# EC Certificate

**Certificate Number:** DGM – 818

This is to certify that the quality system of:

## ORIGIO a/s
**Knardrupvej 2**
**2760 Måløv**
**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 of electronic devices for use in assisted reproductive technology (ART) procedures 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: | 2014-04-11 |
| Expires: | 2017-01-31 |
| Initial date of issue: | 2014-01-27 |
| Reference: | aur2a1401v351f119 |

**Presafe Denmark A/S**
*Notified Body, Identification No. 0543*
Tuborg Parkvej 8, 2900 Hellerup, Denmark

**The following Products/product families in class IIa are covered by the certificate:**

**Suction Pump**
SPUMPV1

Certificate number: DGM – 818
Certificate type: EC Certificate

Date of issue: 2014-04-11
Expires: 2017-01-31
Initial date of issue: 2014-01-27
Reference: aur2a1401v351f119