

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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