РУССКИЙ РЕГИСТР   RUSSIAN REGISTER

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".

10-000101

IQNet
Partner

Certification Association "Russian Register": 101 Rimskogo-Korsakova Ave., 190121, Saint Petersburg, Russia

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

IQNet ®

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

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IQNet ®

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

IQNet
THE INTERNATIONAL CERTIFICATION NETWORK

Alex Stoichitoiu
President of IQNet

Arkady Vladimirtsev,
Director General of
Russian Register

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