

Manufacturer (with Stamp):



Sichuan Nigale Biotechnology Co., Ltd.

Input: Devices on Appendix A/B/C (Only for the device(s) covered by the confirmation letter)				Output: Devices on Confirmation Letter	Device Basic UDI-DI	MDR Device Classification	Legacy Device or Not	Substitute Device or Not	Clarify the device name differences between Appendix ABC Directives and Regulation (if applicable)
Device Name under MD Directive (MEDF0315.01)	Device Models	Device Name under MDR Regulation (MEDF0325.01)	Device Models						
MDD Cert. No.: No. G1 067972 0007 Rev. 02		MDR Cert. No.: N/A							
Disposable Plasma Apheresis Set	P-1000B1	Disposable Plasma Apheresis Set	P-1000B1	Disposable Plasma Apheresis Set	697065870NGL00001VA	IIb	YES	N/A	
Disposable Plasma Apheresis Set	P-1000B2	Disposable Plasma Apheresis Set	P-1000B2	Disposable Plasma Apheresis Set	697065870NGL00001VA	IIb	YES	N/A	
Disposable Plasma Apheresis Set	P-1000B3	Disposable Plasma Apheresis Set	P-1000B3	Disposable Plasma Apheresis Set	697065870NGL00001VA	IIb	YES	N/A	
Disposable Plasma Apheresis Set	P-3000	Disposable Plasma Apheresis Set	P-3000	Disposable Plasma Apheresis Set	697065870NGL00001VA	IIb	YES	N/A	
Disposable Plasma Apheresis Set	P-3001	Disposable Plasma Apheresis Set	P-3001	Disposable Plasma Apheresis Set	697065870NGL00001VA	IIb	YES	N/A	
Disposable Plasma Apheresis Set	P-4004	Disposable Plasma Apheresis Set	P-4004	Disposable Plasma Apheresis Set	697065870NGL00001VA	IIb	YES	N/A	
Disposable Plasma Apheresis Set	P-4007	Disposable Plasma Apheresis Set	P-4007	Disposable Plasma Apheresis Set	697065870NGL00001VA	IIb	YES	N/A	
Disposable Plasma Apheresis Set	P-4009	Disposable Plasma Apheresis Set	P-4009	Disposable Plasma Apheresis Set	697065870NGL00001VA	IIb	YES	N/A	
Disposable Plasma Apheresis Set	P-4011	Disposable Plasma Apheresis Set	P-4011	Disposable Plasma Apheresis Set	697065870NGL00001VA	IIb	YES	N/A	
Disposable Plasma Apheresis Set	P-4013	Disposable Plasma Apheresis Set	P-4013	Disposable Plasma Apheresis Set	697065870NGL00001VA	IIb	YES	N/A	
Disposable Plasma Apheresis Set	P-4014	Disposable Plasma Apheresis Set	P-4014	Disposable Plasma Apheresis Set	697065870NGL00001VA	IIb	YES	N/A	
Disposable Plasma Apheresis Set	P-4017	Disposable Plasma Apheresis Set	P-4017	Disposable Plasma Apheresis Set	697065870NGL00001VA	IIb	YES	N/A	
Disposable Plasma Apheresis Set	P-4018	Disposable Plasma Apheresis Set	P-4018	Disposable Plasma Apheresis Set	697065870NGL00001VA	IIb	YES	N/A	
Disposable Plasma Apheresis Set	P-4019	Disposable Plasma Apheresis Set	P-4019	Disposable Plasma Apheresis Set	697065870NGL00001VA	IIb	YES	N/A	
Disposable Plasma Apheresis Set	P-4021	Disposable Plasma Apheresis Set	P-4021	Disposable Plasma Apheresis Set	697065870NGL00001VA	IIb	YES	N/A	
Disposable Plasma Apheresis Set	P-4023	Disposable Plasma Apheresis Set	P-4023	Disposable Plasma Apheresis Set	697065870NGL00001VA	IIb	YES	N/A	
Disposable Plasma Apheresis Set	P-4025	Disposable Plasma Apheresis Set	P-4025	Disposable Plasma Apheresis Set	697065870NGL00001VA	IIb	YES	N/A	





