



EC DECLARATION OF CONFORMITY

MANUFACTURER:

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

EUROPEAN REPRESENTATIVE:

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PRODUCT:
CODE:

**ENZY-WELL CYTOMEGALOVIRUS IgM
91011, 91171**

CLASSIFICATION:

IVD IN ANNEX II B

CONFORMITY ASSESSMENT ROUTE:

ANNEX APPLIED N° IV EXCLUDING (4, 6)

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.

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH
ZERTIFIZIERSTELLE
RIDLERST. 65 – 80339 MÜNCHEN
GERMANY
No. 0123

(EC) CERTIFICATE:

VI 056726 0002 Rev. 00

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15

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

SIGNATURE:

CHIARA MUZZI
REGULATORY AFFAIRS MANAGER

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ISSUED: MONTERIGGIONI, 11/05/2022

MAGDALENA STOCZKO
REGULATORY SUPERVISOR