

UKCA2021MA0075-4

UK MDR 2002 Responsible Person Agreement -Product Amendment Agreement 英国代表协议-产品变更协议

This agreement is made on 2025/4/17.
本协议于 2025年4月17日 订立。

Between:

Party A 甲方: BERPU MEDICAL TECHNOLOGY CO., LTD,
a company established and existing under the laws of the People's republic of China whose address is
at NO.14 Xingji Road, Yongxing Street, Longwan District, 325000, Wenzhou, Zhejiang Province, PEOPLE'S
REPUBLIC OF CHINA.

Party B 乙方: SUNGO Certification Company Limited,
a company established and existing under the laws of UK whose address is at 3rd floor, 70
Gracechurch Street, London. EC3V 0HR.

Whereas

Party A and Party B made the UK MDR 2002 Responsible Person Agreement on 2024/12/09, contract number is
UKCA2021MA0075-3. Due to the change of product information

- product addition
- product deletion
- model change (add model, remove model)
- CE MDD extension
- UKCA/CE MDR extension

through friendly negotiation, Party A and Party B decide to sign this agreement to update and replace the < Appendix A >
in the original agreement. Please see Appendix A for the changed product information, other contents remain unchanged
from the original agreement:

甲乙双方于 2024 年 12 月 9 日签订了英国代表协议, 协议号为: UKCA2021MA0075-3, 现由于甲方
产品信息变更

- 产品增加
- 产品删减
- 型号变更 (增加型号, 删除型号)
- CE MDD 延期注册
- UKCA/CE MDR 延期注册

经甲、乙双方友好协商决定签署本协议以更新替换原协议中的<附件一>。变更后的产品信息见附录一, 其他内容维
持原协议不变。

This agreement will take effect after both parties have signed and sealed. For products that have been deleted and models
have been changed, Party A shall not continue to use Party B's relevant information as its UK MDR 2002 Responsible Person
Agreement information. Once discovered, Party B will take the initiative to report to the authority. At the same time, all
related problems and responsibilities arising from Party A's unauthorized use of Party B's relevant information shall be
borne by Party A, including the impact on Party B, fines, etc. Party B reserves the right to take legal actions against Party A's
violations.

本协议自双方签字盖章后生效。对于已删减, 型号已变更的产品, 甲方不得再继续使用乙方的相关信息作为其英国
代表信息。一经发现, 乙方将上报主管机构。同时, 因甲方擅自使用乙方相关英代信息而产生的相关问题与责任均
由甲方承担, 包括对乙方造成的影响, 罚款等。乙方保留对甲方违反行为采取法律行动的权利。



Appendix A

For the following product categories:

申请认证的产品名称:

