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| MANUFACTURER:   | DIESSE DIAGNOSTICA SENESE SPA<br>STRADA DEI LAGHI 39<br>53035 MONTERIGGIONI (SI),<br>ITALY  |
| SINGLE REGISTRATION NUMBER  | IT-MF-000013311   |
| AUTHORIZED REPRESENTATIVE:  | NOT APPLICABLE  |
| PRODUCT:<br>CODE:   | <b>CHORUS CLIA PROGRANULIN<br/>82100</b>  |
| INTENDED PURPOSE:   | <p>CHORUS CLIA PROGRANULIN (REF 82100) is an immunoenzymatic assay kit for the automated quantitative determination of Progranulin in human plasma (EDTA) using a disposable device applied on the CHORUS EVO instruments.</p> <p>Progranulin is a biomarker that is particularly useful in the evaluation of neurodegenerative diseases (Alzheimer and Frontotemporal Dementia); its assay is performed as an aid to related diagnosis.</p> <p>It is to be used by professional laboratory personnel only.</p> |
| BASIC UDI-DI  | 803389132CPGN009P   |
| UDI-DI  | 08033891328450  |
| 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<br>RIDLERSTAßE 65 – 80339 MUNICH<br>GERMANY<br>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