LLOYD'S REGISTER QUALITY ASSURANCE LIMITED
Verification of Manufactured Product
in accordance with the requirements of the
***in vitro* Diagnostic Medical Devices Directive 98/79/EC and the**
Medical Devices Regulations 2002:618

As required by Annex IV, Clause 6 of the above Directive and Regulations for products listed in Annex II List A, LRQA have conducted a review of the manufacturer's Quality Control Reports and the test results from LRQA's authorised sub-contractor of the corresponding production samples for the products and batches listed below.

Manufacturer's Name and Address: Cepheid AB, Röntgenvägen 5, SE-171 54 Solna, Sweden			
LRQA Batch Verification Document Dated:		22/08/2017	
LRQA Approval of Conformity Certificate No.:		4000228	
LRQA Design Examination Certificate No.:		0088/4000228/00167	
PEI Test Report No.:	NAT0563 CE/17	Dated:	20/12/2017
Product Description:	Xpert HIV-1 Viral Load (Product code: GXHIV-VL-CE-10)		
Product Batch No(s): Expiry Date:	1000083190 / 33801 2018-11-04		
Comments (if applicable):			

The products and batches listed above are in conformity with the agreed criteria and conditions as defined in the LRQA Batch Verification Document signed and dated 22nd August 2017. This statement of conformity is applicable only to the products and batches listed herein, including sublots of the same product and batch.

for and on behalf of LRQA Ltd

Date: 20/12/2017