



CERTIFICATE IVD NOTIFICATION



Mr. G. Elkayam CEO Obelis sa







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Order No.: GZ 9069-2020 Ref No.: GZ 9190-2020

| A | 100 | of Day | - | 7 |
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| | (| (Recital 29 of the Directive 98, | /79/ | /EC on | In Vitro | Diagnostic | Medical Devices) |
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| (*********** | | 5/LE OII III VILIO DIAGNOSTIC IVI | | | | | | |
|--------------|----------------------------|-----------------------------------|---|------------------------------------|--------------------|------------|--|--|
| # | Catalogue reference number | Commercial Name | Generic Device Term | Short description and intended use | GMDN/ EDMS Code | Class | | |
| 1. | NCVPCR-01 | MERIL | COVID-19 One-Step RT-PCR Kit | As per pack insert | 64747 | Non-Listed | | |
| | NCVPCR-02 | WEINE | COVID 15 ONE Step III Y SIXIII | | | | | |
| | NCVRPD-01 | | | | | | | |
| 2. | NCVRPD-02 | MERIL | COVID-19 IgG/IgM Rapid Test | As per pack insert | 64756 | Non-Listed | | |
| | NCVRPD-03 | | | | | | | |
| | MHLRPD-02 | | | | | | | |
| 3. | MHLRPD-03 | MERISCREEN Malaria | One Step Test for Malaria Pf/Pan Ag | As per pack insert | 52311 | Non-Listed | | |
| J. | MHLRPD-04 | Pf/Pan Ag | one step rest for Walana 11/1 all Ag | | | | | |
| | MHLRPD-05 | | | | | | | |
| 4. | MFLRPD-03 | MERISCREEN Malaria Pf/Pv | One Step Test for Malaria Pf/Pv Ag | As per pack insert | 52311 | Non-Listed | | |
| 4. | MFLRPD-04 | Ag | One Step rest for ividiana 11/1 v Ag | As per pack insert | 32311 | INOTIFICIO | | |
| | RPWMPH-02 | MERISCREEN Malaria Pf | One Step Test for Malaria Pf HRP II Ag | As per pack insert | 52336 | Non-Listed | | |
| 5. | RPWMPH-03 | HRP II Ag | | | | | | |
| | RPWMPH-04 | TIM II Ag | | | | | | |
| | HVWRPD-01 | | One Step test Rapid Test for detection of | | | | | |
| 6 | HVWRPD-02 | MERISCREEN HIV 1-2 WB | anti-HIV in Human Serun/Plasma/Whole | As per pack insert | 48447 | List A | | |
| | TIV WINI B-02 | | blood | | | | | |
| 7 | RPDHBV-01 | MERISCREEN HBsAg | One Step Rapid Test for HBsAg | As per pack insert | 48322 | List A | | |
| 8 | RPDHCV-01 | MERISCREEN HCV | One Step Rapid Test for HCV | As per pack insert | 30829 | List A | | |
| | | | Enzyme immunoassay for the detection | | | | | |
| 9 | HPCELI-01 | Merilisa HCV | of antibodies to Hepatitis C Virus in | As per pack insert | 48365 | List A | | |
| | | | human serum or plasma | 3 | | | | |