No.	Product name 产品名称	Product classification 产品分类	GMDN Code GMDN 代码	Models 型号	Type of change 变更类型
1	STERILE SAFETY INSULIN PEN NEEDLES FOR SINGLE USE	Class IIa	44127	TYPE A:29G,30G,31G,32G,33G,34G TYPE C: 29G,30G,31G,32G,33G,34G	/
2	STERILE SAFETY HYPODERMIC NEEDLES FOR SINGLE USE	Class IIa	59230	18G,19G,20G,21G,22G,23G,24G,25G,26G,27G,28G,29G,30G,31G,32G,33G,34G	/
3	STERILE SYRINGES FOR SINGLE USE WITH NEEDLE	Class IIa	35904	TYPE1: Nominal capacity:1mL, 2mL, 3mL, 5mL, 10mL, 20mL, 30mL, 50mL, 60mL OD of Needle:18G,19G,20G,21G,22G,23G,24G,25G, 26G,27G,28G,29G,30G,31G,32G,33G,34G TYPE2: Nominal capacity:1mL, 2mL, 3mL, 5mL, 10mL, 20mL, 30mL, 50mL, 60mL OD of Needle:18G,19G,20G,21G,22G,23G,24G,25G, 26G,27G,28G,29G,30G,31G,32G,33G,34G TYPE3: Nominal capacity:1mL, 2mL, 3mL, 5mL, 10mL, 20mL OD of Needle:18G,19G,20G,21G,22G,23G,24G,25G, 26G,27G,28G,29G,30G,31G,32G,33G,34G TYPE4: Nominal capacity:0.3mL, 0.5mL, 1mL OD of Needle:20G,21G,22G,23G,24G,25G,26G,27G, 28G,29G,30G,31G,32G,33G,34G TYPE5: Nominal capacity:0.3mL, 0.5mL, 1mL OD of Needle:20G,21G,22G,23G,24G,25G,26G,27G, 28G,29G,30G,31G,32G,33G,34G	/
4	STERILE INSULIN PEN NEEDLES FOR SINGLE USE	Class IIa	44127	34G,33G,32G,31G,30G,29G,28G	/
5	STERILE INSULIN SYRINGES FOR SINGLE USE	Class IIa	38501	0.3ML(U-100),0.5ML(U-40,U-100),1ML(U-40,U-100) OD of Needle:26G,27G,28G,29G,30G,31G,32G,33G, 34G	/
6	STERILE DENTAL NEEDLES FOR SINGLE USE	Class IIa	12740	25G,26G,27G,28G,29G,30G,31G,32G,33G,34G	/
7-1	Multiple Sample Blood Collection Needle	Class IIa	35209	General sets:16G,17G,18G,19G,20G ,21G,22G,23G,24G,25G TYPE C:20G,21G,22G,23G TYPE E:20G,21G TYPE F:20G,21G,22G,23G,24G,25G TYPE L:20G,21G,22G,23G,24G,25G	product addition 产品名称变更 原产品名称"Sterile Blood Collecting Needles for Single Use"




7-2	Multiple Sample Blood Collection Needle	Class IIa	65416	TYPE B:18G,19G,20G,21G,22G,23G,24G,25G,26G,27G TYPE D:20G,21G,22G,23G,24G,25G,26G,27G TYPE I:20G,21G,22G,23G,24G,25G,26G,27G TYPE J:20G,21G,22G,23G,24G,25G,26G,27G	product addition 产品名称变更 原产品名称"Sterile Blood Collecting Needles for Single Use"
7-3	Multiple Sample Blood Collection Needle	Class IIa	58284	TYPE G:20G,21G TYPE H:20G,21G TYPE K:20G,21G	product addition 产品名称变更 原产品名称"Sterile Blood Collecting Needles for Single Use"
8	IRRIGATION NEEDLE FOR SINGLE USE	Class Is	64403	TYPEA:14G,15G,16G,17G,18G,19G,20G,21G,22G,23G,24G,25G,26G,27G,28G,29G,30G,31G,32G,33G TYPEB:14G,15G,16G,17G,18G,19G,20G,21G,22G,23G,24G,25G,26G,27G,28G,29G,30G, TYPEC:20G,21G,22G,23G,24G,25G,26G,27G,28G TYPE D:20G,21G,22G,23G,24G,25G,26G,27G,28G,29G,30G TYPE E:20G,21G,22G,23G,24G,25G,26G,27G,28G,29G,30G	/
9	Sterile Syringes for Single Use	Class Is	47017	TYPE1: 1mL、2mL、3mL、5mL、10mL、20mL、30mL、50mL、60mL TYPE2: 1mL、2mL、3mL、5mL、10mL、20mL	/
10	Sterile Hypodermic Needles for Single Use	Class IIa	59230	34G、33G、32G、31G、30G、29G、28G、27G、26G、25G、24G、23G、22G、21G、20G、19G、18G、17G、16G、15G、14G	/
11	Sterile Irrigation Syringe (With Needle)	Class Is	63095	TYPE A: Nominal capacity:3mL, 6mL, 12mL OD of Needle:33G,32G,31G,30G,29G,28G,27G,26G,25G,24G,23G,22G,21G,20G,19G,18G,17G,16G,15G,14G; TYPE B: Nominal capacity:3mL, 6mL, 12mL OD of Needle:30G,29G,28G,27G,26G,25G,24G,23G,22G,21G,20G,19G,18G,17G,16G,15G,14G; TYPE C: Nominal capacity:3mL, 6mL, 12mL OD of Needle:28G,27G,26G,25G,24G,23G,22G,21G,20G; TYPE D: Nominal capacity:3mL, 6mL, 12mL OD of Needle:30G,29G,28G,27G,26G,25G,24G,23G,22G,21G,20G; TYPE E: Nominal capacity:3mL, 6mL, 12mL OD of Needle:30G,29G,28G,27G,26G,25G,24G,23G,22G,21G,20G;	/
12	Sterile Safety Blood Collection Needle for Single Use	Class IIa	35209 58284 65416	Model SA: SA 18G、SA 19G、SA 20G、SA 21G、SA 22G、SA 23G、SA 24G、SA 25G Model SB: SB 18G、SB 19G、SB 20G、SB 21G、SB 22G、SB 23G、SB 24G、SB 25G Model SC: SC 18G、SC 19G、SC20G、SC 21G、SC 22G、SC 23G、SC 24G、SC 25G Model SD: SD 18G、SD 19G、SD 20G、SD 21G、SD 22G、SD 23G、SD 24G、SD 25G	/

