



EC Certificate - Production Quality Assurance

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

No. CE 566771
Issued To: **HertART Aps**
Udviklingspark Oeresund
Korskildelund 6
Greve
2670
Denmark

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 0086):

Gary Fenton, Global Assurance Director

First Issued: **12 August 2011**

Date: **28 April 2014**

Expiry Date: **11 August 2016**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	Service(s) supplied
Sterilin Limited Thermo Fisher Scientific Parkway Pen-Y-Fan Industrial Estate Newport NP11 3EF United Kingdom	Control of Sterilization Manufacture
Vitrolife Inc. 3601 South Inca Street Englewood Colorado 80110 USA	Testing
Vitrolife Sweden AB Gustaf Werners gata 2 SE-421 32 V. Frölunda Sweden	Administration & Complaints Quality Assurance Testing

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EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
12 August 2011	7582029	First Issue
10 November 2011	7762224	Extension to scope to include pipettes. Change of address for significant subcontractor Thermo Fisher Scientific
28 April 2014	8150563	Change to subcontractors: change of name of Thermo Fisher Scientific and addition of activities for Vitrolife Sweden AB

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