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CE ATITIKTIES DEKLARACIJA

Šiuo dokumentu pažymime, kad priemonės apibūdintos žemiau, atitinka Europos direktyvos 98/79/EC nuostatas, taikomas diagnostiniams medicinos prietaisams ir taip pat Jungtinės Karalystės įstatymus instrumentams 2002 Nr. 618 „Medicinos prietaisų nuostatos“.

Deklaracija galioja IVD medicinos prietaisams, apibūdintiems žemiau, kurie yra mūsų pateikiami į rinką nuo datos arba po jos ir, kurie turi CE ženklą. Deklaracija taip pat galioja visiems IVD medicinos prietaisams, apibūdintiems žemiau, kurie yra pagaminti mūsų ir pateikiami į rinką nuo datos arba po jos trečiųjų šalių sutikimu ir, kurie turi CE ženklą. Visi patvirtinantys dokumentai, susiję su šia deklaracija yra saugomi gamintojo patalpose.

| Produkto kodas | Produkto apibūdinimas | IVD direktyvos klasifikacija | EDMS kodas |
|---------------------|--|--|--|
| Ivairūs (M-----) | MAST ASSURE ESCHERICHIA Coli Antisera – serologinei identifikacijai ir epidemiologiniams tipavimui su polivalentiniu ir monovalentiniu O (somatic) ir H (žiuželinis) tipavimo antiserumais. | Sertifikavimas skyrius III, išskyrus skyrelį 6 | 1501000000 (kodas registruotas 2003/03/24) |

Taikomi standartai: EN ISO 13485:2012, ISO 9001:2008, EN ISO 14971:2012, EN ISO 18113-1:2011,

EN ISO 18113-2:2011, EN ISO 15223-1:2012, EN ISO 15223-2:2010.

Deklaracija padaryta _____ Data: 2017 sausio 4
Dokumentas galioja iki : 2020 gruodžio 31



Product Names:
MAST ASSURE™ Escherichia coli Antisera - for Serological identification and epidemiological typing of bacteria

| Serial No. | Product code | Pack Size | Brand/Trade Name | Indented Purpose of the Medical Device Type |
|------------|--------------|-----------|---|--|
| | M12005 | 2ml | MAST ASSURE Escherichia Coli POLY D1 (O1, O26, O86a, O111, O119, O127a, O128) | Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| | M12006 | 2ml | MAST ASSURE Escherichia Coli POLY D2 (O44, O55, O125, O126, O146, O166) | Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| | M12007 | 2ml | MAST ASSURE Escherichia Coli POLY D3 (O18, O114, O142, O151, O157, O158) | Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| | M12008 | 2ml | MAST ASSURE Escherichia Coli POLY D4 (O6, O27, O78, O148, O159, O168) | Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| | M12009 | 2ml | MAST ASSURE Escherichia Coli POLY D5 (O20, O25, O63, O153, O167) | Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| | M12010 | 2ml | MAST ASSURE Escherichia Coli POLY D6 (O8, O15, O115, O169) | Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| | M12011 | 2ml | MAST ASSURE Escherichia Coli POLY D7 (O28ac, O112ac, O124, O136, O144) | Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| | M12012 | 2ml | MAST ASSURE Escherichia Coli POLY D8 (O29, O143, O152, O164) | Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| | M14263 | 2ml | MAST ASSURE Escherichia Coli POLY 2 Factors O26, O55, O111, O119, O126 | Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| | M14270 | 2ml | MAST ASSURE Escherichia Coli POLY 3 Factors O86, O114, O125, O127, O128 | Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| | M14287 | 2ml | MAST ASSURE Escherichia Coli POLY 4 Factors O44, O112, O124, O142 | Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |



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|------------|--------------|-----------|--|---|
| 79 | M12013 | 2ml | MAST ASSURE Escherichia coli - Mono factor O1 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 1 | M12014 | 2ml | MAST ASSURE Escherichia coli - Mono Factor O26 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 80 | M12015 | 2ml | MAST ASSURE Escherichia coli - Mono factor O86a | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 2 | M12016 | 2ml | MAST ASSURE Escherichia coli - Mono Factor O111 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 3 | M12017 | 2ml | MAST ASSURE Escherichia coli - Mono Factor O119 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 4 | M12018 | 2ml | MAST ASSURE Escherichia coli - Mono Factor O127a | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 81 | M12019 | 2ml | MAST ASSURE Escherichia coli - Mono factor O128 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 82 | M12020 | 2ml | MAST ASSURE Escherichia coli - Mono factor O44 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 83 | M12021 | 2ml | MAST ASSURE Escherichia coli - Mono factor O55 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 84 | M12022 | 2ml | MAST ASSURE Escherichia coli - Mono factor O125 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 85 | M12023 | 2ml | MAST ASSURE Escherichia coli - Mono factor O126 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 86 | M12024 | 2ml | MAST ASSURE Escherichia coli - Mono factor O146 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 87 | M12025 | 2ml | MAST ASSURE Escherichia coli - Mono factor O166 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 88 | M12026 | 2ml | MAST ASSURE Escherichia coli - Mono factor O18 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 89 | M12027 | 2ml | MAST ASSURE Escherichia coli - Mono factor O114 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 90 | M12028 | 2ml | MAST ASSURE Escherichia coli - Mono factor O142 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |



