



EC DECLARATION OF CONFORMITY

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| MANUFACTURER: | DIESSE DIAGNOSTICA SENESE SPA STRADA DEI LAGHI 39 53035 MONTERIGGIONI (SI), ITALY |
| EUROPEAN REPRESENTATIVE: | // |
| PRODUCT: CODE: | CHORUS SARS-CoV-2 IgA 81402 |
| CLASSIFICATION: | IVD NOT IN ANNEX II OR SELF-TESTING IVD |
| CONFORMITY ASSESSMENT ROUTE: | ANNEX APPLIED N° III |

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PREVISIONS OF THE COUNCIL DIRECTIVE 98/79EC FOR IN VITRO DIAGNOSTIC MEDICAL DEVICE. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

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| NOTIFIED BODY: | NOT NECESSARY |
| (EC) CERTIFICATE: | N.A. |
| START OF CE-MARKING: | JUNE 2020 |
| REVISION: | 3 |
| PLACE, DATE OF ISSUE: | MONTERIGGIONI, 24 MAY 2022 |
| EXPIRY DATE: | 25 MAY 2025 |

THE PRESENT EC DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE AND EXCLUSIVE RESPONSIBILITY OF THE MANUFACTURER.

SIGNATURE:

CHIARA MUZZI
REGULATORY AFFAIRS MANAGER

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

ISSUED: MONTERIGGIONI, 24/05/2022

MAGDALENA STOCZKO
REGULATORY SUPERVISOR