

MANUFACTURER:	DIESSSE DIAGNOSTICA SENESE SPA STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SI), ITALY
SINGLE REGISTRATION NUMBER	IT-MF-000013311
AUTHORIZED REPRESENTATIVE:	NOT APPLICABLE
PRODUCT: CODE:	<b>CHORUS MPO</b> <b>86068 - 86068/12</b>
INTENDED PURPOSE:	<p>CHORUS MPO (REF 88062-88062/12) is an immunoassay kit for the semiquantitative determination of anti-myeloperoxidase (MPO) antibodies.</p> <p>As the MPO antibodies are used as a serological marker of autoimmune ANCA Associated vasculitis (AAV), the kit is used as an aid to related diagnosis.</p> <p>The test, performed in human serum, using a disposable device applied on the CHORUS/CHORUS TRIO instruments, must be used by professional laboratory users only.</p>
BASIC UDI-DI	803389132CHORUSMPO00BD
UDI-DI	08033891323530 - 08033891329426
RISK CLASS:	CLASS B
CLASSIFICATION RULE:	RULE 6
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX
<p>WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT IS IN CONFORMITY WITH <b>REGULATION (EU) 2017/746</b> 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.</p>	
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. 02
REVISION:	1
PLACE, DATE OF ISSUE:	MONTERIGGIONI, 05 JUNE 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, 2024-06-05



MAGDALENA STOCZKO  
REGULATORY SUPERVISOR