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:	**CHORUS Promonitor USTEKINUMAB** **86712**
INTENDED PURPOSE:	CHORUS Promonitor USTEKINUMAB is an immunoassay kit for automated quantitative detection of USTEKINUMAB (UTK) in human serum using a disposable device applied on the CHORUS TRIO instrument. The product, used in conjunction with other clinical and laboratory findings, is useful as an aid in the management of patients treated with USTEKINUMAB (UTK), like patients with inflammatory bowel disease (IBD), psoriasis and rheumatic diseases. It must be used by professional laboratory users only.
BASIC UDI-DI	803389132CHORUSUTK00ED
UDI-DI	08033891324506
RISK CLASS:	CLASS B
CLASSIFICATION RULE:	RULE 6
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:	V12 056726 0006 Rev. 01
REVISION:	0
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 31 JANUARY 2024

EXPIRY DATE:	2027-06-26

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, 2024-01-31

MAGDALENA STOCZKO
REGULATORY SUPERVISOR