



EC DECLARATION OF CONFORMITY

MANUFACTURER:

DIESE DIAGNOSTICA SENESE SPA
STRADA DEI LAGHI 39
53035 MONTERIGGIONI (SI)
ITALY

EUROPEAN REPRESENTATIVE:

//

PRODUCT:

CHORUS RUBELLA IgG

CODE:

81030

CLASSIFICATION:

IVD IN ANNEX II B

CONFORMITY ASSESSMENT ROUTE:

ANNEX APPLIED N° IV EXCLUDING (4, 6)

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:

TÜV SÜD PRODUCT SERVICE GMBH
ZERTIFIZIERSTELLE
RIDLERST. 65 – 80339 MÜNCHEN
GERMANY
No. 0123

(EC) CERTIFICATE:

V1 056726 0002 Rev. 00

START OF CE-MARKING:

FEBRUARY 2004

REVISION:

16

PLACE, DATE OF ISSUE:

MONTERIGGIONI, 11 MAY 2022

EXPIRY DATE:

26 MAY 2025

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 DIESE DIAGNOSTICA SENESE SPA

ISSUED: MONTERIGGIONI, 11/05/2022

MAGDALENA STOCZKO
REGULATORY SUPERVISOR