



GLOBAL FORM

04.01.GLB.FRM.00125

EU DECLARATION OF CONFORMITY

Division/Group: RAQA

Revision: 1

MANUFACTURER: Bio-Rad Laboratories, Inc.  
ADDRESS: 4000 Alfred Nobel Drive, Hercules, CA 94547, United States

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

PRODUCT(S) NAME(S) and CATALOG NUMBER(S):

Hemoglobin Capillary Collection System (HCCS) and associated components :

Hemoglobin Capillary Collection System (HCCS) (5 Tests) 196-2051;  
Hemoglobin Capillary Collection System (HCCS) (100 Tests) 196-2052;  
Hemoglobin Capillary Collection System (HCCS) (5000 Tests) 196-2053;  
Separately Available Items:  
Capillaries 196-2100;  
Capillary holders 196-1054;

GENERIC DEVICE GROUP CODE (GMDN nomenclature):  
35968

GENERIC DEVICE GROUP CODE:

EDMS Nomenclature: N/A  
GMDN Nomenclature: 53313

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.:  
Name of Notified Body :  
Notified Body Identification No.:  
Expiration Date :

- 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: 10/08/2019 (Revision 1)

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APPLICABLE HARMONIZED STANDARDS:

ISO 13485:2016, NF EN ISO 13485:2016, EN ISO 14971:2012, EN 13612:2002/AC:2002, EN 13641:2002, EN ISO 15223-1:2016, EN ISO 18113-2:2011, EN ISO 23640:2015

Signature

Hercules, CA

Issued in

Oct 9, 2019

Date

Jackie Buckley

Name

RA Manager

Function

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