# EU DECLARATION OF CONFORMITY

**MANUFACTURER:** Bio-Rad
**ADDRESS: 3 boulevard Raymond Poincaré, 92430 Marnes-la Coquette, France**

**EUROPEAN AUTHORIZED REPRESENTATIVE:** Bio-Rad
**ADDRESS:** 3 Boulevard Raymond Poincaré, 92430 Marnes-la-Coquette, France

**PRODUCT(S) NAME(S) and CATALOG NUMBER(S): Geenius™ HIV 1/ 2 Confirmatory Assay – Code 72460**

**GENERIC DEVICE GROUP CODE** (GMDN nomenclature):
48454

**GENERIC DEVICE GROUP TERM** (GMDN Nomenclature):
HIV1 / HIV2 antibody, IVD kit immunochromatographic test (ITC) rapid

We hereby declare that the above mentioned product(s) meet(s) the provisions of the following Directives

- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* Diagnostic medical devices

**CLASSIFICATION:**

- ☒ ANNEX II-A
- ☐ ANNEX II-B
- ☐ DEVICE FOR SELF TESTING
- ☐ OTHER DEVICE

**CONFORMITY ROUTE**

- ☐ ANNEX III
- ☒ ANNEX IV.3 Full Quality System
- ☒ ANNEX IV.4 Product Design Examination

**EC CERTIFICATE No.:24927**
Name of Notified Body :LNE/G-MED
Notified Body Identification No.: 0459
Expiration Date : 3rd February 2023

- ☐ ANNEX V Type Examination

**EC CERTIFICATE No.:**
Name of Notified Body :
Notified Body Identification No.:
Expiration Date :

- ☐ ANNEX VII Production Quality System

**NEW PRODUCT(S)** (Notification according to article 10 point 4) ☐ YES ☒ NO

**Date of the first issuance of the EU Declaration of Conformity**: April 4th, 2013

| Signature | Marnes-la-Coquette<br>Issued in | February,07th 2018<br>Date |
|---|---|---|
| Fernez Sylvie<br>Name | Regulatory Affairs Manager<br>Function | |