



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 design and development, production, maintenance,
distribution of pulsed ultraviolet xenon medical devices

No: 17.2170.026
of 27th December, 2017

Management system certified since 2008

This certificate is valid until **23rd December, 2020**

Director General of Certification
Association "Russian Register"

Specification of the certification scope is provided in Annex. This certificate becomes invalid if conditions of certification are not fulfilled (<http://www.rusregister.ru/doc/004.00-105.pdf>). This Certificate is the property of Certification Association "Russian Register".



СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА
RUSSIAN REGISTER CERTIFICATION SYSTEM



**Annex to the Certificate
№ 17.2170.026
of 27th December, 2017
registration form № 10-000101**

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

1. Product / service: design and development, production, maintenance, distribution of pulsed ultraviolet xenon medical devices.
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 devices
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. Vladimirtsev



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:

design and development, production, maintenance,
distribution of pulsed ultraviolet xenon medical devices

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: 27th December, 2017

Expires on: 23rd December, 2020

Registration Number: RU-17.2170.026



Alex Stoichitoiu
President of IQNet

Arkady Vladimirtsev,
Director General of
Russian Register



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 FCAV Brazil
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE Mexico 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
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* 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-17.2170.026

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

1. Product / service: design and development, production, maintenance, distribution of pulsed ultraviolet xenon medical devices.
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 devices
3. Exclusions from the processes of product realization: 7.5.2, 7.5.5, 7.5.6, 7.5.7, 7.5.9.2




Alex Stoichitoiu
President of IQNet


Arkady Vladimirtsev,
Director General of
Russian Register



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 FCAV Brazil
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi 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
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com