

MANUFACTURER:

DIESSE DIAGNOSTICA SENESE SPA
STRADA DEI LAGHI 39
53035 MONTERIGGIONI (SI),
ITALY

SINGLE REGISTRATION NUMBER

IT-MF-000013311

AUTHORIZED REPRESENTATIVE:

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PRODUCT:
CODE:

CHORUS COPROCOLLECT
86602

INTENDED PURPOSE:

Single-use device for manual collection of the amount of faeces required to perform the Chorus Calprotectin test (REF. 86600-86600/C03-86601).
It must only be used by professional laboratory personnel.

BASIC UDI-DI

803389132 COPROCOLLECT00 SU

UDI-DI

08033891329525

RISK CLASS:

CLASS A

CLASSIFICATION RULE:

RULE 5C

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:

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REVISION:

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PLACE, DATE OF ISSUE:

MONTERIGGIONI, 23 MAY 2022

EXPIRY DATE:

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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,

2022-05-23

M. Stoczko

MAGDALENA STOCZKO
REGULATORY SUPERVISOR