Declaration of Conformity

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Company Name Address			CHANGZHOU DSB MEDICAL CO., LTD						
			#98, Fumin Road, Qishuyan Economic Development Zone, Qishuyan District, Changzhou City, Jiangsu Province, China						
European	Donne	oontativo	Qisnuyai	n District, Changzhou Ch	y, Jia	ingsu Provir	ice,	China	
Contraction of the local division of the loc		sentative	Wellkand						
Representative Name Address			Wellkang Ltd. The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland						
Conform	t. A	aamaat	The blac	K Church, St. Wary S Flat	se, Di	ubiin 7, D07	P4A	A, Ireland	
Comorni	ity ASSE	ssment	100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100 - 100	the state of the state of the state of the	Cor	tification	Co	rtificato	
		ficate(s)	Identification Number	Date		Certificate Expiry Date			
		MDD Anı cert. No.	nex V 41377404	0413	14 July 2019		27 May 2024		
Registrat	ion Info	ormation		and shi dan set alary say ta	1.00	101- 1 (mar)		La Longer H	
Notified I			Intertek	Semko AB	-		-	1.2.2	
Address			Torsham	nsgatan 43,Box 1103, SE	-164	22 Kista, Sw	/ede	n	
Product	nforma	tion		如 在 教育 是 一 在 的 的 的 的	STREET.				
Product No.	Desc	ription				Classificatio	0.00	Standards Applied	
4531	Urine	snecime	n collectio	n bag sterile,200ml (100p	(20)	Class 1s,	-	EN ISO	
4511				n bag sterile,200ml (100p		Rule 1		13485:201	
4535			······································	n bag sterile,100ml (100p					
4515				collection bag sterile, 100ml (100pcs)					
4540			and the second second second	n bag sterile,10ml (100pc				1.1.1	
Directive documer The dec	93/42/ Itation i laration n Com	EEC as s retained stateme	amended I under the nt is req	e mentioned products me by 2007/47/EC for Me e premises of the manufa uired to include the na Directive 93/42/EEC as	dical Icture ation	Devices. A er. al legislatio	All on o	supportin	
Devices 2003:11d Directive documer Name	eclares 93/42/	that the EEC as	nto the re above me amended under the Sunny H	equirements of the Swe entioned products meet by 2007/47/EC for Me e premises of the manufa	dish the dical	national le provisions Devices.	gisla of t	ng Medica ation LVFs he Counci	
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Devices 2003:11d Directive documer Name Title	eclares 93/42/ ntation i	that the EEC as	nto the re above me amended under the Sunny H Manager #98, Fu	equirements of the Swe entioned products meet by 2007/47/EC for Me e premises of the manufa an nent Representative	dish the dical icture	national le provisions Devices. er. omic Devel	gisla of t All opm	ng Medica ation LVF he Counc supportin	
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Representative Name		Wellkang Ltd.							
Address		The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland							
Conformi	ity Assessment								
EC Certificate(s)		Certificate Number	Certification Date	Certificate Expir					
ISO 1348	5: 2016	0085778-01	09 Jul 2020	14 Jul 2023					
Registrat	ion Information								
	Body Name	N/A							
Address		N/A			n na stand stan Stand stand stan				
Product I	nformation		The second s						
Product No.	Description								
4501	Urine specim	en collection bags non-	sterile,200ml (100pcs)	Class 1,	EN ISO				
4521	Urine specim	en collection bags non-	sterile,200ml (100pcs)	Rule 1	13485:2				
4505	Urine specim	en collection bags non-sterile,100ml (100pcs) 01							
A # 25.94									
DSB Med	lical declares th	en collection bags non- at the above mentioned amended by 2007/47		ovisions of th					
DSB Med Directive documen The decl Europear Devices 2003:11d Directive documen Name	lical declares th 93/42/EEC as ntation is retain laration statem n Communities as transposed eclares that th 93/42/EEC as	at the above mentioned a amended by 2007/47 ed under the premises of nent is required to in Council Directive 93 into the requirements e above mentioned pro- amended by 2007/47 ed under the premises of Sunny Han	Products meet the products meet the products meet the property of the manufacturer. Clude the national legal of the Swedish nat 0 of the Swedish nat 0 of the Swedish nat 0 of the manufacturer.	ovisions of th vices. All s egislation of l, concernin- ional legisla visions of th	Sweden Sweden g Medica tion LVFS e Counci				
DSB Med Directive documen The decl Europear Devices 2003:11d Directive documen Name Title	lical declares th 93/42/EEC as ntation is retained laration statem of Communities as transposed eclares that th 93/42/EEC as ntation is retained	at the above mentioned a amended by 2007/47 ed under the premises of nent is required to in a Council Directive 93 into the requirements e above mentioned pro- amended by 2007/47 ed under the premises of Sunny Han Management Repres	Products meet the products meet the products meet the property of the manufacturer. Clude the national legistry of the Swedish nat oducts meet the prove 7/EC for Medical Depisit the manufacturer.	ovisions of the vices. All s egislation of , concerning ional legisla visions of the vices. All s	Sweden Sweden Medica tion LVFS Counci supporting				
DSB Med Directive documen The decl Europear Devices 2003:11d Directive documen Name Title Place of l	lical declares th 93/42/EEC as ntation is retained laration statem of Communities as transposed eclares that th 93/42/EEC as ntation is retained	at the above mentioned a amended by 2007/47 ed under the premises of nent is required to in a Council Directive 93 into the requirements e above mentioned pro- amended by 2007/47 ed under the premises of Sunny Han Management Repres #98, Fumin Road, Qishuyan District, C	Products meet the products meet the products meet the property of the manufacturer. Clude the national legal of the Swedish nat 0 of the Swedish nat 0 of the Swedish nat 0 of the manufacturer.	ovisions of the vices. All s egislation of l, concerning ional legisla visions of the vices. All s	Sweden G Medica tion LVFS Counci supporting				
Directive documen The decl Europear Devices 2003:11d Directive	lical declares th 93/42/EEC as ntation is retained laration statem of Communities as transposed eclares that th 93/42/EEC as ntation is retained	at the above mentioned a amended by 2007/47 ed under the premises of nent is required to in- council Directive 93 into the requirements e above mentioned pro- amended by 2007/47 ed under the premises of Sunny Han Management Repres #98, Fumin Road,	I products meet the pro 7/EC for Medical De of the manufacturer. clude the national le /42/EEC as amended of the Swedish nat oducts meet the prov 7/EC for Medical De of the manufacturer.	ovisions of the vices. All s egislation of l, concerning ional legisla visions of the vices. All s	Sweden G Medica tion LVFS Counci supporting				

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