

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **FCPC DataControl S.R.L.**, cu sediul în **mun. Chișinău, str. N. Testemițanu 17/6**, tel. **022 273 712**, e-mail: **contact@datacontrol.md** declar pe proprie răspundere, cunoscând prevederile art. **352¹**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Product: Spirale pentru embolizare endovasculară

MicroPlex 10 Platinum Coil System Endovascular Embolization Coils,
MicroPlex 18 Platinum Coil System Endovascular Embolization Coils,
HydroCoil 10 Embolic System Endovascular Embolization Coils,
HydroCoil 18 Embolic System Endovascular Embolization Coils

Model: MicroPlex 10 Platinum Coil System

Cosmos 10

100202CSSR-V	100515CSSR-V	100722CSSR-V
100254CSSR-V	100518CSSR-V	100731CSSR-V
100306CSSR-V	100522CSSR-V	100825CSSR-V
100408CSSR-V	100618CSSR-V	100837CSSR-V
100412CSSR-V	100622CSSR-V	100933CSSR-V
	100626CSSR-V	101036CSSR-V

HyperSoft 3D

100102HS3D-V	100204HS3D-V	100308HS3D-V	100510HS3D-V
100103HS3D-V	100206HS3D-V	100310HS3D-V	100515HS3D-V
100106HS3D-V	100208HS3D-V	100312HS3D-V	100520HS3D-V
100115HS3D-V	100210HS3D-V	100355HS3D-V	100620HS3D-V
100152HS3D-V	100212HS3D-V	100358HS3D-V	101510HS3D-V
100153HS3D-V	100254HS3D-V	100406HS3D-V	102510HS3D-V
100154HS3D-V	100256HS3D-V	100408HS3D-V	102512HS3D-V
100155HS3D-V	100258HS3D-V	100409HS3D-V	
100202HS3D-V	100304HS3D-V	100412HS3D-V	
100203HS3D-V	100306HS3D-V	100415HS3D-V	

HyperSoft Helical

100101HS-V	100106HS-V	100155HS-V	100204HS-V
100102HS-V	100151HS-V	100156HS-V	100206HS-V
100103HS-V	100152HS-V	100201HS-V	100208HS-V

100104HS-V	100153HS-V	100202HS-V	100251HS-V
100105HS-V	100258HS-V	100402HS-V	100508HS-V
100154HS-V	100302HS-V	100403HS-V	100510HS-V
100203HS-V	100303HS-V	100404HS-V	100606HS-V
100252HS-V	100304HS-V	100406HS-V	100608HS-V
100253HS-V	100306HS-V	100408HS-V	100610HS-V
100254HS-V	100308HS-V	100410HS-V	100808HS-V
100256HS-V	100310HS-V	100506HS-V	100810HS-V

Helical 10 Soft

100202HCSR-S-V	100720HCSR-R-V	100404HC-S-V
100203HCSR-S-V	100730HCSR-R-V	100406HC-S-V
100204HCSR-S-V	100820HCSR-R-V	100408HC-S-V
100206HCSR-S-V	100830HCSR-R-V	100410HC-S-V
100208HCSR-S-V	100920HCSR-R-V	100515HC-R-V
100303HCSR-S-V	100930HCSR-R-V	100520HC-R-V
100304HCSR-S-V	101030HCSR-R-V	100615HC-R-V
100306HCSR-S-V	100201HC-S-V	100620HC-R-V
100308HCSR-S-V	100202HC-S-V	100720HC-R-V
100310HCSR-S-V	100203HC-S-V	100730HC-R-V
100404HCSR-S-V	100204HC-S-V	100820HC-R-V
100406HCSR-S-V	100206HC-S-V	100830HC-R-V
100408HCSR-S-V	100208HC-S-V	100920HC-R-V
100410HCSR-S-V	100303HC-S-V	100930HC-R-V
100515HCSR-R-V	100304HC-S-V	101030HC-R-V
100520HCSR-R-V	100306HC-S-V	
100615HCSR-R-V	100308HC-S-V	
100620HCSR-R-V	100310HC-S-V	

VFC

VFC010303-V	VFC152040-V
VFC061020-V	VFC152060-V
VFC061030-V	VFC030606-V
VFC101530-V	VFC030610-V
VFC101540-V	VFC030615-V

Compass 10

100203CM-V	100408CM-V	100612CM-V
100203CMSR-V	100408CMSR-V	100612CMSR-V
100254CM-V	100412CM-V	100618CM-V
100254CMSR-V	100412CMSR-V	100618CMSR-V
100304CM-V	100510CM-V	100721CMSR-V
100304CMSR-V	100510CMSR-V	100824CMSR-V
100355CM-V	100516CM-V	100928CMSR-V
100355CMSR-V	100516CMSR-V	101030CMSR-V

Complex 10

100204CC-V	100512CC-V	100820CC-V
100307CC-V	100615CC-V	100924CC-V
100410CC-V	100718CC-V	101026CC-V

**Model: MicroPlex 18 Platinum Coil System
Endovascular Embolization Coil****Cosmos 18**

180617CS-V	181347CS-V
180619CS-V	181451CS-V
180723CS-V	181652CS-V
180827CS-V	181859CS-V
180931CS-V	182065CS-V
181036CS-V	182263CS-V
181139CS-V	182468CS-V
181243CS-V	

