

## Certificate of CE-Registration

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, **CEpartner4U BV** agrees to perform all duties and responsibilities as the Authorized Representative for

**PLASTI LAB S.A.R.L.**  
**Roumieh Industrial Area,**  
**Main Road, El Khoury Bldg**  
**Beirut-Lebanon**

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have accepted the manufacturer's medical device registrations by CEpartner4U as listed on the product list attached to the manufacturer's Declaration of Conformity:

### IVD devices were registered under number:

|  |   |
|--|---|
| <b>Group 1 : Petri Dishes</b>                  | <b>Notification No.:NL-CA002-2015-34259</b> |
| <b>Group 2 : Specimen Containers</b>           | <b>Notification No.:NL-CA002-2015-34260</b> |
| <b>Group 3 : Blood collection Tubes</b>        | <b>Notification No.:NL-CA002-2015-33912</b> |
| <b>Group 4 : Test Tubes</b>                    | <b>Notification No.:NL-CA002-2015-34261</b> |
| <b>Group 5 : Conical Tubes</b>                 | <b>Notification No.:NL-CA002-2015-34258</b> |
| <b>Group 6 : Vacuum Blood Collection Tubes</b> | <b>Notification No.:NL-CA002-2015-34358</b> |
| <b>Group 7 : Micropipette Tips</b>             | <b>Notification No.:NL-CA002-2015-34359</b> |
| <b>Group 8 : Inoculating Loops</b>             | <b>Notification No.:NL-CA002-2015-35333</b> |

*see appendix*

**with Dutch Competent Authorities as a consequently these IVD devices were entered in EUDAMED by Dutch Competent Authorities**

The manufacturer has provided CEpartner4U with all necessary documentation, together with an appropriate Declaration of Conformity that the IVD medical devices fulfil the essential requirements of Directive 98/79/EC.

Issue date: 2020-12-17



Olga Teirlinck  
Consultant CEpartner4U BV

**Appendix**

| Product Group 1: Petri Dishes |  | Notification No.: NL-CA002-2015-34259 |                   |                             |
|-------------------------------|--|---------------------------------------|-------------------|-----------------------------|
| Product Code(s)               | Product Description                                      | State                                 | Risk class / rule | First date of CE-compliance |
| PD-6X0                        | Petri Dish, 60mm, triple vents                           | Non-sterile                           | Low               | 03/02/2015                  |
| PD-6X0Y                       | Petri Dish, 60mm, triple vents                           | Non-sterile                           | Low               | 17/11/2020                  |
| PD-6X0YZ                      | Petri Dish, 60mm, triple vents                           | Non-sterile                           | Low               | 17/11/2020                  |
| PD-6X1                        | Petri Dish, 60mm, triple vents                           | Sterile                               | Low               | 03/02/2015                  |
| PD-6X1Y                       | Petri Dish, 60mm, triple vents                           | Sterile                               | Low               | 17/11/2020                  |
| PD-6X1YZ                      | Petri Dish, 60mm, triple vents                           | Sterile                               | Low               | 17/11/2020                  |
| PD-602                        | Petri Dish, 60mm, without vents                          | Non-sterile                           | Low               | 17/11/2020                  |
| PD-603                        | Petri Dish, 60mm, without vents                          | Sterile                               | Low               | 17/11/2020                  |
| PD-604                        | Petri Dish, 60mm, six vents                              | Non-sterile                           | Low               | 17/11/2020                  |
| PD-605                        | Petri Dish, 60mm, six vents                              | Sterile                               | Low               | 17/11/2020                  |
| PD-900                        | Petri Dish, 90mm x 14.2mm, triple vents                  | Non-sterile                           | Low               | 03/02/2015                  |
| PD-901                        | Petri Dish, 90mm x 14.2mm, triple vents                  | Sterile                               | Low               | 03/02/2015                  |
| PD-902                        | Petri Dish, 90mm x 14.2mm, triple vents, Double bag      | Sterile                               | Low               | 17/11/2020                  |
| PD-903                        | Petri Dish, 90mm x 14.2mm, single vent                   | Sterile                               | Low               | 17/11/2020                  |
| PD-991                        | Petri Dish, 90mm x 14.2mm, triple vents Perforated Bags  | Sterile                               | Low               | 17/11/2020                  |
| PD-950                        | Petri Dish, 90mm x 15.8mm, triple vents                  | Non-sterile                           | Low               | 03/02/2015                  |
| PD-951                        | Petri Dish, 90mm x 15.8mm, triple vents                  | Sterile                               | Low               | 03/02/2015                  |
| PD-952                        | Petri Dish, 90mm x 15.8mm, without vents                 | Sterile                               | Low               | 17/11/2020                  |
| PD-953                        | Petri Dish, 90mm x 15.8mm, single vents                  | Sterile                               | Low               | 17/11/2020                  |
| PD-993                        | Petri Dish, 90mm x 15.8mm, triple vents, Perforated Bags | Sterile                               | Low               | 17/11/2020                  |

