Digitally signed by Grecu Mihnea Ioan
Date: 2024.01.29 16:02:47 EET
Reason: MoldSign Signature
Location: Moldova

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 733551**

Issued To: **ORIGIO A/S**
Knardrupvej 2
2760 Måløv
Denmark

In respect of:

Design, development, manufacture and final inspection of sterile storage devices and sterile media with and without human serum albumin, gentamicin, GM-CSF, porcine heparin and insulin, for use in Assisted Reproductive Technology (ART) procedures.
Sterile oil overlay of ART media during gamete and embryo culture and micromanipulation.
Those aspects of Annex II relating to securing and maintaining sterility of VTS Vacuum Tube Sets for use in ART procedures.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 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: **2021-04-27** Date: **2021-05-20** Expiry Date: **2024-05-26**

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Supplementary Information to CE 733551

Issued To:

ORIGIO A/S
Knardrupvej 2
2760 Måløv
Denmark

Device code	Device name	Intended purpose per IFU
Class III		
---	SAGE 1-Step™	See CE 733555
---	ORIGIO® Sperm Wash	See CE 733556
---	ORIGIO® Sequential Fert™	See CE 733557
---	ORIGIO® Sequential Cleav™	See CE 733557
---	ORIGIO® Sequential Blast™	See CE 733557
---	ORIGIO® Gradient™ 90	See CE 733558
---	ORIGIO® Gradient™ 40/80	See CE 733558
---	MediCult Vitrification Cooling	See CE 733559
---	MediCult Vitrification Warming	See CE 733559
---	Biopsy Medium	See CE 733560
---	BlastFreeze™	See CE 733560
---	BlastThaw™	See CE 733560
---	CryoSperm™	See CE 733560
---	Embryo Freezing Pack	See CE 733560

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Device code	Device name	Intended purpose per IFU
Class III		
---	Embryo Thawing Pack	See CE 733560
---	Flushing Medium	See CE 733560
---	*ICSI* Cumulase®	See CE 733560
---	MediCult IVM® System	See CE 733560
---	PVP Clinical Grade	See CE 733560
---	PVP Medium	See CE 733560
---	Sperm Freezing Medium	See CE 733560
---	Sperm Preparation Medium	See CE 733560
---	SpermSlow™	See CE 733560
---	SynVitro® Flush	See CE 733560
---	Universal IVF Medium	See CE 733560
---	UTM™ Transfer Medium	See CE 733560
---	EmbryoGen®	See CE 733561
---	BlastGen™	See CE 733561
---	ORIGIO® Handling™	See CE 744875

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Device code	Device Name	Intended purpose per IFU
Class IIb		
44046	ORIGIO® Gradient™ 100	Intended purpose as per IFU
Class IIa		
MD 0109	McGill Cryoleaf™	---
MD 0109	VitriFit™	---
MD 0109	Acidified Tyrodes Solution	---
MD 0109	Liquid Paraffin	---
Class Is		
MD 0102	VTS Vacuum Tube Set	---

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