

#### **CERTIFICATE**

This is to certify that the Quality Management System of

Scientific and Industrial Enterprise "MELITTA", Ltd. 16/10, Miklukho-Maklaya Str., 117997, Moscow, Russia

has been assessed and found to be in accordance with the requirements of

ISO 13485:2016

in respect of development, production, maintenance, sales of pulsed xenon units

No: 21.0370.026 of 9<sup>th</sup> March, 2021

Management system certified since 2008

This certificate is valid until 23rd December, 2023

Director General of Certification Association "Russian Register"

The annex is an integral part of the certificate. The certificate covers only those sites of the company which are stated in this certificate. This certificate becomes invalid if conditions of certification are not fulfilled (http://www.rusregister.ru/doc/004.00-105.pdf).



REGISTER PYCCKMIN PEIMCTP

RUSSIAN REGISTER

10-000247

## CИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА RUSSIAN REGISTER CERTIFICATION SYSTEM



Annex to the Certificate Nº 21.0370.026 of 9<sup>th</sup> March, 2021 registration form Nº 10-000247

### Certification scope of management system of Scientific and Industrial Enterprise "MELITTA", Ltd.

- 1. Product / service: development, production, maintenance, sales of pulsed xenon units:
  - a) Pulsed xenon UV germicidal unit for urgent air disinfection in 1st and 2nd category rooms in the absence of people UIKb-01 "Alfa" (MYURA.941712.001)
  - b) Pulsed germicidal unit for room disinfection "Alfa-02" (MYURA.941712.007)
  - c) Pulsed xenon UV germicidal unit with a remote control and automatic time setting for air disinfection in 1-5th category rooms of up to 75 m3 in the absence of people "Alfa-05" (MYURA.941712.015)
  - d) Mobile pulsed ultraviolet unit for indoor air and surfaces disinfection "Alfa-06" (MYURA.941712.006)
  - e) Portable pulsed ultraviolet unit for indoor air and surfaces disinfection "Alfa-09" (MYURA.941712.009)
  - f) Mobile pulsed ultraviolet unit for indoor air and surfaces disinfection "Yanex-2M" (MYURA.941712.016). Export model
  - g) Portable pulsed ultraviolet unit for indoor air and surfaces disinfection "Yanex-5" (MYURA.941712.023). Export model
  - h) Stationary pulsed ultraviolet unit for indoor air and surfaces disinfection "Yanex-ST" (MYURA.941712.022). Export model

Director General of Certification Association "Russian Register"

A. Vladimirtsev

## CИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА RUSSIAN REGISTER CERTIFICATION SYSTEM



Annex to the Certificate Nº 21.0370.026 of 9<sup>th</sup> March, 2021 registration form Nº 10-000247

#### Certification scope of management system of Scientific and Industrial Enterprise "MELITTA", Ltd.

- 2. Processes of product realization in compliance with ISO 13485:2016:
  - 7.1. Planning of product realization
  - 7.2. Customer-related processes
  - 7.3. Design and development
  - 7.4. Purchasing
  - 7.5. Production and service provision
  - 7.6. Control of monitoring and measuring equipment
- 3. Exclusions from the processes of product realization: 7.5.2, 7.5.5, 7.5.6, 7.5.7, 7.5.9.2.

Director General of Certification Association "Russian Register" A. Vladimirts





THE INTERNATIONAL CERTIFICATION NETWORK

#### CERTIFICATE

Certification Association "Russian Register" has issued an IQNet recognized certificate that the organization:

#### Scientific and Industrial Enterprise "MELITTA", Ltd.

16/10, Miklukho-Maklaya Str., 117997, Moscow, Russia

has implemented and maintains a

Quality Management System

for the following scope:

development, production, maintenance, sales of pulsed xenon units

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: 9<sup>th</sup> March, 2021 Expires on: 23<sup>rd</sup> December, 2023

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: RU-21.0370.026

Alex Stoichitoiu President of IQNet Arkady Vladimirtsev, Director General of Russian Register GO O

IQNet Partners\*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertificinti Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia
\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com



THE INTERNATIONAL CERTIFICATION NETWORK

# ANNEX 1 to IQNet Certificate Number RU-21.0370.026

# Certification scope of management system of Scientific and Industrial Enterprise "MELITTA", Ltd.

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  - b) Pulsed germicidal unit for room disinfection "Alfa-02" (MYURA.941712.007)
  - c) Pulsed xenon UV germicidal unit with a remote control and automatic time setting for air disinfection in 1-5th category rooms of up to 75 m3 in the absence of people "Alfa-05" (MYURA.941712.015)
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  - g) Portable pulsed ultraviolet unit for indoor air and surfaces disinfection "Yanex-5" (MYURA.941712.023). Export model
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THE INTERNATIONAL CERTIFICATION NETWORK

Alex Stoichitoiu President of IQNet Arkady Vladimirtsev, Director General of Russian Register

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THE INTERNATIONAL CERTIFICATION NETWORK

#### ANNEX 1 to IQNet Certificate

Number RU-21.0370.026

(continuation)

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