

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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **12 August 2011**Date: **05 August 2016**Expiry Date: **01 August 2021**

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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**

Elos Medtech Microplast AB
Hästhagsgatan 2
Skara
532 37
Sweden

**Manufacture
Packaging**

Nunc A/S
Kamstrupvej 90
4000 Roskilde
Denmark

**Manufacture
Packaging
Purchasing
Sterilization
Testing**

Sterigenics Denmark A/S
Aa Louis-Hansens Alle 11
Espergaerde
DK-3060
Denmark

Sterilization

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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

Certificate No: **CE 566771**
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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.
24 March 2015	8265964	Change of company address to Sweden and addition of significant subcontractors Elos Medtech Microplast AB and Sterigenics Denmark A/S.
19 October 2015	8374160	Addition of Subcontractor Nunc A/S.
05 August 2016	8570337	Certificate renewal.