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|----------|---|-------------|-----|------------|
| PD-920   | Petri Dish, 90mm, 2 compartments            | Non-sterile | Low | 03/02/2015 |
| PD-921   | Petri Dish, 90mm, 2 compartments            | Sterile     | Low | 03/02/2015 |
| PD-930   | Petri Dish, 90mm, 3 compartments            | Non-sterile | Low | 03/02/2015 |
| PD-931   | Petri Dish, 90mm, 3 compartments            | Sterile     | Low | 03/02/2015 |
| PD-960   | Petri Dish, 90mm x 16mm                     | Non-sterile | Low | 17/11/2020 |
| PD-961   | Petri Dish, 90mm x 16mm                     | Sterile     | Low | 17/11/2020 |
| PD-995   | Petri Dish, 90mm x 16mm,<br>Perforated Bags | Sterile     | Low | 17/11/2020 |
| PD-9X0YZ | Petri Dish 90mm                             | Non-sterile | Low | 17/11/2020 |
| PD-9X1YZ | Petri Dish 90mm                             | Sterile     | Low | 17/11/2020 |
| PD-140   | Petri Dish, 140mm, without vents            | Non-sterile | Low | 03/02/2015 |
| PD-141   | Petri Dish, 140mm, without vents            | Sterile     | Low | 03/02/2015 |
| PD-143   | Petri Dish, 140mm, Triple Vents             | Sterile     | Low | 17/11/2020 |

| Product Group 2: Specimen Container |                                   | Notification No.: NL-CA002-2015-34260 |                   |                             |
|-------------------------------------|-----------------------------------|---------------------------------------|-------------------|-----------------------------|
| Product Code(s)                     | Product Description               | State                                 | Risk class / rule | First date of CE-compliance |
| SCS-3X0                             | Specimen Container, 30ml PS       | Non-sterile                           | Low               | 12/02/2015                  |
| SCS-3X0Y                            | Specimen Container, 30ml PS       | Non-sterile                           | Low               | 17/11/2020                  |
| SCS-3X1                             | Specimen Container, 30ml PS       | Sterile                               | Low               | 12/02/2015                  |
| SCS-3X1Y                            | Specimen Container, 30ml PS       | Sterile                               | Low               | 17/11/2020                  |
| SCS-6X0                             | Specimen Container, 60ml PS       | Non-sterile                           | Low               | 12/02/2015                  |
| SCS-6X0Y                            | Specimen Container, 60ml PS       | Non-sterile                           | Low               | 17/11/2020                  |
| SCS-6X1                             | Specimen Container, 60ml PS       | Sterile                               | Low               | 12/02/2015                  |
| SCS-6X1Y                            | Specimen Container, 60ml PS       | Sterile                               | Low               | 17/11/2020                  |
| SCP-6X0                             | Specimen Container, 60ml PP       | Non-sterile                           | Low               | 12/02/2015                  |
| SCP-6X0Y                            | Specimen Container, 60ml PP       | Non-sterile                           | Low               | 17/11/2020                  |
| SCP-6X1                             | Specimen Container, 60ml PP       | Sterile                               | Low               | 12/02/2015                  |
| SCP-6X1Y                            | Specimen Container, 60ml PP       | Sterile                               | Low               | 17/11/2020                  |
| SSP-6X0                             | Specimen Container, Stool 60ml PP | Non-sterile                           | Low               | 12/02/2015                  |