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13	Scalp Vein Set for Single Use	Class Ila	65416	Model A:18G、19G、20G、21G、22G、23G、24G、25G、26G、27G Model B:18G、19G、20G、21G、22G、23G、24G、25G、26G、27G	/
14	Dispensing Needle for Single Use	Class Is	16627	Model AZ: 13G、14G、15G、16G、17G、18G、19G、20G、21G、22G Model XZ: 13G、14G、15G、16G、17G、18G、19G、20G、21G、22G Model CZ: 13G、14G、15G、16G、17G、18G、19G、20G、21G、22G Model DZ: 13G、14G、15G、16G、17G、18G、19G、20G、21G、22G Model GZ: 13G、14G、15G、16G、17G、18G、19G、20G、21G、22G Model PZ: 13G、14G、15G、16G、17G、18G、19G、20G、21G、22G、23G、24G、25G、26G、27G、28G、29G、30G Model WZ: 13G、14G、15G、16G、17G、18G、19G、20G、21G、22G、23G、24G、25G、26G、27G、28G、29G、30G	/
15-1	Disposable Vacuum Blood Collection Tube	Class A	47592	Lithium heparin: (1, 2, 3, 4, 5, 6, 7, 8, 9,10) mL Sodium heparin: (1, 2, 3, 4, 5, 6, 7, 8, 9,10) mL Trisodium citrate 1:9: (1, 2, 3, 4, 5) mL Trisodium citrate 1:4: (1, 2, 3, 4, 5, 6, 7, 8, 9,10) mL Sodium fluoride/ Sodium heparin: (1, 2, 3, 4, 5, 6) mL Sodium fluoride/ EDTA Na2: (1, 2, 3, 4, 5, 6) mL EDTA K2: (1, 2, 3, 4, 5, 6, 7, 8, 9,10) mL EDTA K3: (1, 2, 3, 4, 5, 6, 7, 8, 9,10) mL EDTA Na2: (1, 2, 3, 4, 5, 6, 7, 8, 9,10) mL Sodium fluoride/potassium oxalate: (1, 2, 3, 4, 5, 6) mL	product addition
15-2	Disposable Vacuum Blood Collection Tube	Class A	42386	Clot activator: (1, 2, 3, 4, 5, 6, 7, 8, 9,10) mL	product addition
15-3	Disposable Vacuum Blood Collection Tube	Class A	47587	Lithium heparin and gel: (1, 2, 3, 4, 5) mL EDTA K2 with gel: (1, 2, 3, 4, 5) mL Trisodium citrate with gel: (8, 10, 11, 12, 15, 16) mL	product addition
15-4	Disposable Vacuum Blood Collection Tube	Class A	47590	No additive: (1, 2, 3, 4, 5, 6, 7, 8, 9,10) mL	product addition
15-5	Disposable Vacuum Blood Collection Tube	Class A	41128	Clot activator with gel: (1, 2, 3, 3.5, 4, 5, 6, 7, 8, 8.5, 9, 10) mL	product addition

Party A 甲方: 2025.04.17
Date


Signature

Party B 乙方: April 17, 2025
Date


Signature