EU Declaration of Conformity

digene® HC2 DNA Collection Device

REF 619234

Basic UDI-DI 4053228MDIGENE0010000016Q

GMDN 32368

Intended Purpose The digene Hybrid Capture® 2 (HC2) DNA Collection Device is intended for the collection and transport of physician-collected cervical specimens and self-collected vaginal specimens to be tested with the digene HC2 High-Risk HPV DNA Test®. THIS DEVICE IS NOT INTENDED FOR PAP COLLECTION.

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Germantown, MD 20874
USA

SRN / Single Registration Number
US-MF-000014502

EC REP QIAGEN GmbH
QIAGEN Strasse 1
40724 Hilden
GERMANY

SRN / Single Registration Number
DE-AR-000004971

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives:

Regulation EU 2017/745 on Medical Devices

RISK CLASS
☒ I ☐ IIa ☐ IIb ☐ III

CONFORMITY ASSESSMENT PROCEDURE

ANNEX II and III Conformity Assessment

Davide Manissero

Signature

QIAGEN Manchester Ltd — Issued in

October 19, 2021 — Date

Davide Manissero MD, MRCPCH, MSc, DTM&H
Name

Chief Medical Officer
VP, Head of Clinical, Medical, Regulatory Affairs (CMRA Unit)
Function