



Quality System Certificate

Certificate Number: DGM – 825

This is to certify that the quality system of:

Kivex Biotec A/S [K-Systems]

Klinthøj Vænge 3-5
3460 Birkerød
Denmark

fulfills the requirements in:

EN ISO 13485:2012

The certificate covers the following activities:

Production, installation and servicing of IVF incubators and IVF work stations

The certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. Certifications to DS/EN ISO 13485:2012, EN ISO 13485:2012, ISO 13485:2003, DS/EN ISO 9001: 2008, EN ISO 9001:2008 and ISO 9001:2008 include the requirements of the applicable corrigenda. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.

Bent Buus
Authorized person

For Presafe Denmark A/S

Date of issue: 2014-12-18
Expires: 2017-12-18
Initial date of issue: 2014-12-18
Reference: aur2a1409v21f809

Presafe Denmark A/S

Tuborg Parkvej 8
2900 Hellerup
Denmark



This is to certify that the quality system of:

Kivex Biotec A/S [K-Systems]
Klintehøj Vænge 3-5
3460 Birkerød
Denmark

has been approved in conformity with the requirements of

Annex V, section 3.2 - Production quality assurance

of Council Directive 93/42/EEC concerning medical devices as transposed into Danish law.

The certificate covers the following activities:

Manufacture and final inspection of IVF incubators in class IIa

The EC certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. This EC certificate is issued pursuant to the Presafe Denmark A/S terms and conditions for the certification of medical devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits as per the Directive.



Bent Buus
Authorized person

For Presafe Denmark A/S

Date of issue: 2014-12-18
Expires: 2019-12-18
Initial date of issue: 2014-12-18
Reference: aur5a1409v21f809

Presafe Denmark A/S

Notified Body, Identification No. 0543

Tuborg Parkvej 8, 2900 Hellerup, Denmark