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**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	ДАТА ВЫПУСКА CURRENT ISSUE	СРОК ДЕЙСТВИЯ EXPIRY DATE
2016-11-14	2016-11-14	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  
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SGQ N°005A, SGA N°006D, SCR N°005F  
SSI N°003G, FSM N°007I, SGE N°006M  
EMAS N°003P, PRD N°005B, PRS N°080C  
ISP N°063E, LAB N°012I, LAT N°02I

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC  
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

®



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](mailto:fedcisq@cisq.com)



*Michael Drechsel*  
**President of IQNET**



*Ing. Claudio Provetti*  
**President of CISQ**

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