

Declaration of Conformity

Cepheid AB
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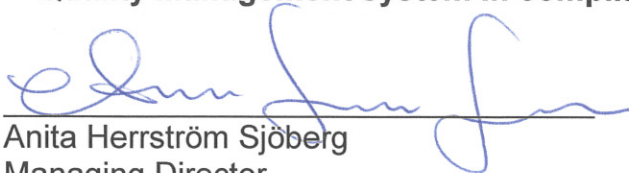
declare under our sole responsibility that the product

Xpert[®] CT Assay

Ref. No: GXCT-CE-10

to which this declaration relates is developed and manufactured in conformity with the requirements of Full Quality Assurance in the IVD Directive 98/79/EC Annex IV (LVFS 2001:7) and that the product is in conformity with the Essential Requirements of the Directive 98/79/EC Annex I (LVFS 2001:7) and Annex II LIST B for Chlamydia Testing.

In addition the above stated product have been developed and manufactured under a Quality Management system in compliance with ISO 13485:2003.



Anita Herrström Sjöberg
Managing Director

20120525

Date

Scope of the CE label:

Xpert[®] CT Assay performed in the GeneXpert system.