



a CooperSurgical Company

**Declaration of Conformity (complete quality assurance system) to
Council Directives 93/42/EEC**

Manufacturer:

ORIGIO a/s

**Knardrupvej 2
DK-2760 Måløv
Denmark**

Device type	Spermatozoa handling media for in-vitro fertilization
Device name	ORIGIO® Sperm Wash
Code	84051010A, 84050060A, 84055060A.
Class	III in accordance with rule no. 2, 3, 5, 13 and 17
Certificate(s)	CE 733551 and CE 733556

Declaration of Conformity

ORIGIO a/s declares that the above-mentioned Art media conform to the relevant provisions of the EC Council Directive 93/42/EEC on the approximation of the laws of the Member States relating to medical devices dated 14 June 1993 as amended by BEK 1263 of 15 December 2008 and is in accordance with Annex II Conformity Assessment Procedure and EN ISO 13485:2016 registered Quality Management System as implemented by European Communities (Medical Devices) as verified by BSI Group The Netherlands B.V. (**CE** 2797).

Authorisation

Signed in Måløv

Date: 2021.Dec.02

Name and authority Hussein Sabtiy, Global Regulatory & Clinical Affairs Director

Signature