

Certificate of CE-Registration

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, **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 manufacture's Declaration of Conformity:

MDD devices were registered under number:

Group 10 : Kidney Dish	Registration No.: NL-CA002-2015-35162
Group 12 : Urinals	Registration No.: NL-CA002-2015-35163
Group 13 : Umbilical Cord Clamp	Registration No.: NL-CA002-2015-35335
Group 14 : Tongue Depressor	Registration No.: NL-CA002-2015-35337
Group 15 : Cervix Spatula	Registration No.: NL-CA002-2015-35336
Group 16 : Medicine Cup	Registration No.: NL-CA002-2015-35164

see appendix

with Dutch Competent Authorities as a consequently these MDD 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 medical devices fulfil the essential requirements of Directive 93/42/EEC.

Issue date: 2020-12-16


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Consultant CEpartner4U BV

C e p a r t n e r 4 U

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Appendix

Product Group 10: Kidney Dish		Registration No.: NL-CA002-2015-35162	
Product Code(s)	Product Description	Risk class / rule	First date of CE-compliance
KD-1XX	Kidney Dish	Class I, Rule 1	10/03/2015

Product Group 12: Urinals		Registration No.: NL-CA002-2015-35163	
Product Code(s)	Product Description	Risk class / rule	First date of CE-compliance
UM-50	Male Urinal	Class I, Rule 1	30/03/2015
UF-50	Female Urinal	Class I, Rule 1	30/03/2015

Product Group 13: Umbilical Cord Clamp		Registration No.: NL-CA002-2015-35335	
Product Code(s)	Product Description	Risk class / rule	First date of CE-compliance
CC-1XX	Umbilical Cord Clamp	Class I, Rule 1	16/03/2015

Product Group 14: Tongue Depressor		Registration No.: NL-CA002-2015-35337	
Product Code(s)	Product Description	Risk class / rule	First date of CE-compliance
TD-XXX	Tongue Depressor	Class I, Rule 1	17/03/2015

Product Group 15: Cervix Spatula		Registration No.: NL-CA002-2015-35336	
Product Code(s)	Product Description	Risk class / rule	First date of CE-compliance
CS-XXX	Cervix Spatula	Class I, Rule 5	27/03/2015

Product Group 16: Medicine Cup		Registration No.: NL-CA002-2015-35164	
Product Code(s)	Product Description	Risk class / rule	First date of CE-compliance
MC-1X0	Medicine Cup without Lid	Class I, Rule 1	13/05/2015
MC-1XX	Lid for Medicine Cup	Class I, Rule 1	13/05/2015