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|------------|--------------|-----------|---|---|
| 91 | M12029 | 2ml | MAST ASSURE Escherichia coli - Mono factor O151 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 5 | M12030 | 2ml | MAST ASSURE Escherichia coli - Mono Factor O157 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 92 | M12031 | 2ml | MAST ASSURE Escherichia coli - Mono factor O158 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 93 | M12032 | 2ml | MAST ASSURE Escherichia coli - Mono factor O6 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 94 | M12033 | 2ml | MAST ASSURE Escherichia coli - Mono factor O27 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 95 | M12034 | 2ml | MAST ASSURE Escherichia coli - Mono factor O78 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 96 | M12035 | 2ml | MAST ASSURE Escherichia coli - Mono factor O148 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 97 | M12036 | 2ml | MAST ASSURE Escherichia coli - Mono factor O159 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 98 | M12037 | 2ml | MAST ASSURE Escherichia coli - Mono factor O168 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 99 | M12038 | 2ml | MAST ASSURE Escherichia coli - Mono factor O20 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 100 | M12039 | 2ml | MAST ASSURE Escherichia coli - Mono factor O25 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 101 | M12040 | 2ml | MAST ASSURE Escherichia coli - Mono factor O63 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 102 | M12041 | 2ml | MAST ASSURE Escherichia coli - Mono factor O153 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 103 | M12042 | 2ml | MAST ASSURE Escherichia coli - Mono factor O167 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 104 | M12043 | 2ml | MAST ASSURE Escherichia coli - Mono factor O8 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 105 | M12044 | 2ml | MAST ASSURE Escherichia coli - Mono factor O15 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |



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|------------|--------------|-----------|---|---|
| 106 | M12045 | 2ml | MAST ASSURE Escherichia coli - Mono factor O115 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 107 | M12046 | 2ml | MAST ASSURE Escherichia coli - Mono factor O169 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 18 | M12047 | 2ml | MAST ASSURE Escherichia coli - Mono factor O28ac | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 109 | M12048 | 2ml | MAST ASSURE Escherichia coli - Mono factor O112ac | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 110 | M12049 | 2ml | MAST ASSURE Escherichia coli - Mono factor O124 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 111 | M12050 | 2ml | MAST ASSURE Escherichia coli - Mono factor O136 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 112 | M12051 | 2ml | MAST ASSURE Escherichia coli - Mono factor O144 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 113 | M12052 | 2ml | MAST ASSURE Escherichia coli - Mono factor O29 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 114 | M12053 | 2ml | MAST ASSURE Escherichia coli - Mono factor O143 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 115 | M12054 | 2ml | MAST ASSURE Escherichia coli - Mono factor O152 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 116 | M12055 | 2ml | MAST ASSURE Escherichia coli - Mono factor O164 | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |



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|------------|--------------|-----------|---|---|
| 117 | M12056 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-2 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 118 | M12057 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-4 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 119 | M12058 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-5 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 120 | M12059 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-6 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 121 | M12060 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-7 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 122 | M12061 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-9 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 123 | M12062 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-10 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 124 | M12063 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-11 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 125 | M12064 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-12 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 126 | M12065 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-16 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 127 | M12066 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-18 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 128 | M12067 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-19 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 129 | M12068 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-20 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 130 | M12069 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-21 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 131 | M12070 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-27 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 132 | M12071 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-28 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |



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|------------|--------------|-----------|---|---|
| 133 | M12072 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-34 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 134 | M12073 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-40 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 135 | M12074 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-41 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 136 | M12075 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-42 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 137 | M12076 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-45 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |
| 138 | M12077 | 5ml | MAST ASSURE Escherichia coli - Mono factor H-51 | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |

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|------------|--------------|-----------|--|---|
| 139 | M12001 | 51x 2ml | MAST ASSURE Escherichia coli Antiserum Set 1 consisting of 8 polyvalent and 43 O (OK) monovalent sera. | Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination. |
| 140 | M12002 | 22x 5ml | MAST ASSURE Escherichia coli Antiserum Set 2 consisting of 22 H monovalent sera. | Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method. |