

MANUFACTURER: **DIESSE DIAGNOSTICA SENESE SPA** STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SI), **ITALY EUROPEAN REPRESENTATIVE:** // PRODUCT: CHORUS CFT COXSACKIE VIRUS B MIX CODE: 85251 **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 2004 **REVISION:** 8 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: CHIARA MUZZI **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