

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

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Roumieh Industrial Area,
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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:

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

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, 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 VBC-18WXYZ VBC-20WXYZ VBC-24WXYZ VBC-27WXYZ VBC-30WXYZ VBC-35WXYZ VBC-36WXYZ VBC-40WXYZ VBC-45WXYZ VBC-50WXYZ	Vacuum Blood Collection Tube 13x75 mm, with or without anticoagulant, with or without gel	Sterile	Low	02/02/2015
VBC-500XYZ VBC-600XYZ	Vacuum Blood Collection Tube 13x100 mm, with or without anticoagulant, with or without gel	Sterile	Low	02/02/2015
VBC-700XYZ VBC-800XYZ VBC-900XYZ 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

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