

MANUFACTURER:

DIESSSE 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 CLEANING SOLUTION 2000**  
**83609**

INTENDED PURPOSE:

To be used in CHORUS instruments as a wash solution for the tubes and as resuspending solution for the lyophilized products of the CFT line.  
It must only be used by professional laboratory personnel.

BASIC UDI-DI

803389132CHORUS0028

UDI-DI

08033891322571

RISK CLASS:

CLASS A

CLASSIFICATION RULE:

RULE 5A

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, 2022-06-15

*M. Stoczko*

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MAGDALENA STOCZKO  
REGULATORY SUPERVISOR