



## EU DECLARATION OF CONFORMITY

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

**EUROPEAN AUTHORIZED REPRESENTATIVE:** /  
**ADDRESS:**

**PRODUCT(S) NAME(S) and CATALOG NUMBER(S):** See annex

**GENERIC DEVICE GROUP CODE (GMDN nomenclature):**  
CT 796

**GENERIC DEVICE GROUP TERM (GMDN Nomenclature):**  
Shigella IVDs

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

☐ ANNEX V Type Examination

**EC CERTIFICATE No.:**

**Name of Notified Body :**

**Notified Body Identification No.:**

**Expiration Date :**

**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:** Septembre 12, 2003

Signature

Sylvie FERNEZ

Name

Marnes-la-Coquette

Issued in

March, 07th, 2018

Date

Regulatory Affairs Manager

Function

This document contains proprietary information. Do not reproduce, transfer to other documents, or disclose to others without prior authorization.



## EU DECLARATION OF CONFORMITY

Device name	Cat#
Antiserum Shigella flexneri polyvalent	57151
Antiserum Shigella dysenteriae monovalent	57161
Antiserum Shigella sonnei polyvalent	57171
Antiserum Shigella dysenteriae polyvalent A1+ A2	57182
Antiserum Shigella boydii polyvalent C1+ C2 + C3	57183

This document contains proprietary information. Do not reproduce, transfer to other documents, or disclose to others without prior authorization.