Disposable Blood Component Apheresis set	P-2000 I E	Disposable Blood Component Apheresis set	P-2000 I E	Disposable Blood Component Apheresis set	697065870NGL00002VC	I Ib	YES	N/A	
Disposable Blood Component Apheresis set	P-2000 I F	Disposable Blood Component Apheresis set	P-2000 I F	Disposable Blood Component Apheresis set	697065870NGL00002VC	I Ib	YES	N/A	
Disposable Blood Component Apheresis set	P-2000 I G	Disposable Blood Component Apheresis set	P-2000 I G	Disposable Blood Component Apheresis set	697065870NGL00002VC	I Ib	YES	N/A	
Disposable Blood Component Apheresis set	P-2000 I J	Disposable Blood Component Apheresis set	P-2000 I J	Disposable Blood Component Apheresis set	697065870NGL00002VC	I Ib	YES	N/A	
Disposable Blood Component Apheresis set	P-2000 I M	Disposable Blood Component Apheresis set	P-2000 I M	Disposable Blood Component Apheresis set	697065870NGL00002VC	I Ib	YES	N/A	
Disposable Blood Component Apheresis set	P-2000 I N	Disposable Blood Component Apheresis set	P-2000 I N	Disposable Blood Component Apheresis set	697065870NGL00002VC	I Ib	YES	N/A	
Disposable Blood Component Apheresis set	P-2000 I P	Disposable Blood Component Apheresis set	P-2000 I P	Disposable Blood Component Apheresis set	697065870NGL00002VC	I Ib	YES	N/A	
Disposable Blood Component Apheresis set	P-2000 I Q	Disposable Blood Component Apheresis set	P-2000 I Q	Disposable Blood Component Apheresis set	697065870NGL00002VC	I Ib	YES	N/A	
Disposable Blood Component Apheresis set	P-2000 I R	Disposable Blood Component Apheresis set	P-2000 I R	Disposable Blood Component Apheresis set	697065870NGL00002VC	I Ib	YES	N/A	
Disposable Blood Component Apheresis set	P-2000 I S	Disposable Blood Component Apheresis set	P-2000 I S	Disposable Blood Component Apheresis set	697065870NGL00002VC	I Ib	YES	N/A	
Disposable Blood Component Apheresis set	P-2000 I V	Disposable Blood Component Apheresis set	P-2000 I V	Disposable Blood Component Apheresis set	697065870NGL00002VC	I Ib	YES	N/A	
Disposable Blood Component Apheresis set	P-2000 I X	Disposable Blood Component Apheresis set	P-2000 I X	Disposable Blood Component Apheresis set	697065870NGL00002VC	I Ib	YES	N/A	
Plasma Separator	DigiPla 80	Plasma Separator	DigiPla 80	Plasma Separator	697065870NGL00006VL	I Ib	YES	N/A	
Plasma Separator	DigiPla 90	Plasma Separator	DigiPla 90	Plasma Separator	697065870NGL00006VL	I Ib	YES	N/A	
Blood Component Separator	NGL XCF 3000	Blood Component Separator	NGL XCF 3000	Blood Component Separator	697065870NGL00007VN	I Ib	YES	N/A	
Blood Cell Processor	NGL BBS 926	Blood cell processor	NGL BBS 926	Blood Cell Processor	697065870NGL00008VQ	I Ia	YES	N/A	

Disposable Plastic Blood Bag	350ml (single bag)	Disposable Plastic Blood Bag	S-350	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	The model used in MDD is a general description, while the model used in MDR is split into each model, and they are only inconsistent in the model expression, which is actually one-to-one correspondence. The design of the product itself, the material and the production process have not changed.
Disposable Plastic Blood Bag	400ml (single bag)	Disposable Plastic Blood Bag	S-400	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	450ml (single bag)	Disposable Plastic Blood Bag	S-450	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	500ml (single bag)	Disposable Plastic Blood Bag	S-500	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	350ml (single bag)	Disposable Plastic Blood Bag	S-350PN	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	400ml (single bag)	Disposable Plastic Blood Bag	S-400PN	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	450ml (single bag)	Disposable Plastic Blood Bag	S-450PN	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	500ml (single bag)	Disposable Plastic Blood Bag	S-500PN	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	350ml (double bag)	Disposable Plastic Blood Bag	D-350	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	400ml (double bag)	Disposable Plastic Blood Bag	D-400	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	450ml (double bag)	Disposable Plastic Blood Bag	D-450	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	500ml (double bag)	Disposable Plastic Blood Bag	D-500	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	350ml (double bag)	Disposable Plastic Blood Bag	D-350PN	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	400ml (double bag)	Disposable Plastic Blood Bag	D-400PN	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	450ml (double bag)	Disposable Plastic Blood Bag	D-450PN	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	500ml (double bag)	Disposable Plastic Blood Bag	D-500PN	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	350ml (triple bag)	Disposable Plastic Blood Bag	T-350	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	400ml (triple bag)	Disposable Plastic Blood Bag	T-400	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	450ml (triple bag)	Disposable Plastic Blood Bag	T-450	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	
Disposable Plastic Blood Bag	500ml (triple bag)	Disposable Plastic Blood Bag	T-500	Disposable Plastic Blood Bag	697065870NGL00003VE	IIb	YES	N/A	

