

MANUFACTURER:

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

SINGLE REGISTRATION NUMBER

IT-MF-000013311

AUTHORIZED REPRESENTATIVE:

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PRODUCT:  
CODE:**VACU-TEC DOUBLE LABEL  
10200/W**

INTENDED PURPOSE:

Single-use vacuum tube containing anticoagulant (sodium citrate) to be used for manual sampling and whole blood collection for the determination of Erythrocyte Sedimentation Rate (ESR) in DIESSSE VES instruments. All the tubes must be used by professional laboratory users only.

BASIC UDI-DI

803389132 ESRTUBES00 JL

UDI-DI

08033891320546

RISK CLASS:

CLASS A

CLASSIFICATION RULE:

RULE 5C

CONFORMITY ASSESSMENT ROUTE:

ARTICLE 17, ANNEX II and ANNEX III

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT IS IN CONFORMITY WITH **REGULATION (EU) 2017/746** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON IN VITRO DIAGNOSTIC MEDICAL DEVICE. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

REFERENCE TO ANY CS APPLIED:

NOT APPLICABLE

NOTIFIED BODY:

NOT NECESSARY

(EU) CERTIFICATE:

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REVISION:

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PLACE, DATE OF ISSUE:

MONTERIGGIONI, 23 MAY 2022

EXPIRY DATE:

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

SIGNATURE:



MARIA CLAUDIA ALCARO  
PERSON RESPONSIBLE FOR THE REGULATORY  
COMPLIANCE

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

ISSUED: MONTERIGGIONI, 2022-05-23

*M. Stoczko*

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MAGDALENA STOCZKO  
REGULATORY SUPERVISOR