EU DECLARATION OF CONFORMITY

	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA Single Registration Number (SRN): US-MF-000010979
EC REP	Cepheid Europe SAS Vira Solelh 81470 Maurens-Scopont France Single Registration Number (SRN): FR-AR-000001368
Device Trade Name	Xpert® Urine Transport Reagent Kit
Basic UDI-DI	081164701-GXUTR-2L
REF	GXUTR-CE-30
Device Intended Purpose	**Intended Use** The Xpert® Urine Transport Reagent Kit is designed to collect, preserve, and transport urine specimens to the laboratory for analysis with the Xpert® Bladder Cancer Monitor and the Xpert® Bladder Cancer Detection tests. **Intended User / Environment** The Xpert Urine Transport Reagent Kit is intended to be used by trained users.

We, as the manufacturer of the device take sole responsibility for and hereby declare that the above mentioned device meets the provisions of the following Regulation:

Regulation EU 2017/746 on *in vitro* Diagnostic Medical Devices	
Risk Class	A ☒ B☐ C☐ D☐
Classification Rule	Annex VIII, Rule: 5 (c) specimen receptacle
Conformity Assessment Route	☐ Annex IX(I) Quality Management System ☐ Annex IX(II) Technical Documentation ☐ Annex X Type Examination ☐ Annex XI Production Quality Assurance ☒ Annex II & III (class A only)
Common Specification	Not applicable
Notified Body	Not applicable
Notified Body Number	Not appliable
Certificate(s)	Not applicable

Signed on behalf of Cepheid by:

Signature

September 27, 2022
Date of Issue

Lena Kirsel
Senior Manager of Regulatory Affairs
Regulatory Affairs

Place of Issue: Solna, Sweden