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|-----------|---|-------------|-----|------------|
| SSP-6X0Y  | Specimen Container, Stool 60ml PP                 | Non-sterile | Low | 17/11/2020 |
| SSP-6X1   | Specimen Container, Stool 60ml PP                 | Sterile     | Low | 12/02/2015 |
| SSP-6X1Y  | Specimen Container, Stool 60ml PP                 | Sterile     | Low | 17/11/2020 |
| SCP-1X0   | Specimen Container, 120ml PP                      | Non-sterile | Low | 12/02/2015 |
| SCP-1X0Y  | Specimen Container, 120ml PP                      | Non-sterile | Low | 17/11/2020 |
| SCP-1X1   | Specimen Container, 120ml PP                      | Sterile     | Low | 12/02/2015 |
| SCP-1X1Y  | Specimen Container, 120ml PP                      | Sterile     | Low | 17/11/2020 |
| SSP-1X0   | Specimen Container, Stool 120ml PP                | Non-sterile | Low | 12/02/2015 |
| SSP-1X0Y  | Specimen Container, Stool 120ml PP                | Non-sterile | Low | 17/11/2020 |
| SSP-1X1   | Specimen Container, Stool 120ml PP                | Sterile     | Low | 12/02/2015 |
| SSP-1X1Y  | Specimen Container, Stool 120ml PP                | Sterile     | Low | 17/11/2020 |
| SCP-5X0   | Specimen Container, 150ml PP                      | Non-sterile | Low | 12/02/2015 |
| SCP-5X0Y  | Specimen Container, 150ml PP                      | Non-sterile | Low | 17/11/2020 |
| SCP-5X1   | Specimen Container, 150ml PP                      | Sterile     | Low | 12/02/2015 |
| SCP-5X1Y  | Specimen Container, 150ml PP                      | Sterile     | Low | 17/11/2020 |
| SSP-5X0   | Specimen Container, Stool 150ml PP                | Non-sterile | Low | 12/02/2015 |
| SSP-5X0Y  | Specimen Container, Stool 150ml PP                | Non-sterile | Low | 17/11/2020 |
| SSP-5X1   | Specimen Container, Stool 150ml PP                | Sterile     | Low | 12/02/2015 |
| SSP-5X1Y  | Specimen Container, Stool 150ml PP                | Sterile     | Low | 17/11/2020 |
| SCP-325   | 24 Hour Urine Container, 2.5L, White              | Non-Sterile | Low | 12/02/2015 |
| SCP-325H  | 24 Hour Urine Container, 2.5L, White, with holder | Non-Sterile | Low | 17/11/2020 |
| SCP-325A  | 24 Hour Urine Container, 2.5L, Amber              | Non-Sterile | Low | 17/11/2020 |
| SCP-325AH | 24 Hour Urine Container, 2.5L, Amber, with Holder | Non-Sterile | Low | 17/11/2020 |
| SCP-300   | 24 Hour Urine Container, 3L                       | Non-Sterile | Low | 12/02/2015 |

| Product Group 3: Blood Collection Tubes |   | Notification No.: NL-CA002-2015-33912 |                   |                             |
|---|---|---------------------------------------|-------------------|-----------------------------|
| Product Code(s)                         | Product Description   | State                                 | Risk class / rule | First date of CE-compliance |
| BCP-21X                                 | Blood Collection Tube 2.5 mL + Push Cap with or without anticoagulant | Sterile                               | Low               | 30/01/2015                  |

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|---------|--|-------------|-----|------------|
| BCS-20X | Blood Collection Tube 2.5 mL + Screw Cap with or without anticoagulant | Sterile     | Low | 30/01/2015 |
| BCP-51X | Blood Collection Tube 5 mL + Push Cap with or without anticoagulant    | Non-Sterile | Low | 30/01/2015 |
| BCS-50X | Blood Collection Tube 5 mL + Screw Cap with or without anticoagulant   | Sterile     | Low | 30/01/2015 |
| BCS-10X | Blood Collection Tube 10 mL + Screw Cap with or without anticoagulant  | Non-sterile | Low | 30/01/2015 |

| Product Group 4: Test Tubes |                                     | Notification No.: NL-CA002-2015-34261 |                   |                             |
|-----------------------------|-------------------------------------|---------------------------------------|-------------------|-----------------------------|
| Product Code(s)             | Product Description                 | State                                 | Risk class / rule | First date of CE-compliance |
| TT-5XX                      | Test Tube 5 mL with or without Cap  | Non-sterile                           | Low               | 16/02/2015                  |
| TT-1XX                      | Test Tube 10 mL with or without Cap | Non-sterile                           | Low               | 16/02/2015                  |
| TC-XXX                      | Test Tube Cap                       | Non-sterile                           | Low               | 16/02/2015                  |

