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:	//
PRODUCT: CODE:	ESR CONTROL 10430
INTENDED PURPOSE:	Dual-level control material to be used for monitoring the precision of DIESSE instruments used for the determination of Erythrocyte Sedimentation Rate (ESR). It must only be used by professional laboratory personnel.
BASIC UDI-DI	803389132 ESRCTRL00 N6
UDI-DI	08033891321017
RISK CLASS:	CLASS A
CLASSIFICATION RULE:	RULE 5B
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:	//
REVISION:	0
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 24 MAY 2022
EXPIRY DATE:	//

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, 2022-05-24

M. Stoczko

MAGDALENA STOCZKO
REGULATORY SUPERVISOR