Cepheid

# EC DECLARATION OF CONFORMITY

**Manufacturer:**

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

**Product name:** Xpert® HIV-1 Qual XC
**Catalogue number(s):** GXHIV-QA-XC-CE-10

We, the manufacturer, hereby declare, under our sole responsibility, that the product(s) stated above conforms to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (IVDD), (LVFS 2001:7).

**Product classification**: Annex II, list A
**Conformity Assessment route**: Annex IV
**Notified Body:** BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands
Notified Body number: 2797
EC Certificate – Full Quality Assurance: CE 708525
EC Design-Examination Certificate: CE 742686

Signed on behalf of Cepheid AB by:

Lena Kirsel

Signature
*Lena Kirsel*
*Senior Manager of Regulatory Affairs*

February 2, 2023

Date of Issue

**Place of Issue:** Solna, Sweden

*This Declaration of Conformity (DoC) has been issued due to an update made to the limitation statement for the device. This update does not impact the design or intended use of the device, hence the update made is not deemed a significant change according to MDCG 2022-6 and are allowable under the IVDR (EU) 2017/746 Article 110(3) Transitional Provisions as amended by Regulation (EU) 2022/112. The preceding DoC for the device was issued on May 23, 2022 and should be used in conjunction with this DoC.

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Signature
*Lena Kirsel*
*Senior Manager of Regulatory Affairs*

May 23, 2022
Date of Issue

**Place of Issue:** Solna, Sweden