Compass 18

180409CM-V	180721CM-V	181339CM-V
180413CM-V	180825CM-V	181443CM-V
180511CM-V	180928CM-V	181648CM-V
180516CM-V	181030CM-V	181855CM-V
180612CM-V	181134CM-V	182060CM-V
180618CM-V	181237CM-V	

Helical 18 Soft

180204HC-S-V	180512HC-S-V	180930HC-R-V
180208HC-S-V	180615HC-S-V	181030HC-R-V
180304HC-S-V	180520HC-R-V	181230HC-R-V
180308HC-S-V	180620HC-R-V	181430HC-R-V
180406HC-S-V	180730HC-R-V	181630HC-R-V
180410HC-S-V	180830HC-R-V	181830HC-R-V
		182030HC-R-V

Complex 18

180204CC-V	180820CC-V	181332CC-V
180307CC-V	180923CC-V	181434CC-V
180410CC-V	181026CC-V	181639CC-V
180512CC-V	181128CC-V	181844CC-V
180615CC-V	181231CC-V	182050CC-V
180717CC-V		

**Model: HydroCoil 10 Embolic System
HydroFrame 10**

100405HFRM-V	100612HFRM-V	100826HFRM-V
100408HFRM-V	100619HFRM-V	100833HFRM-V

100410HFRM-V
100412HFRM-V
100415HFRM-V
100510HFRM-V
100515HFRM-V
100519HFRM-V
100520HFRM-V

100623HFRM-V
100626HFRM-V
100715HFRM-V
100723HFRM-V
100728HFRM-V
100731HFRM-V
100817HFRM-V

100836HFRM-V
100931HFRM-V
100933HFRM-V
101036HFRM-V
101139HFRM-V

HydroSoft Helical

100101H2HS-V
100102H2HS-V
100103H2HS-V
100104H2HS-V
100105H2HS-V
100151H2HS-V
100152H2HS-V
100153H2HS-V

100154H2HS-V
100155H2HS-V
100201H2HS-V
100202H2HS-V
100203H2HS-V
100204H2HS-V
100206H2HS-V
100208H2HS-V

100254H2HS-V
100256H2HS-V
100304H2HS-V
100306H2HS-V
100308H2HS-V
100310H2HS-V
100404H2HS-V
100406H2HS-V

100408H2HS-V
100506H2HS-V
100508H2HS-V
100510H2HS-V
100515H2HS-V
100520H2HS-V
100606H2HS-V
100608H2HS-V

100610H2HS-V
100615H2HS-V
100620H2HS-V
100715H2HS-V
100720H2HS-V
100730H2HS-V
100815H2HS-V

100820H2HS-V
100830H2HS-V
100920H2HS-V
100930H2HS-V
101020H2HS-V
101030H2HS-V

HydroSoft 3D

100202HFRM-V
100254HFRM-V
100306HFRM-V
100102HFRM-V
100103HFRM-V
100152HFRM-V
100153HFRM-V

100154HFRM-V
100203HFRM-V
100204HFRM-V
100206HFRM-V
100208HFRM-V
100210HFRM-V
100256HFRM-V

100258HFRM-V
100304HFRM-V
100308HFRM-V
100310HFRM-V

HydroFill

100202HFIL-V
100203HFIL-V
100204HFIL-V
100206HFIL-V
100304HFIL-V
100306HFIL-V
100404HFIL-V
100406HFIL-V

100408HFIL-V
100410HFIL-V
100508HFIL-V
100510HFIL-V
100515HFIL-V
100606HFIL-V
100608HFIL-V
100610HFIL-V

100615HFIL-V
100620HFIL-V
100710HFIL-V
100715HFIL-V
100720HFIL-V
100820HFIL-V
100830HFIL-V
100920HFIL-V

100930HFIL-V
101030HFIL-V
101120HFIL-V
101130HFIL-V
101140HFIL-V
101220HFIL-V
101230HFIL-V
101240HFIL-V

101330HFIL-V
101340HFIL-V
101350HFIL-V
101430HFIL-V
101440HFIL-V

101450HFIL-V
101630HFIL-V
101640HFIL-V
101650HFIL-V

101840HFIL-V
101850HFIL-V
102040HFIL-V
102050HFIL-V

102240HFIL-V
102250HFIL-V
102440HFIL-V
102450HFIL-V

**Model: HydroCoil 18 Embolic System
HydroFrame 18**

180619HFRM-V
180723HFRM-V
180827HFRM-V
180931HFRM-V
181036HFRM-V

181139HFRM-V
181243HFRM-V
181347HFRM-V
181445HFRM-V
181546HFRM-V

181644HFRM-V
181850HFRM-V
182048HFRM-V
182245HFRM-V
182450HFRM-V

Sunt autentice și corespund realității.

Semnătura _____

Grabazei Alexandru, director

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