By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 566771**

Issued To: **HertART Aps**
Gustaf Werners gata 2
V Frölunda
SE-421 32
Sweden

In respect of:

Manufacture of sterile dishes, tubes and pipettes for in vitro fertilization procedures.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2011-08-12** Date: **2020-04-20** Expiry Date: **2024-05-26**

...making excellence a habit.™

bsi.

By Royal Charter

EC Certificate - Production Quality Assurance

Supplementary Information to CE 566771

Issued To:

HertART Aps
Gustaf Werners gata 2
V Frölunda
SE-421 32
Sweden

NBOG code	Device Description
Class IIa	
MD 0109	IVF dishes
MD 0109	IVF tubes
MD 0109	IVF pipettes

First Issued: **2011-08-12** Date: **2020-04-20** Expiry Date: **2024-05-26**

...making excellence a habit.™