Cepheid®

EC DECLARATION OF CONFORMITY

Manufacturer:

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Product name: Xpert® CT/NG
Catalogue number(s): GXCT/NGX-CE-10
GXCT/NGX-CE-120

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 B
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

Signed on behalf of Cepheid AB by:

Signature
Lena Kirsel
Senior Manager of Regulatory Affairs

May 23, 2022
Date of Issue

Place of Issue: Solna, Sweden