75P ECO+100%,
OBB 75S ECO+100%,
ORBB 15x1 Gorizont, ORBB 15x2 Gorizont, ORBB 15x3 Gorizont MAX EFFECT, ORBB 15x1 Vertical,
ORBB 15x2 Vertical, ORBB 15x3 Vertical MAX EFFECT, ORBB 30x1 Gorizont, ORBB 30x2 Gorizont,
ORBB 30x3 Gorizont MAX EFFECT, ORBB 30x1 Vertical, ORBB 30x2 Vertical, ORBB 30x3 Vertical MAX EFFECT,
ORBB 25x1 Gorizont+100%, ORBB 25x2 Gorizont+100%, ORBB 25x3 Gorizont MAX EFFECT+100%,
ORBB 25x1 Vertical+100%, ORBB 25x2 Vertical+100%, ORBB 25x3 Vertical MAX EFFECT+100%, ORBB 55x1
Gorizont +100%, ORBB 55x2 Gorizont+100%, ORBB 55x3 Gorizont MAX EFFECT+100%,
ORBB 55x1 Vertical+100%, ORBB 55x2 Vertical+100%, ORBB 55x3 Vertical MAX EFFECT+100%,
EKARAN Jalousie 15, EKARAN Jalousie 15 FAN, EKARAN Jalousie 15x2, EKARAN Jalousie 15x2 FAN,
EKARAN Jalousie 30, EKARAN Jalousie 30 FAN, EKARAN Jalousie 30x2, EKARAN Jalousie 30x2 FAN,
EKARAN Jalousie 25+100%, EKARAN Jalousie 25 FAN+100%, EKARAN Jalousie 25x2+100%,
EKARAN Jalousie 25x2 FAN+100%, EKARAN Jalousie 55+100%, EKARAN Jalousie 55 FAN+100%,
EKARAN Jalousie 55x2+100%, EKARAN Jalousie 55x2 FAN+100%,
SUN BABY, SUN UNIVERSAL, SUN POWER,
QUARTZ 125 MULTIFIX, QUARTZ 125, QUARTZ 240,
MININ MULTIFIX, MININ PORTABLE, MININ ELITE, MININ MULTIFIX IR, MININ PORTABLE IR, MININ ELITE IR,
MED 15, MED 30 MED 30x2 EKARAN, **MED 30x3**, MED 30x6, **MED 30x3 TIMER**, MED 30x6 TIMER

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CE marking remarks:

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A handwritten signature in blue ink, appearing to be 'Rafał Kalinowski'.

