



ES PROHLÁŠENÍ O SHODĚ

VÝROBCE:

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

EVROPSKÝ
ZÁSTUPCE:

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PRODUKTY:

CHORUS ADENOVIRUS IgA	81198, 81198/12
CHORUS ADENOVIRUS IgG	81196, 81196/12
CHORUS ASPERGILLUS GALACTOMANNAN Ag	81178
CHORUS BORDETELLA PERTUSSIS TOXIN IgA	81274
CHORUS BORDETELLA PERTUSSIS TOXIN IgG	81272
CHORUS BORRELIA IgG	81046, 81046/C03
CHORUS BORRELIA IgG CSF	81048
CHORUS BORRELIA IgM	81047, 81047/C03
CHORUS BRUCELLA IgG	81164
CHORUS BRUCELLA IgM	81166
CHORUS CHIKUNGUNYA IgG	81133
CHORUS CLOSTRIDIUM DIFFICILE GDH	81168
CHORUS CLOSTRIDIUM DIFFICILE A/B TOXINS	81170
CHORUS DENGUE IgG	81154
CHORUS DENGUE IgM	81156
CHORUS DENGUE IgM CAPTURE	81157
CHORUS DIPHTHERIA IgG	81266, 81266/12
CHORUS ECHINOCOCCUS IgG	81284
CHORUS EPSTEIN BARR EARLY ANTIGEN IgG	81058, 81058/12
CHORUS EPSTEIN BARR EARLY ANTIGEN IgM	81059, 81059/12
CHORUS EPSTEIN BARR EBNA IgG	81057
CHORUS EPSTEIN BARR VCA IgG	81055
CHORUS EPSTEIN BARR VCA IgM II	81054
CHORUS HELICOBACTER PYLORI IgA	81062
CHORUS HELICOBACTER PYLORI IgG	81060
CHORUS HELICOBACTER PYLORI Ag	81063
CHORUS HERPES SIMPLEX 1+2 IgG	81020
CHORUS HERPES SIMPLEX 1+2 IgM	81021
CHORUS HERPES SIMPLEX 2 IgG RECOMBINANT	81029
CHORUS HSV 1 SCREEN	81018
CHORUS HSV 2 SCREEN	81019
CHORUS INFLUENZA A IgA	81192, 81192/12
CHORUS INFLUENZA A IgG	81190, 81190/12
CHORUS INFLUENZA B IgA	81195, 81195/12
CHORUS INFLUENZA B IgG	81193, 81193/12
CHORUS LEGIONELLA PNEUMOPHILA 1-6 IgG	81090, 81090/12
CHORUS LEGIONELLA PNEUMOPHILA 1 IgG	81091, 81091/12
CHORUS LEGIONELLA PNEUMOPHILA IgM	81093, 81093/12
CHORUS LEGIONELLA URINARY ANTIGEN	81301
CHORUS MEASLES IgG	81072
CHORUS MEASLES IgM	81073, 81073/12

CHORUS MUMPS IgG	81075
CHORUS MUMPS IgM	81076, 81076/12
CHORUS MYCOPLASMA PNEUMONIAE IgA	81033
CHORUS MYCOPLASMA PNEUMONIAE IgG	81034
CHORUS MYCOPLASMA PNEUMONIAE IgM	81035
CHORUS PARVOVIRUS B19 IgG	81150
CHORUS PARVOVIRUS B19 IgM	81152
CHORUS POLIOVIRUS IgG	81264, 81264/12
CHORUS Q-FEVER PHASE II IgG	81171
CHORUS Q-FEVER PHASE II IgM	81172
CHORUS RESPIRATORY SYNCYTIAL VIRUS IgA	81037, 81037/12
CHORUS RESPIRATORY SYNCYTIAL VIRUS IgG	81036, 81036/12
CHORUS SARS-CoV-2 ANTIGEN	81410
CHORUS SARS-CoV-2 IgA	81402
CHORUS SARS-CoV-2 IgG	81400
CHORUS SARS-CoV-2 IgM	81401
CHORUS SARS-CoV-2 "NEUTRALIZING" Ab	81408
CHORUS SARS-CoV-2 SCREEN SERUM	81406
CHORUS suPAR	81412
CHORUS suPAR Extended	81414
CHORUS SYPHILIS SCREEN RECOMBINANT	81100
CHORUS TETANUS IgG	81270, 81270/12
CHORUS TICK-BORNE ENCEPHALITIS VIRUS IgG	81276
CHORUS TICK-BORNE ENCEPHALITIS VIRUS IgM	81277
CHORUS TOSCANA VIRUS IgG	81067, 81067/12
CHORUS TOSCANA VIRUS IgM	81068, 81068/12
CHORUS TOXOCARA IgG	81280
CHORUS TREPONEMA IgG	81050, 81050/12
CHORUS TREPONEMA IgM	81051, 81051/12
CHORUS VARICELLA IgG	81078
CHORUS VARICELLA IgM	81079, 81079/12
CHORUS WEST NILE VIRUS IgG	81174
CHORUS WEST NILE VIRUS IgM	81176
CHORUS ZIKA IgG	81158
CHORUS ZIKA IgM CAPTURE	81161