| Product Group 5: Conical Tubes |   | Notification No.: NL-CA002-2015-34258 |                   |                             |
|--------------------------------|---|---------------------------------------|-------------------|-----------------------------|
| Product Code(s)                | Product Description                                       | State                                 | Risk class / rule | First date of CE-compliance |
| CTS-150                        | Conical Tube 15 mL + Screw Cap                            | Sterile                               | Low               | 17/02/2015                  |
| CTS-150X                       | Conical Tube 15 mL + Screw Cap                            | Sterile                               | Low               | 17/11/2020                  |
| CTS-15X                        | Conical Tube 15 mL + Screw Cap                            | Non-sterile                           | Low               | 17/02/2015                  |
| CTS-15XY                       | Conical Tube 15 mL + Screw Cap                            | Non-sterile                           | Low               | 17/11/2020                  |
| CTS-15XYZ                      | Conical Tube 15 mL + Screw Cap                            | Non-sterile                           | Low               | 17/11/2020                  |
| CTS-500                        | Conical Tube 50 mL + Screw Cap                            | Sterile                               | Low               | 17/02/2015                  |
| CTS-500X                       | Conical Tube 50 mL + Screw Cap                            | Sterile                               | Low               | 17/11/2020                  |
| CTS-5XY                        | Conical Tube 50 mL + Screw Cap                            | Non-sterile                           | Low               | 17/02/2015                  |
| CTS-5XYZ                       | Conical Tube 50 mL + Screw Cap                            | Non-sterile                           | Low               | 17/11/2020                  |
| CTS-50XYZ                      | Conical Tube 50 mL + Screw Cap                            | Non-sterile                           | Low               | 17/11/2020                  |
| CTS-600                        | Conical Tube 50 mL Self-Standing (with skirt) + Screw Cap | Sterile                               | Low               | 17/02/2015                  |
| CTS-600X                       | Conical Tube 50 mL Self-Standing (with skirt) + Screw Cap | Sterile                               | Low               | 17/11/2020                  |
| CTS-6XY                        | Conical Tube 50 mL Self-Standing (with skirt) + Screw Cap | Non-sterile                           | Low               | 17/02/2015                  |

|           |   |             |     |            |
|-----------|---|-------------|-----|------------|
| CTS-6XYZ  | Conical Tube 50 mL Self-Standing (with skirt) + Screw Cap | Non-sterile | Low | 17/11/2020 |
| CTS-60XYZ | Conical Tube 50 mL Self-Standing (with skirt) + Screw Cap | Non-sterile | Low | 17/11/2020 |

**Product Group 6: Vacuum Blood Collection Tubes**      **Notification No.: NL-CA002-2015-34358**

| Product Code(s)  | Product Description  | State       | Risk class / rule | First date of CE-compliance |
|--|--|-------------|-------------------|-----------------------------|
| VBC-16WXYZ<br>VBC-18WXYZ<br>VBC-20WXYZ<br>VBC-24WXYZ<br>VBC-27WXYZ<br>VBC-30WXYZ<br>VBC-35WXYZ<br>VBC-36WXYZ<br>VBC-40WXYZ<br>VBC-45WXYZ<br>VBC-50WXYZ | Vacuum Blood Collection Tube 13x75 mm, with or without anticoagulant, with or without gel  | Sterile     | Low               | 02/02/2015                  |
| VBC-500XYZ<br>VBC-600XYZ   | Vacuum Blood Collection Tube 13x100 mm, with or without anticoagulant, with or without gel | Sterile     | Low               | 02/02/2015                  |
| VBC-700XYZ<br>VBC-800XYZ<br>VBC-900XYZ<br>VBC-100XYZ   | Vacuum Blood Collection Tube 16x100 mm, with or without anticoagulant, with or without gel | Sterile     | Low               | 17/11/2020                  |
| VBCTQ-100  | Tourniquet   | Non-Sterile | Low               | 02/02/2015                  |
| VBCH-100   | Tube Holder for Vacuum Blood Collection Tube   | Non-Sterile | Low               | 02/02/2015                  |
| VBCH-101   | Tube Holder for Vacuum Blood Collection Tube   | Sterile     | Low               | 02/02/2015                  |

