


EU DECLARATION OF CONFORMITY

	<p>Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA</p> <p>Single Registration Number (SRN): US-MF-000010979</p>
EC REP	<p>Cepheid Europe SAS Vira Solelh 81470 Maurens-Scopont France</p> <p>Single Registration Number (SRN): FR-AR-000001368</p>
Device Trade Name	Xpert® Urine Transport Reagent Kit
Basic UDI-DI	081164701-GXUTR-2L
REF	GXUTR-CE-30
Device Intended Purpose	<p>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.</p> <p>Intended User / Environment The Xpert Urine Transport Reagent Kit is intended to be used by trained users.</p>

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:

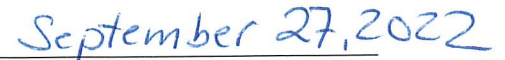
Regulation EU 2017/746 on <i>in vitro</i> Diagnostic Medical Devices	
Risk Class	A <input checked="" type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/>
Classification Rule	Annex VIII, Rule: 5 (c) specimen receptacle
Conformity Assessment Route	<input type="checkbox"/>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

Signed on behalf of Cepheid by:



Signature

Lena Kirsell
Senior Manager of Regulatory Affairs
Regulatory Affairs



Date of Issue

Place of Issue: Solna, Sweden