EU DECLARATION OF CONFORMITY

MANUFACTURER:	DIESSE DIAGNOSTICA SENESE SPA STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SI), ITALY
SINGLE REGISTRATION NUMBER	IT-MF-000013311
AUTHORIZED REPRESENTATIVE:	NOT APPLICABLE
PRODUCT: CODE:	VACU-TEC S.C. STERILE 10602
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 DIESSE VES instruments. The tubes must be used by professional laboratory users only.
BASIC UDI-DI	803389132ESRTUBES00JL
UDI-DI	08033891321093
RISK CLASS:	CLASS A
CLASSIFICATION RULE:	RULE 5C
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX

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:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTAßE 65 – 80339 MUNICH GERMANY No. 0123
(EU) CERTIFICATE:	V11 056726 0003 Rev. 00
REVISION:	0
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 17 NOVEMBER 2023
EXPIRY DATE:	2027-07-18

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, 2023-11-17

MAGDALENA STOCZKO
REGULATORY SUPERVISOR