



## EC DECLARATION OF CONFORMITY

**MANUFACTURER:** DIESE DIAGNOSTICA SENESE SPA  
STRADA DEI LAGHI 39  
53035 MONTERIGGIONI (SI),  
ITALY

**EUROPEAN REPRESENTATIVE:** //

**PRODUCT:** **CHORUS HELICOBACTER PYLORI IgA CONTROL  
SERUM**

**CODE:** **81509**

**CLASSIFICATION:** IVD NOT IN ANNEX II OR SELF-TESTING IVD

**CONFORMITY ASSESSMENT ROUTE:** ANNEX APPLIED N° III

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PREVISIONS OF THE COUNCIL DIRECTIVE 98/79EC FOR IN VITRO DIAGNOSTIC MEDICAL DEVICE. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

**NOTIFIED BODY:** NOT NECESSARY

**(EC) CERTIFICATE:** N.A.

**START OF CE-MARKING:** FEBRUARY 2011

**REVISION:** 7

**PLACE, DATE OF ISSUE:** MONTERIGGIONI, 24 MAY 2022

**EXPIRY DATE:** 25 MAY 2026

**THE PRESENT EC DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE AND EXCLUSIVE RESPONSIBILITY OF THE MANUFACTURER.**

**SIGNATURE:**

  
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CHIARA MUZZI  
REGULATORY AFFAIRS MANAGER

THIS IS THE CERTIFIED COPY OF THE ORIGINAL DOCUMENT STORED IN ARCHIVE OF DIESE DIAGNOSTICA SENESE SPA

ISSUED: MONTERIGGIONI, 24/05/2022

  
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MAGDALENA STOCZKO  
REGULATORY SUPERVISOR