

To Whom It May Concern:

Clearline filtered and non-filtered hand held pipette tips (Part Numbers below) have been CE Marked and appropriately registered as an IVDD and comply with the requirements of DIRECTIVE 98/79/EC.

The Authorized Representative is Emergo Europe, Molenstraat 15, 2513 BH, The Hague, Netherlands.

Attached please find the DOC as lodged with the Competent Authority of the Netherlands.

QA Signature

Jeff Dunn

Director of Quality Assurance

Sorenson BioScience

Clearline Pipette Tip Catalog Numbers

028200CL	015020CL	014220CL	014200CL	037660TCL	035100ACL
035200CL	035210CL	035230CL	035260CL	030560ACL	032240CL
038000CL	014210CL	017370CL	134000CL	030570ACL	032260CL
038000TCL	035220CL	035240CL	037640CL	032230CL	027110CL
130340CL	036060CL	130510CL	037640TCL	03590ACL	027120CL
134760CL	036060TCL	130510TCL	037660CL	032250CL	134750CL



CE TECHNICAL FILE

Appendix G - Declaration of Conformity

EC Declaration of Conformity (Directive 98/79/EC)

Manufacturer:

Sorenson Bioscience, Inc. 6507 South 400 West Salt Lake City, Utah 84107

Product Details: See EC Declaration of Conformity List (attached product codes)

Classification: IVDD, Non Annex II, Self -Declaration

We hereby declare the devices named in the EC Declaration of Conformity List (see attached) comply with the requirements of DIRECTIVE 98/79/EC, on in vitro diagnostic medical devices.

Standards Applied: EN ISO 9001:2008, EN ISO 14971:2007, EN ISO 15223

Name: Jeffrey Dunn

Position: Quality Manager

Place: Sorenson BioScience, 6507 South 400 West, Salt Lake City, UT 84107

Signature?

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Name: Matt Buttard

Position: Manager Quality Systems and Compliance

Place: Corning Incorporated I Life Sciences I 836 North Street I Building 300, Suite

3401 | Tewksbury, MA 01876

Signature: Mulle M

Date: 4/14/13

Date: 4-3-13

Catalog Numbers

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