

## EC DECLARATION OF CONFORMITY

MANUFACTURER: DIESSE DIAGNOSTICA SENESE SPA STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SI), **ITALY** // **EUROPEAN REPRESENTATIVE: CHORUS BRUCELLA IgG** PRODUCT: CODE: 81164 **CLASSIFICATION:** IVD NOT IN ANNEX II OR SELF-TESTING IVD CONFORMITY ASSESSMENT ROUTE: ANNEX APPLIED Nº 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: DECEMBER 2019 REVISION: 3 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: **REGULATORY AFFAIRS MANAGER** 

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

ISSUED: MONTERIGGIONI, 24/05/2022

MAGDALENA STOCZKO REGULATORY SUPERVISOR

M. Stoules