

СЕРТИФИКАТ №.
CERTIFICATE N. 9124.IRUM

НАСТОЯЩИМ ПОДТВЕРЖДАЕМ, ЧТО СИСТЕМА МЕНЕДЖМЕНТА КАЧЕСТВА, ДЕЙСТВУЮЩАЯ В
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

ООО «ИНФЕРУМ»

РОССИЙСКАЯ ФЕДЕРАЦИЯ, 620100, Г. ЕКАТЕРИНБУРГ,
УЛ. СИБИРСКИЙ ТРАКТ, 12, СТР. 1, ОФ. 206

INFERUM, LLC

B.1, 12, SIBIRSKY TRACT STR., OF. 206,
EKATERINBURG, 620100, RUSSIAN FEDERATION

ПРОИЗВОДСТВЕННЫЕ ПЛОЩАДКИ
по следующим адресам:

PRODUCTION UNITS
at the following addresses:

Российская Федерация, 623417, Свердловская обл.,
г. Каменск-Уральский, ул. Механизаторов, 74
74, Mekhanizatorov str., Kamensk-Uralsky, Sverdlovsk oblast,
623417, Russian Federation

соответствует требованиям стандарта
IS IN COMPLIANCE WITH THE STANDARD

EN ISO 13485:2012

ДЛЯ СЛЕДУЮЩЕЙ ОБЛАСТИ ДЕЯТЕЛЬНОСТИ
FOR THE FOLLOWING ACTIVITIES

Проектирование, разработка, производство и продажа медицинских
изделий для динамической электростимуляции
*Designing, development, manufacture and distribution of medical
devices based on dynamic electro-neurostimulators*

Дальнейшие разъяснения относительно применимости требований EN ISO 13485:2012 могут быть получены от организации
Further clarifications regarding the applicability of EN ISO 13485:2012 requirements may be obtained by consulting the organization

**ИСПОЛЬЗОВАНИЕ И СРОК ДЕЙСТВИЯ СЕРТИФИКАТА ДОЛЖНЫ УДОВЛЕТВОРЯТЬ
ТРЕБОВАНИЯМ ПРАВИЛ ПО СЕРТИФИКАЦИИ СИСТЕМ МЕНЕДЖМЕНТА**
*THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS
OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS*

ДАТА: ПЕРВИЧНАЯ СЕРТИФИКАЦИЯ
DATE: *FIRST CERTIFICATION*

2016-11-14

ДАТА ВЫПУСКА
CURRENT ISSUE

2016-11-14

СРОК ДЕЙСТВИЯ
EXPIRY DATE

2019-11-13

Организация обязана пройти процесс сертификации в соответствии с (требованиями)
ISO 13485:2016 до 28.02.2019; в противном случае срок действия данного сертификата истекает
*The Organization shall obtain the certification according to ISO 13485:2016
within 2019/02/28; otherwise the validity of this certificate will expire*



IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO
Management Systems Division - Flavio Omago

Only the English text is authentic

CISQ è la Federazione Italiana di
Organismi di Certificazione dei
sistemi di gestione aziendale.

CISQ is the Italian Federation
of management system
Certification Bodies.



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

IQNet and its partner
CISQ/IMQ-CSQ
 hereby certify that the organization

INFERUM, LLC

74, Mekhanizatorov str., Kamensk-Uralsky, Sverdlovsk oblast,
 623417, Russian Federation

for the following field of activities
Designing, development, manufacture and distribution of medical
devices based on dynamic electro-neurostimulators

Further clarifications regarding the applicability of EN ISO 13485:2012 requirements may be obtained by consulting the organization

has implemented and maintains a
Quality Management System
which fulfills the requirements of the following standard

EN ISO 13485:2012

Issued on: 2016 – 11 – 14

Expiry date: 2019 – 11 – 13

Registration Number: IT – 109363

The status of validity of the certificate can be verified at <http://www.cisq.com> or by e-mail to fedcisq@cisq.com



Michael Drechsel

President of IQNET



Ing. Claudio Provetti

President of CISQ

IQNet Partners:**

AENOR Spain AFNOR Certification France Vinçotte Belgium APCER Portugal CCC Cyprus
 CISQ Italy CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany
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 IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc..

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

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