

# Declaration of Conformity

Cepheid AB  
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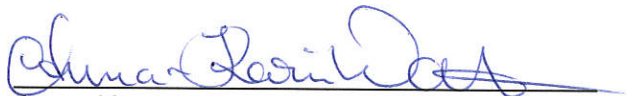
declare under our sole responsibility that the product

**Xpert® C.difficile BT**


Ref. No GXCDIFFBT-CE-10

to which this declaration relates is developed and manufactured in conformity with the requirements of Full Quality Assurance in the Directive 98/79/EC Annex III (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).

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



Anna Karin Wahlström  
Director, Regulatory & Quality Assurance



Date

**Scope of the CE label:**

Xpert C.difficile BT performed performed in the GeneXpert® DX System or GeneXpert® Infinity Systems