**Product Group 7: Micropipette Tips**      **Notification No.: NL-CA002-2015-34359**

| Product Code(s) | Product Description   | State       | Risk class / rule | First date of CE-compliance |
|-----------------|---|-------------|-------------------|-----------------------------|
| MT-101          | Micro-Pipette Tips, Universal, 100 - 1000 µl Blue Box Of 16000 Pcs                      | Non-sterile | Low               | 19/02/2015                  |
| MT-102          | Micro-Pipette Tips, Universal, 5 - 200 µl Yellow Box Of 30000 Pcs                       | Non-sterile | Low               | 19/02/2015                  |
| MT-103          | Micro-Pipette Tips, Universal, 5-200 µl White Box Of 30000                              | Non-sterile | Low               | 19/02/2015                  |
| MT-201          | Micro-Pipette Tips, Universal, 100 - 1000 µl Blue in Rack Sterile 30 Rack/Box Of 96 Pcs | Sterile     | Low               | 19/02/2015                  |
| MT-202          | Micro-Pipette Tips, Universal, 5 - 200 µl Yellow in Rack Sterile 50 Rack/Box            | Sterile     | Low               | 19/02/2015                  |

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|----------|--|-------------|-----|------------|
| MT-111   | Filter Tips 1000 ul, Blue, Sterile, Box Of 16000 Pcs                           | Sterile     | Low | 11/11/2020 |
| MT-111XY | Filter Tips 1000 ul, Blue, Sterile, Box Of 16000 Pcs                           | Sterile     | Low | 11/11/2020 |
| MT-112   | Filter Tips 200 ul, Yellow, Sterile, Box Of 30000 Pcs                          | Sterile     | Low | 11/11/2020 |
| MT-112XY | Filter Tips 200 ul, Yellow, Sterile, Box Of 30000 Pcs                          | Sterile     | Low | 11/11/2020 |
| MT-122   | Filter Tips 200 ul, Yellow, Sterile, Box Of 30000 Pcs                          | Sterile     | Low | 11/11/2020 |
| MT-122XY | Filter Tips 200 ul, Yellow, Sterile, Box Of 30000 Pcs                          | Sterile     | Low | 11/11/2020 |
| MT-211   | Filter Tips in rack 1000 ul, Blue, Sterile, 96 pcs per Rack, 30 Racks per Box  | Sterile     | Low | 11/11/2020 |
| MT-211XY | Filter Tips in rack 1000 ul, Blue, Sterile, 96 pcs per Rack, 30 Racks per Box  | Sterile     | Low | 11/11/2020 |
| MT-212   | Filter Tips in rack 200 ul, Yellow, Sterile, 96 pcs per Rack, 50 Racks per Box | Sterile     | Low | 11/11/2020 |
| MT-212XY | Filter Tips in rack 200 ul, Yellow, Sterile, 96 pcs per Rack, 50 Racks per Box | Sterile     | Low | 11/11/2020 |
| MT-222   | Filter Tips in rack 100 ul, Yellow, Sterile, 96 pcs per Rack, 50 Racks per Box | Sterile     | Low | 11/11/2020 |
| MT-222XY | Filter Tips in rack 100 ul, Yellow, Sterile, 96 pcs per Rack, 50 Racks per Box | Sterile     | Low | 11/11/2020 |
| MT-301   | Rack for Blue Tips Box Of 54 Pcs   | Non-sterile | Low | 19/02/2015 |
| MT-302   | Rack for Yellow Tips Box Of 96 Pcs   | Non-sterile | Low | 19/02/2015 |

| Product Group 8: Inoculating Loops |                              | Notification No.: NL-CA002-2015-35333 |                   |                             |
|------------------------------------|------------------------------|---------------------------------------|-------------------|-----------------------------|
| Product Code(s)                    | Product Description          | State                                 | Risk class / rule | First date of CE-compliance |
| IL-01X                             | Inoculating Loops 1µL, Soft  | Sterile                               | Low               | 02/03/2015                  |
| IL-01XY                            | Inoculating Loops 1µL, Soft  | Sterile                               | Low               | 17/11/2020                  |
| IL-02X                             | Inoculating Loops 1µL, Hard  | Sterile                               | Low               | 02/03/2015                  |
| IL-02XY                            | Inoculating Loops 1µL, Hard  | Sterile                               | Low               | 17/11/2020                  |
| IL-10X                             | Inoculating Loops 10µL, Soft | Sterile                               | Low               | 02/03/2015                  |
| IL-10XY                            | Inoculating Loops 10µL, Soft | Sterile                               | Low               | 11/11/2020                  |

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|         |                              |         |     |            |
|---------|------------------------------|---------|-----|------------|
| IL-12X  | Inoculating Loops 10µL, Hard | Sterile | Low | 02/03/2015 |
| IL-12XY | Inoculating Loops 10µL, Hard | Sterile | Low | 11/11/2020 |