KLASIFIKACE: IVD VYJMA PŘÍLOHY II NEBO IVD PRO SEBETESTOVÁNÍ

POSTUP
POSUZOVÁNÍ SHODY: DLE PŘÍLOHY III

PROHLAŠUJEME TÍMTO, ŽE VÝŠE UVEDENÉ PRODUKTY JSOU V SOULADU SE SMĚRNICÍ RADY 98/79EC PRO IN VITRO DIAGNOSTIKU. VEŠKERÁ SOUVISEJÍCÍ DOKUMENTACE JE UCHOVÁNA V PROSTORÁCH VÝROBCE.

NOTIFIKOVANÁ OSOBA: NEVYŽADOVÁNA

(EC) CERTIFIKÁT: N.A.

DATUM ZAHÁJENÍ
OZNAČENÍ CE: ÚNOR 2004
S VÝJIMKOU:

2009	CHORUS LEGIONELLA PNEUMOPHILA IgG, CHORUS LEGIONELLA PNEUMOPHILA IgM
2010	CHORUS INFLUENZA A IgA, CHORUS INFLUENZA A IgG, CHORUS INFLUENZA B IgA, CHORUS INFLUENZA B IgG, CHORUS ADENOVIRUS IgA , CHORUS ADENOVIRUS IgG
2011	CHORUS MYCOPLASMA PNEUMONIAE IgA
2012	CHORUS RESPIRATORY SYNCYTIAL VIRUS IgA, CHORUS RESPIRATORY SYNCYTIAL VIRUS IgG
2013	CHORUS HERPES SIMPLEX 2 IgG RECOMBINANT
2015	CHORUS EPSTEIN-BARR VCA IgM II, CHORUS LEGIONELLA URINARY ANTIGEN, CHORUS BORRELIA IgG, CHORUS BORRELIA IgM, CHORUS POLIOVIRUS IgG
2016	CHORUS BORRELIA IgG CSF, CHORUS CHIKUNGUNYA IgG, CHORUS DIPHTHERIA IgG, CHORUS TETANUS IgG, CHORUS PARVOVIRUS B19 IgG, CHORUS PARVOVIRUS B19 IgM
2017	CHORUS HELICOBACTER PYLORI Ag, CHORUS TOXOCARA IgG, CHORUS TICK-BORNE ENCEPHALITIS VIRUS IgG, CHORUS TICK-BORNE ENCEPHALITIS VIRUS IgM, CHORUS CLOSTRIDIUM DIFFICILE GDH CHORUS CLOSTRIDIUM DIFFICILE A/B TOXINS, CHORUS ECHINOCOCCUS IgG
2018	CHORUS DENGUE IgG, CHORUS DENGUE IgM, CHORUS BORDETELLA PERTUSSIS TOXIN IgA, CHORUS BORDETELLA PERTUSSIS TOXIN IgG
2019	CHORUS Q-FEVER PHASE II IgG, CHORUS Q-FEVER PHASE II IgM, CHORUS BRUCELLA IgG, CHORUS BRUCELLA IgM
2020	CHORUS SARS-CoV-2 IgA, CHORUS SARS-CoV-2 IgG, CHORUS SARS-CoV-2 IgM, CHORUS SARS-CoV-2 SCREEN SERUM, CHORUS SARS-CoV-2 ANTIGEN
2021	CHORUS SARS-CoV-2 "NEUTRALIZING" Ab, CHORUS ASPERGILLUS GALACTOMANNAN Ag, CHORUS ZIKA IgG
2022	CHORUS suPAR, CHORUS ZIKA IgM CAPTURE, CHORUS DENGUE IgM CAPTURE, suPAR Extended, CHORUS WEST NILE VIRUS IgG, CHORUS WEST NILE VIRUS IgM

REVIZE: 38

MÍSTO, DATUM VYDÁNÍ: MONTERIGGIONI, 13. BŘEZNA 2023

PLATNOST: 25 KVĚTEN 2025

VÝŠE UVEDENÉ ES PROHLÁŠENÍ O SHODĚ BYLO VYDÁNO NA VÝLUČNOU ODPOVĚDNOST VÝROBCE.

PODPIS:



CHIARA MUZZI
REGULATORY AFFAIRS MANAGER

TOTO JE CERTIFIKOVANÁ KOPIE ORIGINÁLNÍHO DOKUMENTU ULOŽENÉHO V ARCHIVU DIESSE DIAGNOSTICA SENESE SPA

VYDÁNO: MONTERIGGIONI, 13/03/2023



MAGDALENA STOCZKO
REGULATORY SUPERVISOR