Disposable Plastic Blood Bag	350ml (triple bag)	Disposable Plastic Blood Bag	T-350PN	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	The model used in MDD is a general description, while the model used in MDR is split into each model, and they are only inconsistent in the model expression, which is actually one-to-one correspondence. The design of the product itself, the material and the production process have not changed.
Disposable Plastic Blood Bag	400ml (triple bag)	Disposable Plastic Blood Bag	T-400PN	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	450ml (triple bag)	Disposable Plastic Blood Bag	T-450PN	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	500ml (triple bag)	Disposable Plastic Blood Bag	T-500PN	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	350ml (triple bag)	Disposable Plastic Blood Bag	T-350TPN	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	400ml (triple bag)	Disposable Plastic Blood Bag	T-400TPN	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	450ml (triple bag)	Disposable Plastic Blood Bag	T-450TPN	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	500ml (triple bag)	Disposable Plastic Blood Bag	T-500TPN	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	350ml (quadruple bag)	Disposable Plastic Blood Bag	Q-350	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	400ml (quadruple bag)	Disposable Plastic Blood Bag	Q-400	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	450ml (quadruple bag)	Disposable Plastic Blood Bag	Q-450	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	500ml (quadruple bag)	Disposable Plastic Blood Bag	Q-500	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	350ml (quadruple bag)	Disposable Plastic Blood Bag	Q-350PN	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	400ml (quadruple bag)	Disposable Plastic Blood Bag	Q-400PN	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	450ml (quadruple bag)	Disposable Plastic Blood Bag	Q-450PN	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	500ml (quadruple bag)	Disposable Plastic Blood Bag	Q-500PN	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	350ml (quadruple bag)	Disposable Plastic Blood Bag	Q-350TPN	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	400ml (quadruple bag)	Disposable Plastic Blood Bag	Q-400TPN	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	450ml (quadruple bag)	Disposable Plastic Blood Bag	Q-450TPN	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	
Disposable Plastic Blood Bag	500ml (quadruple bag)	Disposable Plastic Blood Bag	Q-500TPN	Disposable Plastic Blood Bag	697065870NGL00003VE	Iib	YES	N/A	

Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (350ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ T-350	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	The model used in MDD is a general description, while the model used in MDR is split into each model, and they are only inconsistent in the model expression, which is actually one-to-one correspondence. The design of the product itself, the material and the production process have not changed.
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (400ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ T-400	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (450ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ T-450	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (500ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ T-500	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (350ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ T-350PN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (400ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ T-400PN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (450ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ T-450PN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (500ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ T-500PN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (350ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ Q-350	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (400ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ Q-400	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (450ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ Q-450	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	

Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (500ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ Q-500	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	The model used in MDD is a general description, while the model used in MDR is split into each model, and they are only inconsistent in the model expression, which is actually one-to-one correspondence. The design of the product itself, the material and the production process have not changed.
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (350ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ Q-350PN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (400ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ Q-400PN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (450ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ Q-450PN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (500ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ Q-500PN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (350ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ Q-350TPN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (400ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ Q-400TPN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (450ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ Q-450TPN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (500ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ Q-500TPN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (350ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ P-350	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (400ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ P-400	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	

Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (450ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ P-450	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	The model used in MDD is a general description, while the model used in MDR is split into each model, and they are only inconsistent in the model expression, which is actually one-to-one correspondence. The design of the product itself, the material and the production process have not changed.
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (500ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ P-500	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (350ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ P-350PN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (400ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ P-400PN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (450ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ P-450PN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (500ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ P-500PN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (350ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ P-350TPN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (400ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ P-400TPN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (450ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ P-450TPN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	
Disposable Blood Bag with in-line Leukoreduced Filter	NGL-RF-XZ (500ml)	Disposable Blood Bag with in-line Leukoreduced Filter	NGL/RF-XZ P-500TPN	Disposable Blood Bag with in-line Leukoreduced Filter	697065870NGL00004VG	Iib	YES	N/A	

Note: Devices with intersection between Appendix ABC Directives and Regulation should be covered with the Confirmation Letter.

Name and Function of the undersigned: \_\_\_\_\_ General Manager

Signature with Stamp: YANG Yong

Date: 2024-02-06

