

SIGNATURE:

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: | // |
| 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: | // |
| REVISION: | 0 |
| PLACE, DATE OF ISSUE: | MONTERIGGIONI, 23 MAY 2022 |
| EXPIRY DATE: | // |
| THE PRESENT EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE AND EXCLUSIVE RESPONSIBILITY OF THE MANUFACTURER. | |
| | Merie Olada Alcero |

MARIA CLAUDIA ALCARO
PERSON RESPONSIBLE FOR THE REGULATORY
COMPLIANCE

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THIS IS THE CERTIFIED COPY OF THE ORIGINAL DOCUMENT STORED IN ARCHIVE OF DIESSE DIAGNOSTICA SENESE SPA

ISSUED: MONTERIGGIONI, 2022-05-23

M. Stoales

MAGDALENA STOCZKO REGULATORY SUPERVISOR

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